Chronic pain
Consultation on draft guideline - Stakeholder comments table
03/08/2020 – 14/08/2020

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Abbott Laboratories U.K Limited	Evidence ReviewJ	007	0032 (Table 1)	The draft guidelines state there is limited evidence on the short- or long-term effectiveness of NSAIDs and therefore, recommends against the use of NSAIDs for chronic primary pain. However, we are concerned that the systematic literature review designed to identify clinical outcome data relating to NSAIDs was limited to randomised controlled trials (RCTs) and will not have captured any long-term or real-world evidence. Such data should be considered to make a full assessment on long-term effectiveness, especially in the absence of good-quality RCTs (as per the NICE Processes and Methods Guideline, section 5.2.2.6). Noting the search included broader terms for chronic pain rather than more specific for chronic primary pain, we found that replicating the NICE Evidence Review search in Embase, limiting the intervention to NSAIDs and using a filter for study designs beyond RCTs identified over 9,000 results. An initial screen of these abstracts suggests that at least 274 of these studies include outcomes within the scope of the search. Therefore, our concern is that there is an extended evidence base covering chronic pain in general and potentially chronic primary pain, and this, in line with NICE methods, should be considered to review the	Thank you for your comment. When agreeing the protocol for the review questions, the most appropriate study design to answer the question is discussed and agreed. For intervention reviews of effectiveness this is widely agreed to be RCTs or systematic reviews of RCTs. Non- randomised studies were agreed as not sufficient quality for this question. There was evidence available for NSAIDs, although it was very limited. This evidence did not show a benefit of NSAIDs for chronic primary pain. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. The search

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				potential clinical effectiveness of NSAIDs in chronic primary pain.	terms used were deliberately broader than 'chronic primary pain' to ensure that evidence wasn't missed due to the range in terminology that may be used by studies to define the population of interest. The committee agreed it was not appropriate to extrapolate evidence from other painful conditions to inform this recommendation and so the evidence base was only for chronic primary pain, as defined in the scope and protocol.
Abbott Laboratories U.K Limited	Guideline	001	004	Suggest reconsider title as currently say is for chronic pain but document is focused on chronic primary pain (CPP) only.	Thank you for your comment. The title has now been revised to clearly include chronic primary pain.
Abbott Laboratories U.K Limited	Guideline	005	017	Chronic primary pain (CPP) may be confused with chronic pain in general as it is only newly included in ICD-11. It would be beneficial to include a table with the different types of chronic pain including CPP as per the ICD-11 classification especially for people with chronic pain, their families and carers. For example, the International Association for the Study of Pain characterises chronic primary pain as a disability or emotional distress and not better accounted for by another diagnosis of chronic pain	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well

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				and categorises chronic secondary pain separately into the following six categories: Chronic cancer-related pain, chronic postsurgical or post-traumatic pain, chronic neuropathic pain, chronic secondary headache or orofacial pain, chronic secondary visceral pain and chronic secondary musculoskeletal pain http://www.iasp-pain.org/PublicationsNews/NewsDetail.aspx?ItemNumber=8340	as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Abbott Laboratories U.K Limited	Guideline	006	008	As this is the first mention of chronic primary pain may be useful to provide ICD-11 definition here.	Thank you for your comment. A short definition has been included in the overview section and more detail has been added to the context that has been moved to the beginning of the guideline. This also links to a longer definition at the end of the document.
Abbott Laboratories U.K Limited	Guideline	009	010-024	As a general comment we would like to highlight that many of these treatments are approved for pain from a range of indications, but do not have a specific indication for chronic primary pain which is the focus of this current guidance.	Thank you for your comment. We have noted this where there is a recommendation to consider using any of the unlicensed treatments, or a recommendation for research.
Abbott Laboratories U.K Limited	Guideline	009	013	This section may be misinterpreted by the readers of this guideline: "It should be made clear that chronic primary	Thank you for your comment. We have included information about off-

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				pain (CPP) is not an approved indication for NSAIDs and any use for CPP is off label". The NSAID ibuprofen is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies. In the treatment of non-articular rheumatic conditions, the NSAID ibuprofen is indicated in periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low back pain; it can also be used in soft tissue injuries such as sprains and strains. The NSAID ibuprofen is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache, including migraine headache. The proposed wording in the draft guideline would mean an off-label indication for the NSAID ibuprofen, and there is no safety or efficacy data in this population. Therefore, we would suggest the inclusion of text that highlights that ibuprofen is not indicated for use in chronic primary pain.	license use where a medicine is recommended or there is a research recommendation, however we do not state this where the recommendation is not to use the medicine, and therefore does not conflict with the licensed indication. We have included a comment in the discussion of the evidence in the review chapter to highlight that there are no medicines that have a specific marketing authorisation for chronic primary pain or types of chronic primary pain in the UK.
Abbott Laboratories U.K Limited	Guideline	010	011	May be optimal to provide this information prior to providing recommendations based on the definitions as non-healthcare professionals are part of target audience	Thank you for your comment. A brief definition for the populations has been added to the guideline overview page and more detail is provided in

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					the context section that has been moved to the start of the guideline.
Abbott Laboratories U.K Limited	Guideline	011	007	Should this be chronic primary pain, also for line 9?	Thank you for your comment. The review for pain management programmes was for all types of chronic pain. However, on consideration of stakeholder comments this research recommendation has now been removed as it was considered there has already been extensive amounts of research in this area.
Abbott Laboratories U.K Limited	Guideline	012	009	Should this be chronic primary pain, also for line 11?	Thank you for your comment. The review for pain management programmes was for all types of chronic pain. However, on consideration of stakeholder comments this research recommendation has now been removed as it was considered there has already been extensive amounts of research in this area.
Abbott Laboratories U.K Limited	Guideline	013-016		Appears the terms chronic pain and chronic primary pain are used interchangeably.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled;

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					definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Abbott Laboratories U.K Limited	Guideline	024	026	Suggest divide NSAIDs and Benzodiazepines into two different paragraphs since we are talking about very different classes of drugs with different modes of action and non-healthcare professionals are part of target audience.	Thank you for your comment. Whilst we note and understand your rationale, it was agreed as better to have all recommendations against use of drugs together for ease for users of the guideline.
Abbott Laboratories U.K Limited	Guideline	024	028	It should be made clear that ibuprofen, an NSAID, is not indicated for the treatment of chronic primary pain.	Thank you for your comment. We have included information about off-

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					license use where a medicine is recommended or there is a research recommendation, however we do not state this where the recommendation is not to use the medicine, and therefore does not conflict with the licensed indication. We have included a comment in the discussion of the evidence in the review chapter to highlight that none of medicines considered in this review are not licensed for chronic primary pain in the UK.
Abbott Laboratories U.K Limited	Guideline	025	004-009	We are concerned that the recommendations cite "the risk of harm with NSAIDs (gastrointestinal bleeding)" as a factor in recommending against NSAID use in chronic primary pain. Whilst acknowledging the known risk of gastrointestinal (GI) bleeding with NSAIDs, it does not appear that an evidence review of latest research into safety of NSAIDs in chronic primary pain or chronic pain in general has been performed; conversely, a full systematic literature review has been conducted for safety of opioids and gabapentinoids. Recent clinical practice guidelines in Asia have recommended use of NSAIDs with consideration of patient GI risk profile (Ho et al. A J Pain Res. 2020; 13:	Thank you for your comment. Separate reviews for safety were undertaken for gabapentinoids and opioids only because of the increasing awareness for potential for harms from dependence and long term use of these medicines. The committee agreed that healthcare professionals are more aware of the harms of NSAIDs and their expert opinion and knowledge could also help inform recommendations on this aspect. This

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				1925–1939). Although targeted for Asian practice, the evidence base considered included studies in non-Asian populations. Abbott considers this as being particularly important given there are factors that must be understood further. For example, GI bleeding risk can be reduced with eradication treatment for potential *H. pylori*infection, as this has been shown to be an independent risk factor for GI bleeding (Sostres et al. Am J Gastroenterol 2015; 110:684–689). We feel this should also be considered in light of NICE guidance recommending NSAIDs for long term use in other conditions causing chronic pain.	was included as part of the consideration for the recommendation, but there was also lack of evidence of their effectiveness for chronic primary pain.
Abbott Laboratories U.K Limited	Guideline	025	004-009	This paragraph may be misinterpreted by the readers of this guideline. Ibuprofenis indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies. In the treatment of non-articular rheumatic conditions, ibuprofen is indicated in periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low back pain; it can also be used in soft tissue injuries such as sprains and strains. Ibruprofen is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache, including migraine headache.	Thank you for your comment. No medicines have a specific marketing authorisation for chronic primary pain or types of chronic primary pain in the UK but the review covered those that are frequently used off-license. We have added a statement in the discussion of evidence in the review chapter to that effect. It has not been included in the rationale for the recommendation, as the off-license use does not impact on the decision to recommend against it. This was based

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				The proposed wording would mean an off-label indication for the NSAID ibuprofen, and there is no safety or efficacy data in this population. Therefore, we would suggest the inclusion of text that highlights that ibuprofen is not indicated for this use in chronic primary pain.	on lack of evidence for effectiveness for chronic primary pain.
Abbott Laboratories U.K Limited	Guideline	026	020	The guideline in its current format does not clearly differentiate the classification and categories of chronic pain and this may lead to misinterpretation and confusion amongst clinicians to the value of NSAIDS in approved licenced indications in secondary chronic pain. This could undermine prescriber and patient confidence in approved indications for NSAIDs and result in appropriate patients not receiving access and treatment to medicines for which they are indicated and could benefit from. Much clearer classification between definitions and categories is needed to support interpretation and understanding by NHS prescribers.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.

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Abbott Laboratories U.K Limited	Guideline	027	007	Suggest clarifying that in such a situation chronic primary pain should be considered as a possible diagnosis.	Thank you for your comment. The context section has now been revised and a recommendation has been added for when to consider a diagnosis of chronic primary pain.
Abbott Laboratories U.K Limited	Guideline	028	005,007 ,008	Should this be chronic primary pain?	Thank you for your comment. This section has now been revised.
Abbott Laboratories U.K Limited	Guideline	Gene ral	General	Abbott is concerned that readers, of which include healthcare professionals and lay persons (patients/carers), may be confused between chronic pain and chronic primary pain and hence misinterpret the recommendations to include all chronic conditions causing pain, of which warrant pharmacological treatment.	Thank you for your comment. Additional text with definitions has been added to each section, and headings reworded to clarify which sections apply to chronic primary pain only, and what the definition is for this population. We hope this has added some clarity for readers.
Abbott Laboratories U.K Limited	Guideline	Gene ral	General	The confusion relating to the use of chronic pain and chronic primary pain in these recommendations may be compounded by the clinical evidence search being limited to only randomised controlled trials (RCTs), thereby excluding the wider evidence base of non-randomised controlled trials studies, especially in light of the small volume of RCTs identified.	Thank you for your comment. We do not agree that the use of RCTs is related to any confusion between populations covered in the guideline and recommendations. As stated above, we have added headings and definitions to clarify populations covered. In many cases there were sufficient RCTs available. Where they were lacking, the committee agreed a

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					priori when setting the protocol that evidence from observational studies would not be sufficient quality to inform recommendations for a condition affecting such a large population which would therefore require robust evidence to inform recommendations.
Abbott Laboratories U.K Limited	Guideline	General	General	On review of the evidence documents, we are conscious that the risk of harm with NSAIDs is cited, however there has not been a review conducted looking at safety evidence for this widely-used group of treatments.	Thank you for your comment. The committee agreed that healthcare professionals are more aware of the harms of NSAIDs and this is well documented. The committee's expert opinion and knowledge was used to help decision making in cases where evidence wasn't available from the review. This was included as part of the consideration for the recommendation, but there was also lack of evidence of their effectiveness for chronic primary pain which informed the recommendation.
Action on Pain	General	General	General	In a court of law evidence has to be to such a standard as to convince the jury to beyond reasonable doubt before making a guilty decision.	Thank you for your comment. The decision making process followed to make recommendations is as per

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				In a civil court the burden of proof is somewhat lower being one of the balance of probabilities yet still requiring a high degree of credible evidence. You may well ask where the relevance of this is to the document being commented on yet it is very clear. In both cases decisions are made based on credible and reliable evidence. Using this criteria it is obvious to any reasonable person that throughout this document the evidence provided on which you make your recommendations is extremely poor. Indeed some of the references used are over 25 years old baring little relevance to healthcare today. We highlight two examples the first being pain management programmes where the sparse evidence provided bears little resemblance to the feedback we receive as a national charity with over 22 years experience. During that time we have often been involved in the delivery of pain management programmes either for chronic pain in the round or for a particular condition. One recurring theme is that the committee must give due weight to is that almost without exception there is little follow up after the end of the programme. Simply put nobody knows how that patient is doing six months after the programme finishes so how can there be any credible measure of success or failure? Through our helpline and visitors to our mobile information unit we gain credible intelligence which shows that from the	Developing NICE guidelines: The Manual and as set out in the methods chapter for this guideline. A number of factors are considered when forming recommendations including the quality of the evidence, size of the body of evidence, relevance and applicability to current context, for both the clinical and economic evidence. The committee's discussion around the evidence and how this informed the recommendation is detailed in each evidence review and in the rationales attached to each recommendation in the guideline. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment and often without much evidence from long term follow up. This was considered by the committee

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				people who talk with us having been on a pain management programme over 60% have indicated they benefited from it We certainly do not recognise the cost factors included in the document related to pain management programmes which again reflects the lack of credibility in your assertions Let us now turn to the recommendations on usage of TENs which show a worrying lack of insight by the committee again based on very poor evidence which in some cases is so dated as to be no longer relevant. Here at Action on Pain we have a mass of experience and expertise with TENs covering over twenty years which has provided invaluable knowledge as to effective usage of TENs. Let us make it very clear that we readily accept that TENs does not work for everyone then neither does medication. Yet what is does do is to provide a form of pain relief that has no side effects as well as having the potential to being a valuable asset in helping patients to come off the cocktail of medications so often prescribed by doctors. You should be totally aware that a common theme we have found over the years is that when we ask patients have they used TENs they often say yes but it did not help. Yet when we probe a bit deeper we invariably find that they have not used it correctly because of poor advice received from the relevant	and reflected in the recommendations. In the case of pain management programmes the committee considered that the evidence base was not sufficiently consistent to inform a recommendation for or against pain management programmes. The cost of all treatments in the guideline has to be considered, by looking at the cost effectiveness. If there is lack of evidence of benefit there is an opportunity cost which must be considered. For TENS in people with chronic primary pain, only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for any of the patient reported outcome measures.

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				healthcare professional or retailer selling the machines. A prime example of this is where we discovered that many people were only using the machine for 30 minutes a day. Why-because that was the maximum the machine could be set to and they were none the wiser. In every case we would provide relevant and coherent advice asking for feedback from the patient. It is safe to say that the positive response we receive from patients fully justifies the use of TENS. Where we believe the committee has made a grave error is to rely too heavily on poor evidence rather than seeking the expertise of organisations such as Action on Pain who deal with this on a daily basis rather than a short research trial. The strongest and compelling evidence is the anecdotal evidence which is totally absent from this document yet clearly has a major part to play yet the committee has totally ignored it we would suggest at its peril. What the committee needs to fully understand and take on board is that if the patient feels that it is working for them then TENs is doing its job especially if it reduces medicines intake. To be able to go about your daily life using a TENs machine is a far better option than being on medications with side effects which impede your daily wellbeing. Equally TENs is a low cost option which based on our experience has a credible success rate. We do wonder how you can turn your back on this experience by recommending the denial of TENs	NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended. All healthcare professionals on the committee are currently in clinical practice and were recruited according to the composition that was agreed appropriate during the scoping process (including the stakeholder workshop) to cover the appropriate range of expertise for the scope of the guideline. Both healthcare professional members and lay members are recruited according to policies set out in the NICE manual. The names of all members of the committee are available on the guideline page on the NICE website.

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				to patients who will benefit from it. That is the reality which is missing within this document. In conclusion we believe this document is a poorly conceived piece of work that has no place in the provision of pain management services in the NHS. We are aware that many healthcare professionals working in NHS pain clinics share our serious reservations citing the obvious detrimental effect for their patients. We also believe that the consist of the committee is too heavily weighted with members who through being enmeshed in research are far away from the day to day reality that people with chronic pain have to face. We also note whilst not making any adverse comment about the two lay members that they are totally anonymous with no detail of what they do and where they come from which again cannot be right. Taking this all into consideration we are minded to seek a judicial review if this document is not revisited in considerable depth taking evidence from credible sources including those such as Action on Pain .	
Action on Pain	Guideline	006	010	Promote exercise. Whilst fully supporting exercise regimes we are concerned that this recommendation may imply that a supervised exercise programme is the key	Thank you for your comment. The evidence reviewed in the guideline demonstrated effectiveness of

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				treatment approach. However, we frequently promote functional activity with patients who struggle or are too fearful of the concept of an actual exercise programme	supervised group exercise programmes. The committee agreed that the type of exercise may depend on the type of pain, but also that people are more likely to continue with exercise if the programme offered suits their lifestyle and physical ability and addresses their individual health needs. They agreed that the choice of programme as well as the content should take into account people's abilities and preferences. This might include providing individual exercise advice for different members of a group. This was highlighted in the recommendation and in more detail in the rationale underpinning the recommendation.
Action on Pain	Guideline	007	007	This recommendation may be challenging in practice as currently with the covid pandemic the physiotherapists who would offer acupuncture in a community setting are unable to work in that arena (GP surgeries) as the GPs are not agreeing to the therapists returning so they are currently working in secondary care. Also without covid some therapists are not confident or do not have the	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national

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				expertise to treat patients with chronic pain so they would automatically refer patients onto a chronic pain clinic in secondary care. Whilst we agree that acupuncture could be offered in a primary setting, offering acupuncture in a chronic pain clinic enables an experienced and fully qualified practitioner to use the time to reinforce self-management strategies; reassurance and education.	guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in

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					other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Action on Pain	Guideline	008	004	There is strong anecdotal evidence that TENS can be helpful to patients with chronic pain. It also enables the patient to take responsibility for their treatment. The guidelines report there is limited evidence on its effectiveness but we believe this is often due to the patients' poor understanding of how to effectively use the TENS machine i.e – poor understanding of the treatment programme selection, time worn, electrode placement. We therefore feel the guideline is too dogmatic and would prefer that it states that…'TNS may be considered but may not be effective. Practitioners need to ensure that patients understand how to appropriately use the machine.' We are concerned that patients may miss out on trialling a low cost piece of equipment that has little if no side effects and may reduce the need for medication particularly as the guidelines are potentially limiting these any way.	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any

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					evidence of benefit this should not be recommended.
Action on Pain	Guideline	009	013	We are concerned that this recommendation may limit patients who may present with degenerative joints eg in the spine where the occasional use of an NSAID (being mindful of the GI effects) could be helpful to them.	Thank you for your comment. This recommendation and review was for the chronic primary pain population only, rather than other types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline.
Action on Pain	Guideline	009	015	We are concerned that this recommendation my limit patients who present with chronic primary pain with a neuropathic component where the GP reads these guidelines and will then not prescribe gabapentinoids. There is a risk that patients who are refused such medication will seek it via other routes such as buying	Thank you for your comment. The reviews for pharmacological interventions was for the chronic primary pain population only, rather than all types of pain. Chronic pain

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				them illegally on the street, many of which could be counterfeit. The guidelines also recognise that more research is needed for their use in CRPS but surely this will also apply to patients with neuropathic pain of a chronic primary nature.	already covered in existing NICE guideline was also excluded from the specific intervention reviews – such as the NICE guideline for management of neuropathic pain in adults CG173. The committee agreed that gabapentinoids should not be recommended for chronic primary pain. The expert opinion of the committee was that CRPS is sometimes thought of a neuropathic pain and it was noted that there had been two subtypes of CRPS listed in ICD-11. The committee therefore agreed it was appropriate to include a research recommendation for the use of gabapentinoids for CRPS only. The committee do acknowledge that chronic primary and chronic secondary pain can coexist, a recommendation has now been added to highlight this. Clinical judgement should be used to determine the appropriate treatment option relevant to the type of pain being treated

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03/08/2020 – 14/08/2020

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					according to the relevant NICE guideline.
Arthritis and Musculoskeletal Alliance (ARMA)	Guideline	General	General	As currently worded, this document creates significant confusion about which recommendations refer to chronic primary pain and which to all forms of chronic pain. We have spoken to clinicians who have been unclear about this distinction and believe that all the recommendations in the guidance cover all forms of chronic pain. The introduction and layout of the guidance need to make this much clearer. The paragraph highlighting the key NICE guidelines related to specific conditions (1.2) also needs to be made stronger, making it clear that these guidelines should be used when managing these conditions. The way in which the publication of the guidelines was publicised has also exacerbated the confusion. Most media coverage used the term chronic pain throughout. The headline of the news story on the NICE website also used the term chronic pain not chronic primary pain. Although the article explained the definition of chronic primary pain, the headline: "Commonly used treatments for chronic pain can do more harm than good and should not be used, says NICE in draft guidance" was misleading as it omitted the word primary. When the final guideline is published it is essential that all communications from NICE are both accurate and make	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. It is our intention that this will improve clarity for all readers and

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				strenuous efforts to reduce the amount of misreporting in general media. Media communication also needs to make explicit reference to paragraph 1.3.13 on the need for care around withdrawal of medicines for those already taking them.	users of the guideline, including the media.
Arthritis and Musculoskeletal Alliance (ARMA)	Guideline	027 & 028	027 line 004 – 0028 line 022	The context section is unhelpful in relation to the distinction between chronic pain and chronic primary pain. It refers to chronic pain throughout with no reference to chronic primary pain. We would also like to see a reference here to the importance of appropriately and quickly treating painful conditions, such as arthritis, in line with the relevant NICE guidelines. For many people the cause of their pain can be diagnosed and treated, and this is an important part of reducing and managing chronic pain. In this context we believe it is inaccurate to say that a clear diagnosis is rarely available.	Thank you for your comment. The context section has been revised to more clearly explain the distinction between chronic primary and chronic secondary pain. A recommendation has also been added to highlight that secondary pain should be managed according to other relevant NICE guidelines and there is a link to direct towards them.
Arthritis and Musculoskeletal Alliance (ARMA)	Guideline	General	General	Challenges to implementing the guidance: A significant barrier to implementing the guideline will be the lack of availability of the recommended interventions. Access to non-pharmacological interventions for pain management is currently very limited in many areas. Without investment in commissioning of alternatives to pharmacological interventions, pharmacological interventions will remain a significant aspect of chronic primary pain management.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain

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					will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Arthritis and Musculoskeletal Alliance (ARMA)	Evidence Review Social interventions	General	General	There does not seem to have been any review of the effectiveness of peer support, which is widely recognised to be valuable in supporting people to manage pain. We are not aware of any RCT, but many peer support group programmes have been evaluated. This seems an omission from the evidence review and from the guidance.	Thank you for your comment. Peer led pain management programmes were considered within the review, but there was insufficient evidence on these. The evidence for peer support groups was not specifically reviewed within the guideline however.
Arthritis and Musculoskeletal Alliance (ARMA)	Guideline	014	022 - 024	Challenges to implementing the guidance: A second significant barrier is the need for longer consultations and increased follow up, noted in the guideline draft. We do not believe this is realistic if it is going to be delivered in primary care. A significant increase in community based multi-disciplinary pain teams with sufficient capacity to deliver these longer conversations is required for this guideline to be implemented. This increased need would be supported by provision of group interventions, supported self management and peer support. Wider and faster access to such interventions could help reduce the pressure on primary care and community pain teams, so	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				enabling the improved conversations required to implement the guidance	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Association for Dance Movement Psychotherapy	General	015 and 017	020 and 018	All the aspects identified will likely be affected by chronic pain whether explained medically or not i.e. • lifestyle and day-to-day activities, including work and sleep disturbance • physical and psychological wellbeing • social interaction and relationships However, none of the recommendations (such as exercise, physiotherapy, pharmaceuticals, pain management programmes, social or psychological interventions), for managing such conditions appear to include evidence improving all these aspects. We know the perception of pain is subjective. A holistic embodied psycho-social intervention such as The BodyMind Approach provides opportunities to integrate the body-felt physical sensation of the pain with the patient's emotional inner world, lived bodily experience, lifestyle, relationships and subjective wellbeing. The outcomes of this innovative intervention demonstrate patients learn to	Thank you for your comment. The committee looked for evidence in a range of outcomes and detailed in the rationales where evidence of benefit was observed. For all of those recommended (exercise, acupuncture, psychological therapies and antidepressants), benefits were seen in quality of life, which the committee agree encompasses elements of each of the three areas highlighted. Evidence for the BodyMind approach was not identified that was relevant to any of the reviews within the

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				self-manage their pain to live well. Additionally, it can be shown patents have no need to return the GP or A&E, be referred for more tests and scans, resulting in cost savings for the NHS. An action plan is designed by the patient as a result of their learning during the intervention, which they carry out with minimal support for six months post intervention. The BodyMind Approach (designed specifically for unexplained pain and derived from dance movement psychotherapy) is a biopsychosocial intervention. It works with the bi-directionality between body and mind (the latter is not only the brain) to connect emotional and physical aspects involved with the experience of pain through generating practices from mindful movement, presence, the arts, somatics, emotional regulation, and facilitated group work. The improvement in self (and body) compassion appears key to the positive, encouraging outcomes from this methodology. More research on a larger scale is required to confirm early outcomes. Chronic pain is notoriously difficult to treat and very debilitating for patients. It will be important to educate all healthcare professionals and commissioners in primary care on emerging interventions with encouraging results. For more information: Payne, H & Fordham, R. (2008) *Group BodyMind Approach to Medically Unexplained Symptoms: Proof of Concept & Potential Cost Savings*. Unpublished Report, East of	guideline and therefore recommendations cannot be made.

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				England Development Authority and The University of Hertfordshire Payne, H (2009a) Medically unexplained conditions and the BodyMind approach. *Counselling in Primary Care Review, 10,1, 6-8.* Payne, H.(2009b) The BodyMind Approach to psychotherapeutic groupwork with patients with medically unexplained symptoms: a review of the literature, description of approach and methodology selected for a pilot study. *European Journal for Counselling and Psychotherapy. 11, 3,287-310.* Payne, H. (2009c) Pilot study to evaluate dance movement psychotherapy (The BodyMind Approach) with patients with medically unexplained symptoms: Participant and facilitator perceptions and a summary discussion. *Int.Journal for Body, Movement & Dance in Psychotherapy. 5, 2, 95-106.* Payne, H. & Stott, D. (2010) Change in the moving bodymind: Quantitative results from a pilot study on the BodyMind Approach (BMA) as groupwork for patients with medically unexplained symptoms (MUS). *Counselling and Psychotherapy Research, 10,4, 295-307.* Payne, H (2014) Patient experience: push past symptom mysteries. *The Health Service Journal, 124, 6390, 26-7.* Lin, Y & Payne , H (2014) The BodyMind Approach™, Medically Unexplained Symptoms and Personal Construct Psychology. *Body, Movement and Dance in Psychotherapy, 9, 3.*	

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				Payne, H (2014) The BodyMind Approach: the treatment of people with medically unexplained symptoms. *The Psychotherapist, summer, issue 57, 30-32* Gallagher, S & Payne, H (2015)The role of embodiment and inter-subjectivity in clinical reasoning, *Body, Movement and Dance in Psychotherapy, 9, 4* Payne, H (2015)The Body speaks its Mind:The BodyMind Approach™ for patients with medically unexplained symptoms in UK primary care. *Arts in Psychotherapy, 42,19-27.* Payne, H & Brooks S (2016)Clinical outcomes and cost benefits from The BodyMind Approach™ for patients with medically unexplained symptoms in primary health care in England: Practice-based evidence. *Arts in Psychotherapy, 47, 55–65* Payne, H (2016). The BodyMind Approach™. *Healthcare, Counselling and Psychotherapy Journal*, BACP,16, 4,14-18. Payne, H & Brooks, S (2017)Moving on:The BodyMind Approach™ for medically unexplained symptoms.*Public Mental Health Journal*, 10, 2. Payne, H (2017) Transferring research from a Unversity into the National Health Service; Implications for impact. *Health Research Systems and Policy*, Opinion Piece,15:56 DOI 10.1186/s12961-017-0219-3 Payne, H (2017) The BodyMind Approach: Supporting people with medically unexplained symptoms/somatic symptom disorder. *Journal of Psychotherapy and Counselling Psychology Reflections*, 2, 2.	

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				Sanders, T; Winter, D & Payne H (2018) Personal constructs of mind-body identity in people who experience medically unexplained symptoms. *Journal of Constructivist Psychology, Dec 2018, 0(0), 1–16, 2018, print / 1521-0650 online*. DOI: 10.1080/10720537.2018.1515047 Payne, H & Brooks, S (2018) Different strokes for different folks:The BodyMind Approach as a learning tool for patients with medically unexplained symptoms to self-manage.*Frontiers in Psychology*,https://doi.org/10.3389/fpsyg.2018.02222http://journal.frontiersin.org/article/10.3389/fpsyg.2018.02222/full?&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Psychology&id=371037 Payne, H & Brooks, S (2019) Medically unexplained symptoms and attachment theory: The BodyMind Approach®. *Frontiers in Psychology*,10:1818. doi: 10.3389/fpsyg.2019.01818 http://journal.frontiersin.org/article/10.3389/fpsyg.2019.01818/full?&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Psychology&id=433131 Payne, H, Jarvis, J & Roberts, A (2020) The BodyMind Approach as transformative learning to promote self-	

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				management for patients with medically unexplained symptoms. *J. of Transformative Education, April issue.* Payne, H & Brooks, S (2020)A qualitative analysis of patient perceptions of The BodyMind Approach for people with medically unexplained symptoms. forthcoming *Frontiers in Psychology* Payne, H & Brooks, S (2020) Learning to manage medically unexplained symptoms: The BodyMind Approach and the chronic stress response. In preparation	
Bangor University	Guideline	General	General	The major flaw in this guidance is the focus on the ICD11 diagnostic category of "Chronic primary pain". Although it embraces commonly used clinical diagnoses, it is not a concept that has wide currency. It is largely a diagnosis of exclusion distinguished from other pain conditions by the lack of an identified physiological mechanism for the pain and the effects of the pain in causing distress to the patient and disruption to everyday life. This nosological concept gives primacy to physiological mechanisms in understanding pain. This misconstrues the nature of pain, which is not a physical stimulus but a perception. This is constructed from a physical stimulus and factors such as the experience, expectations, knowledge meanings and mood of the patient which are influenced by the social contexts in which the patients live their lives. All pain patients' experiences of pain are constructed from these factors. To identify these psychological and social factors	Thank you for your comment. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the

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				as significant only in "Chronic primary pain" is to create a false dichotomy. The non-identification of physiological mechanisms as a basis for diagnostic categorisation relies on factors entirely separate from the patient such as the state of current medical knowledge and understanding, and the skills and resources availableto the diagnostician. Failure to identify mechanisms does not mean that such mechanisms do not exist. Furthermore, although there are significant specific treatments that are appropriate in the management of pain associated with particular pathologies, the principles of managing chronic pain do not vary according to putative causation. The detailed exploration of patient histories, circumstances and needs encouraged in the recommendations on assessment are appropriate to understanding all chronic pain. The suggestion that there is a specific role for antidepressants and that analgesic medications should be completely avoided is not, in our opinion, helpful. Medication has a limited but distinct role in the management of chronic pain. An emphasis on non-pharmacological treatments, especially those that are rehabilitative rather than aspiring to symptom elimination, is importance. Unfortunately, the guidelines as currently drafted are somewhat nihilistic, and as such are likely to be ignored.,	similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS).
Birmingham Community	Evidence E	gene ral	general	Should changes be made to provide clear justification as to the inclusion of the chronic neck pain literature but not	Thank you for your comment. On consideration of each of the

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Healthcare NHS Foundation Trust.				other chronic musculoskeletal literature, the recommendations are made on incomplete neck pain data. Upon reviewing Evidence Review E there appears to be several trials that are missing (Waling, Jarvholm et al. 2002, Borisut, Vongsirinavarat et al. 2013, Rudolfsson, Djupsjobacka et al. 2014, Lee and Kim 2016, Li, Lin et al. 2017, Kaur, Mali et al. 2018, Ulug, Yilmaz et al. 2018, Shiravi, Letafatkar et al. 2019). The inclusion of these trials is likely to increase sample size for meta-analysis, which could have an impact the imprecision rating in GRADE, potentially changing recommendations. Borisut, S., et al. (2013). "Effects of strength and endurance training of superficial and deep neck muscles on muscle activities and pain levels of females with chronic neck pain." J Phys Ther Sci25(9): 1157-1162. Kaur, A., et al. (2018). "To Compare the Immediate Effects of Active Cranio Cervical Flexion Exercise Versus Passive Mobilization of Upper Cervical Spine on Pain, Range of Motion and Cranio Cervical Flexion Test in Patients with Chronic Neck Pain." Indian Journal of Physiotherapy & Occupational Therapy12(3): 22-27. Lee, K. W., et al. (2016). "Effect of thoracic manipulation and deep craniocervical flexor training on pain, mobility, strength, and disability of the neck of patients with chronic nonspecific neck pain: a randomized clinical trial." J Phys Ther Sci28(1): 175-180.	references provided, we agree that some of these studies in other types of chronic primary musculoskeletal pain were erroneously excluded from the review. Borisut et al., Lee et al. Ulug et al. and Waling et al. have now been added to the review. This did not have a significant impact on the results of the review, but provided more evidence of benefit of exercise. The remaining studies were excluded for the following reasons: Kaur et al. was excluded as there were no outcomes relevant to the review protocol. Li et al. was excluded as the control group did not meet the review protocol criteria. Rudolfsson et al. was excluded as the interventions were not relevant to the review protocol.

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				Li, X., et al. (2017). "Comparison of the effectiveness of resistance training in women with chronic computer-related neck pain: a randomized controlled study." Int Arch Occup Environ Health90(7): 673-683. Rudolfsson, T., et al. (2014). "Effects of neck coordination exercise on sensorimotor function in chronic neck pain: a randomized controlled trial." J Rehabil Med46(9): 908-914. Shiravi, S., et al. (2019). "Efficacy of Abdominal Control Feedback and Scapula Stabilization Exercises in Participants With Forward Head, Round Shoulder Postures and Neck Movement Impairment." Sports Health11(3): 272-279. Ulug, N., et al. (2018). "Effects of Pilates and yoga in patients with chronic neck pain: A sonographic study." J Rehabil Med50(1): 80-85. Waling, K., et al. (2002). "Effects of training on female trapezius Myalgia: An intervention study with a 3-year follow-up period." Spine (Phila Pa 1976)27(8): 789-796.	Shiravi et al. was excluded because the control group did not meet the review protocol criteria.
Birmingham Community Healthcare NHS Foundation Trust.	Evidence E	General	general	It is also noted that Jordan, Bendix et al. (1998)and (Khan, Soomro et al. 2014)were excluded due to incorrect outcome measures despite them providing measures of pain (11 point box scale) and pain and disability (VAS/Northwick Park Neck Pain Questionnaire) respectively. The inclusion of these trials is likely to increase sample size for meta-analysis, which could have	Thank you for your comment. These studies have been checked again for ability to extract relevant outcomes. None are relevant to be included in the review, for the following reasons: Jordan et al. all outcomes were reported as median and 95%

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				an impact the imprecision rating in GRADE, potentially changing recommendations. Jordan, A., et al. (1998). "Intensive training, physiotherapy, or manipulation for patients with chronic neck pain. A prospective, single-blinded, randomized clinical trial." Spine (Phila Pa 1976)23(3): 311-318; discussion 319. Khan, M., et al. (2014). "The effectiveness of isometric exercises as compared to general exercises in the management of chronic non-specific neck pain." Pak J Pharm Sci27(5 Suppl): 1719-1722.	confidence intervals, or range only. These cannot be fully quality assessed and therefore are not reported here. The exclusion reason is stated as 'no useable outcomes' rather than 'no relevant outcomes' to reflect this. On review of Khan et al. it was also determined that the comparator was not relevant to this review protocol (two different types of strengthening exercise are compared to each other). The exclusion reason has been updated in the excluded studies list.
Birmingham Community Healthcare NHS Foundation Trust.	Evidence E	general	general	The NICE team have used the term "strength exercise" in Evidence Review E, without providing a definition of what this means. It is therefore unknown if "strength exercise" refers to any exercise training with goal of improving outcomes of strength or is being used synonymously with resistance training. The latter is inappropriate, and the former is only valid if used correctly. It is recommended that NICE remove all reference to strength exercise and replace with resistance training or provide a definition to demonstrate that the aim of these exercise interventions is to improve any aspect of neuromuscular function or motor capacity.	Thank you for your comment. The types of exercise were used to guide the review. Where there was lack of clarity as to where an intervention should be grouped, the committee were asked to advise. These terms have been removed from the recommendation as the review did not inform whether one type of exercise was better than another, and it was agreed this should be informed

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				Justification Exercise training to improve outcomes of strength requires specific exercise and dosage parameters (Bird, Tarpenning et al. 2005, American College of Sports 2009). Although cross over exists, should different dosages of exercise be used than that recommended for strength, exercise is likely to be ineffective in achieving strength outcomes or likely to result in other physiological outcomes such as power, endurance or hypertrophy. This would therefore invalidate the categorisation of "strength exercise". With this in mind, it isn't clear how the team have come to the conclusion that some trials have delivered "strength exercise" when the trials themselves have not provided sufficient dosage information to make that judgment e.g. Etnier, Karper et al. (2009), Rendant, Pach et al. (2011)and Espi-Lopez, Ingles et al. (2016). Further to this, where dosage information is provided the team have categorised the intervention as "strength exercise", when it is not appropriate e.g. Ylinen, Takala et al. (2003)reported a dosage of 3x20 @ 2kg for upper limb resistance training, which is a parameter for endurance changes rather than strength (Bird, Tarpenning et al. 2005, American College of Sports 2009). In addition Chiu, Hui-Chan et al. (2005), Falla, Lindstrom et al. (2013)and Suvarnnato, Puntumetakul et al. (2019)all describe a	by the needs and preferences of the person.

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				craniocervical flexion exercise under low load aimed at improving motor control. The NICE team have included these as strengthening interventions, despite evidence demonstrating the dosage parameters used have little effect on strength (Falla, Jull et al. 2006, O'Leary, Jull et al. 2012, Blomgren, Strandell et al. 2018, Suvarnnato, Puntumetakul et al. 2019). A further argument against categorising interventions as "strength exercise" is that the current dosage parameter recommendations are only valid for a healthy population. It is currently unknown whether the same dosage parameters apply to unhealthy or chronic pain populations. Chronic pain populations may only require much smaller dose to elicit strength changes or they may be unable to tolerate the recommendations for a healthy population (Wallis, Webster et al. 2015). It is recommended that NICE remove all reference to strength exercise and replace with resistance training or provide a definition to demonstrate that the aim of these exercise interventions is to improve any aspect of neuromuscular function or motor capacity. American College of Sports, M. (2009). "American College of Sports Medicine position stand. Progression models in resistance training for healthy adults." Med Sci Sports Exerc41(3): 687-708.	

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				Bird, S. P., et al. (2005). "Designing resistance training programmes to enhance muscular fitness: a review of the acute programme variables." Sports Med35(10): 841-851. Blomgren, J., et al. (2018). "Effects of deep cervical flexor training on impaired physiological functions associated with chronic neck pain: a systematic review." BMC Musculoskelet Disord19(1): 415. Chiu, T. T., et al. (2005). "A randomized clinical trial of TENS and exercise for patients with chronic neck pain." Clin Rehabil19(8): 850-860. Espi-Lopez, G. V., et al. (2016). "Effect of low-impact aerobic exercise combined with music therapy on patients with fibromyalgia. A pilot study." Complement Ther Med28: 1-7. Etnier, J. L., et al. (2009). "Exercise, fibromyalgia, and fibrofog: a pilot study." J Phys Act Health6(2): 239-246. Falla, D., et al. (2006). "An endurance-strength training regime is effective in reducing myoelectric manifestations of cervical flexor muscle fatigue in females with chronic neck pain." Clin Neurophysiol117(4): 828-837. Falla, D., et al. (2013). "Effectiveness of an 8-week exercise programme on pain and specificity of neck muscle activity in patients with chronic neck pain: a randomized controlled study." Eur J Pain17(10): 1517-1528. O'Leary, S., et al. (2012). "Training mode-dependent changes in motor performance in neck pain." Arch Phys Med Rehabil93(7): 1225-1233.	

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				Rendant, D., et al. (2011). "Qigong Versus Exercise Versus No Therapy for Patients With Chronic Neck Pain." Spine36(6): 419-427. Suvarnnato, T., et al. (2019). "Effect of specific deep cervical muscle exercises on functional disability, pain intensity, craniovertebral angle, and neck-muscle strength in chronic mechanical neck pain: a randomized controlled trial." J Pain Res12: 915-925. Suvarnnato, T., et al. (2019). "Effect of specific deep cervical muscle exercises on functional disability, pain intensity, craniovertebral angle, and neck-muscle strength in chronic mechanical neck pain: a randomized controlled trial." Journal of pain research12: 915-925. Wallis, J. A., et al. (2015). "The maximum tolerated dose of walking for people with severe osteoarthritis of the knee: a phase I trial." Osteoarthritis Cartilage23(8): 1285-1293. Ylinen, J., et al. (2003). "Active neck muscle training in the treatment of chronic neck pain in women: a randomized controlled trial." JAMA289(19): 2509-2516.	
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	004	001.1	There is evidence that when assessing and managing chronic pain it is not only about what is being delivered, but critically by identify the competences most likely to produce effective delivery of an assessment/ intervention – Who is delivering it – In what context – The critical competencies for effective delivery	Thank you for your comment. We will pass this information to our local practice collection team. More information on local practice can be found here: www.nice.org.uk/sharedlearning

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				– Are HCP's competent to deliver There is evidence that bespoke services are more effective than generic (2017 Rona Moss-Morris Professor of Psychology as Applied to Medicine National Clinical Advisor to IAPT NHS England)and with better clinical outcomes • best outcomes are for condition specific services • patients respond better to clinical interventions which are tailored to their physical condition Cochrane conclude that a multidisciplinary approach is needed, conventional analgesics are usually not effective and only a minority of individuals achieve worthwhile pain relief. Our trust has had experience of implementing the following approach and would be willing to submit its experiences to the NICE shared learning database. (Contact Dr Adam Cleary Consultant Clinical Psychologist adam.cleary@nhs.net) A competence framework for psychological interventions with people with persistent physical health conditions (Anthony D. Roth and Stephen Pilling April 2015 Research Department of Clinical, Educational and Health Psychology, UCL) For example in detailing competences for Assessment, Formulation, Engagement and Planning Also	

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				Meta-competences – overarching, higher-order competences which practitioners need to use to guide the implementation of any assessment or intervention.	
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	005 & 010	017 & 011 respectively	It is not clear that the evidence for chronic neck pain was included when making recommendations. While Section 1.2 "Managing all types of chronic pain" alludes to specific conditions (e.g. Low back pain, osteoarthritis) being excluded from this review if existed guidelines are already in use, the wording could suggest that all "specific conditions" were excluded. The definition of chronic primary pain further in the document (pg 10) does not provide much more clarity, not does it make it clear that neck pain is included in the review, but low back pain and osteoarthritis were excluded.	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. Chronic neck pain was included within the chronic primary pain definition (as a chronic primary musculoskeletal pain). Low back pain was excluded from the scope of this guideline for the specific management reviews due to there already being existing NICE guidance on this topic. Osteoarthritis is also excluded for the same reason and is not considered a chronic primary pain.
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	006	1.2.1	There is evidence to suggest the usefulness of Mindfulness Based Stress Reduction (MBSR) as effective group treatment for chronic pain, when compared to Cognitive Behavioural Therapy group interventions (Khoo, Eve-Ling & Small, Rebecca & Cheng, Wei & Hatchard, Taylor & Glynn, Brittany & Rice, Danielle & Skidmore, Becky & Kenny, Samantha & Hutton, Brian &	Thank you for your comment. This review was for chronic primary pain only, rather than all types of chronic pain. The references of the systematic reviews you highlight were checked for any studies relevant to this review protocol. No new studies were

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				Poulin, Patricia. (2019). Comparative evaluation of group-based mindfulness-based stress reduction and cognitive behavioural therapy for the treatment and management of chronic pain: A systematic review and network meta-analysis. Evidence-Based Mental Health. 22. 26-35. 10.1136/ebmental-2018-300062; Evidence suggests improved mental health following a Mindfulness- based pain management group programme (Brown, Christopher & Jones, Anthony. (2012). Psychobiological Correlates of Improved Mental Health in Patients With Musculoskeletal Pain After a Mindfulness-based Pain Management Program. The Clinical journal of pain. 29. 10.1097/AJP.0b013e31824c5d9f.)	identified. The evidence reviewed for mindfulness for chronic primary pain in this guideline was not sufficient to inform a recommendation, however the committee agreed results were promising and therefore recommended further research to inform future updates of the guideline.
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	006	1.2.2	There is evidence that social and environmental factors are important factors in maintaining emotional equilibrium and quality of life e.g Model of Adjustment to Long Term Conditions Moss-Morris, R. (2013).. British Journal of Health Psychology (2013), DOI:10.1111/bjhp.12072	Thank you for your comment. The committee agree these may be important factors, the editorial reference you provide cannot be included in the review as it is not a primary study and not specific to chronic pain. It also doesn't reference any evidence that would meet the criteria for this review protocol. We searched for all relevant evidence for social interventions specific to people with chronic pain for this question. We also undertook reviews on factors

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					that were barriers to managing chronic pain, but no relevant evidence specific to chronic pain was identified.
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	007	008	Advocating the use of Acupuncture to treat Chronic Primary Pain is in direct contradiction to the recommendations in NG59 (LBP and Sciatica) which explicitly state: "Do not offer acupuncture for managing low back pain with or without sciatica"	Thank you for your comment. The committee were aware of the recommendation and evidence review underpinning the recommendation in NG59. The review for this guideline excluded evidence in people with low back pain and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica. De novo economic modelling also supported the recommendation for chronic primary pain.
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	007	015	Consider adding new bullet point "is used as an adjunct to other treatments e.g. Exercise & Psychological Therapy". Used alone, acupuncture is a passive treatment that could create dependency. The focus of Chronic Pain Management is to reduce dependency and promote self-management therefore Acupuncture must only be an adjunct to treatments that promote self-management	Thank you for your comment. We do not have evidence that acupuncture is more effective as an adjunct to treatment. Nor any evidence for dependency. We have included a research recommendation for repeat courses of acupuncture however and

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					the recommendation is limited to a course of acupuncture that the evidence supported as being clinically and cost effective for chronic primary pain.
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	007	1.3.3	There is evidence from within expert reference groups (A competence framework for psychological interventions with people with persistent physical health conditions. Anthony D. Roth and Stephen Pilling April 2015 Research Department of Clinical, Educational and Health Psychology, UCL) and from the wider evidence base for two sets of recommended psychological interventions: a) a number of approaches based on the application of Cognitive Behaviour Therapy (CBT) including ACT. Cochranefound sufficient evidence across a large evidence base (59 studies, over 5000 participants) that CBT has small or very small beneficial effects for reducing pain, disability, and distress in chronic pain. b) Short term Psychodynamic Therapies ; an approach that can be applied to a wide range of presentations including where there are barriers to effective engagement in self-management	Thank you for your comment. The reviews for specific interventions included in this guideline, and the relevant recommendations, are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the

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				Short term dynamic psychotherapies have empirical support from 50 randomized controlled trials and a large number of case series for chronic pain, anxiety, depression, somatic symptom disorders and substance addiction. There is evidence for this is condition specific chronic pain such as Fibromyalgia, Chronic Fatigue, Low back pain, headaches, pelvic pain, IBS. The latter set of interventions/ recommendations (b) are missing from the guidance.	relevant guidelines to enable more easy navigation between the recommendations for different topics. The committee agreed that the evidence reviewed for psychological therapies for chronic primary pain demonstrated sufficient evidence of clinical and cost effectiveness to warrant recommendations to consider both CBT and ACT. For psychodynamic psychotherapy, in this population the committee agreed there wasn't enough evidence to inform a recommendation, but the evidence was promising. They included a research recommendation to inform future updates of this guideline.
Birmingham Community Healthcare NHS Foundation Trust.	Guideline	011	012	There is evidence that mindfulness, and in particular Mindfulness based stress reduction (MBSR) can be a useful strategy in the management of chronic pain (Morone, N. E. (2019). Not Just Mind Over Matter: Reviewing With Patients How Mindfulness Relieves Chronic Low Back Pain. *Journal of Evidence-Based Integrative Medicine*, *24*, N.PAG. https://doi.org/10.1177/2515690X19838490) and	Thank you for your comment. This review was for chronic primary pain only, rather than all types of chronic pain, and excludes chronic pain covered in existing NICE guidelines. The references you have highlighted have been checked for relevance to

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				Majeed, Muhammad & Ali, Ali Ahsan & Sudak, Donna. (2017). Mindfulness-based Interventions for Chronic Pain: Evidence and Applications. Asian Journal of Psychiatry. 32. 10.1016/j.ajp.2017.11.025. Mindfulness when delivered online can remain effective in the treatment of chronic pain as evidenced in Henriksson, J., Wasara, E., & Rönnlund, M. (2016). Effects of Eight-Week-Web-Based Mindfulness Training on Pain Intensity, Pain Acceptance, and Life Satisfaction in Individuals With Chronic Pain. *Psychological Reports*, *119*, 586 - 607. Mindfulness has been shown to bring about pain relief associated with higher-order brain regions: Zeidan, F., Emerson, N. M., Farris, S.R. Ray, J.N., Jung, Y., McHaffie, J.G., and Coghill, R.C. (2015). Mindfulness Meditation-Based Pain Relief Employs Different Neural Mechanisms Than Placebo and Sham Mindfulness Meditation-Induced Analgesia. *Journal of Neuroscience*, 35 (46) 15307-15325; DOI: 10.1523/JNEUROSCI.2542-15.2015	this review protocol. None of these were relevant to include however: Morone et al. 2019 is a commentary referring to an associated study by the same author. This study is in people with chronic low back pain and therefore was excluded from the review of psychological therapies in this guideline. Majeed et al. was excluded due to being a literature review article (not a systematic review). References were checked for inclusion. Henriksson et al. was excluded due to the study population not being specific to chronic primary pain. The final two studies in your comment relate to mechanisms of action rather than being studies of effectiveness. The evidence reviewed for mindfulness for chronic primary pain in this guideline was not sufficient to inform a recommendation, however the committee agreed results were

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					promising and therefore recommended further research to inform future updates of the guideline.
Birmingham Community Healthcare NHS Foundation Trust.	Methods	general	general	If the chronic neck pain evidence is included this would support the inclusion of other chronic musculoskeletal conditions such as shoulder pain (Holmgren, Bjornsson Hallgren et al. 2012, Maenhout, Mahieu et al. 2013, Littlewood, Bateman et al. 2016)achilles pain (Silbernagel, Thomee et al. 2001, Norregaard, Larsen et al. 2007)and plantar heel pain (Rathleff, Molgaard et al. 2015)which have been excluded. For consistency, if chronic neck pain is included in the review, so too should other specific chronic musculoskeletal conditions. Holmgren, T., et al. (2012). "Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study." BMJ344(feb20 1): e787. Littlewood, C., et al. (2016). "A self-managed single exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy: a randomised controlled trial (the SELF study)." Clinical Rehabilitation30(7): 686-696. Maenhout, A. G., et al. (2013). "Does adding heavy load eccentric training to rehabilitation of patients with unilateral subacromial impingement result in better	Thank you for your comment. Where the diagnosis of shoulder pain falls within that of chronic primary pain it would be included in the management reviews, however if it is due to an underlying cause and is a chronic secondary pain, it would not be included in these, but would be covered by the section of the guideline covering all types of chronic pain. All of the references provided have been checked for their relevance to the exercise review protocol (which was for chronic primary pain). None of the study populations are chronic primary pain, and therefore these are not relevant to include. The systematic review by Silbernagel et al. also does not include any studies that

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				outcome? A randomized, clinical trial." Knee Surg Sports Traumatol Arthrosc21(5): 1158-1167. Norregaard, J., et al. (2007). "Eccentric exercise in treatment of Achilles tendinopathy." Scand J Med Sci Sports17(2): 133-138. Rathleff, M. S., et al. (2015). "High-load strength training improves outcome in patients with plantar fasciitis: A randomized controlled trial with 12-month follow-up." Scand J Med Sci Sports25(3): e292-300. Silbernagel, K. G., et al. (2001). "Eccentric overload training for patients with chronic Achilles tendon pain--a randomised controlled study with reliability testing of the evaluation methods." Scand J Med Sci Sports11(4): 197-206.	would be relevant to this review protocol.
Birmingham Community Healthcare NHS Foundation Trust.	methods	general	general	Another chronic musculoskeletal condition excluded is low back pain. While the guidelines do direct the clinician to other guidelines specifically for low back pain and sciatica, those cited guidelines states that they do not consider chronic low back pain separately from acute or subacute. While there is merit in this approach is unclear why it applies to low back pain but not neck pain. Furthermore, this lack of consistency provides a dilemma for the clinician managing chronic low back pain.	Thank you for your comment. The low back pain guideline took the approach that chronic and acute pain could be managed similarly unless evidence indicated otherwise. The scope for this guideline was to focus on chronic pain and for chronic primary pain only, therefore the committee can only comment on chronic pain in this context. Recommendations in the low back pain guideline should be followed where those are appropriate.

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					Further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
BNF Publications	Guideline	General	General	We have taken a look at the draft NICE guidance on the management of primary chronic pain in individuals aged 16 years and over, which is currently out for consultation. We are in the process of writing guidance for the management in children, based on the Scottish Government guidelines – Management of chronic pain in children and young people, other paediatric sources, and expert advice; therefore we have a couple of comments/questions regarding the draft guidelines which we hope you are able to clarify, as follows: • For children, would a multidisciplinary team approach encompass all interventions, including pharmacological and non-pharmacological options? This	Thank you for your comment. The committee agreed that the evidence for the interventions recommended was for them as standalone treatments. Evidence for pain management programmes did not enable a recommendation to be made for or against. The committee did not comment on the service delivery of

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				approach is not mentioned in the draft guidelines and we were wondering if this was being considered as part of management in children aged 16 to 17 years? • Would the initiation of pharmacological treatments require specialist assessment/involvement? This approach is not mentioned in the draft guidelines and we were wondering if this was being considered as part of management in children aged 16 to 17 years? • For the pharmacological management, the draft guidelines suggest the use of antidepressants off-label (Recommendation 1.3.8) and other pharmacological therapies are not recommended (Recommendation 1.3.11). We understand that the use of paracetamol and non-steroidal anti-inflammatory drugs would likely have been trialled in the acute phase and not continued in chronic pain if ineffective. However, we were wondering at what point in the management of chronic pain would the antidepressant be started (such as after trialling or at the same time as non-pharmacological options)? • Given that the use of antidepressants in chronic pain is off-label, will their use only be initiated following review/advice of a pain specialist?	the interventions, which can be determined locally. On consideration of the stakeholder comments the committee agreed it was appropriate for the recommendation for antidepressants to be for people aged 18 and over. A separate recommendation has been added to state that specialist advice should be sought if considering pharmacological treatment for people aged 16 and 17.
Boston Scientific Ltd	Guideline	005	018	We would also ask the committee to consider referencing NICE SCS TA159 within the document (section 1.2 available guidance). Given the complex nature of chronic pain highlighting a broader array of possible resources may	Thank you for your comment. This list is not exhaustive, but links to the most directly relevant guidelines to consider.

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				support decision making within the primary care environment. NICE TA159: https://www.nice.org.uk/guidance/ta159/chapter/1-Guidance .	
Boston Scientific Ltd	Guideline	028	003	We would ask the committee to reconsider its wording of the below statement describing current practice. We acknowledge the complexity of chronic pain but believe therapies such as SCS are capable of delivering meaningful and sustained patient benefit. Furthermore, the development of GP referral tools (e-tool reference link below) may further optimise utilisation of this intervention. *Current practice: There is no medical intervention, pharmacological or non-pharmacological, that is helpful for more than a minority of people with chronic pain, and benefits of treatments are modest in terms of effect size and duration. Additional morbidity resulting from treatment for chronic pain is not unusual, so it is important to evaluate the treatments we offer for chronic pain, to focus resources appropriately and to minimise harm.* https://onlinelibrary.wiley.com/doi/epdf/10.1002/ejp.1562	Thank you for your comment. The context section has been revised and this section has been removed.

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Boston Scientific Ltd	Guideline	General	General	We ask the committee to consider adding a guidance statement that highlights the need for specialist/secondary care referral when indicated; to support primary care decision making and facilitate timely and appropriate referrals when indicated. *This is consistent with other NICE guidance including:* ▪ Low back pain and sciatica overview: https://pathways.nice.org.uk/pathways/low-back-pain-and-sciatica ▪ Neuropathic pain in adults: pharmacological management in non-specialist settings: https://www.nice.org.uk/guidance/cg173	Thank you for your comment. The committee agree that specialist assessment for diagnosis and management of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The committee have included one recommendation to seek specialist advice if pharmacological management is being considered for young adults aged 16-17.

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British Acupuncture Council	Evidence review G	044	028-041	We welcome the more nuanced discussion of sham acupuncture than has generally been seen in NICE guidelines	Thank you for your comment.
British Acupuncture Council	Evidence review G	044/045	007/016	The evidence review found acupuncture to be clinically superior to sham as well as usual care, making it easy for the committee to endorse it. This was not the case for low back pain (the 2016 version), osteoarthritis or depression (though the final version remains to be seen), and the question remains why the sham comparison is afforded such importance for acupuncture reviews but not those for exercise, manual or psychological therapies. In that acupuncture is a complex intervention with no specifically identifiable mechanism of action, it aligns much more closely with the above treatments than with pharmaceuticals, where a placebo comparator is a feasible and useful option. Given the discussion on page 49 concerning the contrast with the low back pain guideline, we would assume that, if acupuncture had not cleared the minimal important difference hurdle in relation to sham, then the conclusions of the committee would have been very different. We believe that the acupuncture-sham focus introduces a potential bias against acupuncture in the way in which evidence is interpreted and recommendations made across the range of possible interventions.	Thank you for your comment. Ideally there would be evidence of treatment-specific effects for any intervention provided by the NHS. However, exercise, manual therapies and psychological therapies were not considered to have an appropriate placebo and so the approach taken for acupuncture was not considered possible for these interventions. Attention control was used in some studies of psychological therapies but this was not considered to approximate sham and was not frequently done. As you note in this evidence-base there was benefit with acupuncture over both sham and usual care and acupuncture has been recommended. We are unable to comment on decision-making by other guideline committees.

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British Acupuncture Council	Evidence review G	045	026-029	We welcome the committee's view that the variable interventions across studies reflect typical variation in practice, and that this lack of standardisation was not taken to be an impediment to recommending acupuncture (as has sometimes been the case previously)	Thank you for your comment.
British Acupuncture Council	Evidence review G	045-048	007-027	Group acupuncture is mentioned in the introductory section as an alternative delivery mode but this is not considered as an option in the economic evaluation. So called multibed clinics would substantially reduce the intervention costs, with at least 3-4 patients treated per practitioner per hour.	Thank you for your comment. Sensitivity analysis 7 in the cost effectiveness analysis explored lower costs of acupuncture due to people receiving acupuncture in synchrony. The details of this are provided in the 'Acupuncture modelling report'.
British Acupuncture Council	Guideline	General	General	We welcome the committee's work in this extensive and important area and particularly the recommendation for acupuncture	Thank you for your comment.
British Acupuncture Council	Guideline	General	General	We are well aware of the opposition in some quarters that was provoked by the endorsement of acupuncture in the 2009 low back pain guideline, and the fact that there was not a large take-up subsequently in primary care. Is there any reason to think that things will be different this time, especially given the resource implications and the apparently perilous state of NHS finances? We would suggest that considerable effort will need to go into promoting these guidelines for clinical practice. Educational programmes may be required to help GPs and service commissioners understand which patients may benefit most from acupuncture and what	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain

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				acupuncture resources are available, and with what characteristics. Also professional acupuncturists will need help in understanding how they might work with orthodox health care professionals that wish to refer chronic pain patients.	will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
British Acupuncture Council	Guideline	General	General	The definition of chronic primary pain is such that conditions like chronic low back pain would presumably have been included here if not already covered in existing guidance. Even as it is, low back pain is commonly comorbid with various other painful conditions, so it is entirely feasible that there will be patients for whom two (or more) different guidelines will be relevant. Given that the recommendations on certain treatments (e.g. acupuncture) differ between guidelines how will this be managed?	Thank you for your comment. The committee acknowledge that types of chronic pain, and chronic primary pain, can coexist. Where there is overlap, clinical judgement should be used to determine the appropriate treatment option relevant to the guidance for the type of pain they are treating.

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British Acupuncture Council	Guideline	General	General	Many of our patients with chronic pain use combinations of acupuncture and medication, including various of the drugs that will no longer be supported. Although we welcome the shift away from pharmacological interventions there is no doubt that a particular drug may be useful as part of a package of measures for a given individual. There is some evidence that adjunctive acupuncture may reduce drug side effects. It may also help people who experience distressing symptoms when withdrawing from addictive drugs such as opioids.	Thank you for your comment. Combinations of acupuncture and pharmacological treatment were not considered as interventions of interest within the reviews of either intervention included in this guideline. It is the view of the committee that there is no reason to suggest that the medicines will be any more effective if offered in combination with a non-pharmacological therapy however. This review only looked at the use of acupuncture for the management of chronic primary pain and so we cannot comment on its role in withdrawal.
British Association for Behavioural and Cognitive Psychotherapies	Evidence review F	114	13 onwards	The rationale for using a three month timeframe is discussed, but most psychological therapies for persistent pain would take longer than three months to have their full expected effect, since improvement after completing the active intervention is usually expected. For example someone who is very physically de-conditioned may take some time to learn new approaches to becoming more active, with further time required to reach full potential; someone who has been very socially isolated may take	Thank you for your comment. This review was for chronic primary pain only, rather than all types of chronic pain. The references of the systematic reviews you highlight were checked for any studies relevant to this review protocol. No new studies were identified. The evidence reviewed for mindfulness for chronic primary pain

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				longer than three months to develop new social activities and improve pain management/quality of life as a result.	in this guideline was not sufficient to inform a recommendation, however the committee agreed results were promising and therefore recommended further research to inform future updates of the guideline.
British Association for Behavioural and Cognitive Psychotherapies	Evidence review F	125	17 onwards	The evidence review suggests that the ACT interventions are often carried out by ACT and CBT trained therapists, which would be expected. It could be made clearer in the guidelines that CBT and ACT are not completely distinct therapies, rather that they have theoretical and practice elements in common as well as important differences in some of the approach. There is a similar implication that behavioural interventions are separate, rather than a subset of cognitive and behavioural interventions. The concern being that if this is not clearer, it could lead to misunderstandings, for example, when commissioning training and services.	Thank you for your comment. The committee agree there are overlapping elements and approaches in the different psychological therapies considered in the guideline review, however when setting the protocol it was considered that they are sometimes offered as distinct therapies and all needed to be reviewed. The committee agreed that healthcare professionals implementing these recommendations and delivering the therapies would have an understanding of the therapies and further detail on the overlapping elements and theories behind them

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					was beyond the remit of this guideline.
British Association for Behavioural and Cognitive Psychotherapies	Guideline	004	general	The assessment process as described does not appear to take into account the history, development, course of the pain itself and what has already been tried; what medications are prescribed; and what is actually being taken and how	Thank you for your comment. The committee agreed these are important factors to consider. Additional recommendations have been added to this section to address these issues.
British Association for Behavioural and Cognitive Psychotherapies	guideline	007	002	We welcome the guideline recommending psychological therapy, specifically CBT and ACT. The guideline does mention that the level of training of the therapist may have an impact on outcomes; however, there was no recommendation as to what level should be required.	Thank you for your comment. The evidence reviewed did not inform what level of training was required. The guideline recommendations assume that all people delivering the interventions recommended should be appropriately trained to do so. This has been added to the recommendation for clarity.
British Association for Behavioural and Cognitive Psychotherapies	guideline	018	020	The guideline mentions that 'psychotherapy' is not recommended but not which type(s). Since cognitive-behavioural psychotherapy and Acceptance and Commitment therapy are both recommended, this is confusing and could be unhelpful.	Thank you for your comment. The review covered psycho-dynamic and psycho-analytic psychotherapy within the broader heading of psychotherapy. Both CBT and ACT were considered as separate

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					interventions. This is detailed in the PICO table at the beginning of the evidence review and in the full protocol in appendix A. The only psychotherapy evidence identified was for psychodynamic psychotherapy. This has been clarified in the discussion of the evidence and in the research recommendation.
British Association for Behavioural and Cognitive Psychotherapies	guideline	23 onwards	general	It would be helpful if the guidance included comments on which pharmacological interventions are useful in shorter-term pain, since the difficulties described often seem to arise from well-intentioned shorter term prescribing which, after some time, then leaves the person with pain needing to withdraw from medications which are not recommended and are harmful in longer term use. Overall, the guidance could address more fully the way that many people with pain have followed health care advice which may have been helpful had their pain been short term; but the promotion of self-management and non=pharmacological approaches tends not to occur until it is already chronic; so reducing the likelihood of pain becoming chronic in conditions where this is possible could be emphasised more.	Thank you for your comment. The committee agree that the intended short term use of these medicines can result in longer term use and result in harms. They considered that there is no evidence that the interventions not recommended for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain

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					however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up (for example, stressful life events). Recommendations have also been included for considerations in people who are already receiving these medicines. These include explaining the lack of evidence of effectiveness; the risks of continuing harmful medication; encouraging people to stop or reduce use if they are reporting little benefit or significant harms.
British Association for Behavioural and Cognitive Psychotherapies	Guideline	general	general	While the guideline does reference the Patient Experience guideline, which did include an equality impact assessment, the guideline should include specific reference to how inequalities affect people who have chronic pain. There seemed to be no guidance about the disproportionate impact of persistent pain on minority communities; the role of socio-economic deprivation and discrimination on outcomes in pain; nor guidance on specific training for health care professionals who work with people who have pain on working with diversity and	Thank you for your comment. An equality impact assessment has been completed for this guideline and is available on the guideline webpage. The committee agreed that the recommendations should equally apply to all groups, and did not discriminate against any particular group. Separate recommendations

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				awareness of bias in types of treatment offered to different communities. There could also be reference to cross-cultural differences in the way that pain is understood and the way that psychological treatments to help with chronic pain are engaged with. One possible reference to help with this is the IAPT/BABCP Postive Practice Guide available here: https://www.babcp.com/files/IAPT-BAME-PPG-2019.pdf The principles mentioned in the guideline development process on patient experience mentions 'unlawful discrimination'; this does not address those systemic issues which affect chronic pain outcomes; there should at least be consideration of these factors more overtly, and probably a research recommendation.	were not thought necessary for any of these groups, however the committee do agree these factors need to be considered in the assessment of people with chronic pain and included a recommendation highlighting this: 1.1.7 Be sensitive to the person's socioeconomic, cultural and ethnic background, and faith group, and think about how these might influence their symptoms, understanding and choice of management.
British Association for Behavioural and Cognitive Psychotherapies	guideline	general	general	The assessment process described did not look at excluding other causes for the persistent pain condition; and it may be helpful to state more overtly that reasonable investigations will have been completed to reach a conclusion that it is primary chronic pain.	Thank you for your comment. The assessment recommendations have now been amended to include consideration of other causes of the pain and when to consider a diagnosis of chronic primary pain.
British Association for Behavioural	guideline	general	general	The guidance mentions the aim of pain reduction throughout. Our current understanding of the evidence is that this is probably not a helpful measure of outcome for people with persistent pain, and that quality of life	Thank you for your comment. When setting the protocol the committee agreed the outcomes that were critical and important for decision making.

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and Cognitive Psychotherapies				measures without measuring pain intensity would give a more useful measure. Is it possible that the aim to reduce pain intensity may give an unhelpful impression from outcome studies, particularly in non-biomedical interventions.	The committee agree that the primary goal of interventions for chronic primary pain is often not to reduce pain. For this review pain reduction was rated as an important outcome, but pain self-efficacy and pain interference were rated as critical. Other critical outcomes were quality of life, physical function and psychological distress. These are detailed in the protocol in the evidence review chapter (Evidence review F). The committee considered the body of evidence across all of the outcomes when making decisions about the recommendation.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	009	013 – 020	This is a sensible approach, but it must be applied fairly to all interventions. This approach was not applied fairly in NG59. It looks as though you have applied this more fairly in this guideline and that is to be commended.	Thank you.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	015	1 Table 2 Row 1	Witt 2006 (b) ref 33 Please note that the design of this study was such that by 24 weeks follow-up, both groups had received 12 weeks acupuncture treatment, so it is inappropriate to use the	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated.

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				24-week time point from this trial for calculations of long-term cost-effectiveness.	Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	019	35 Table 3 Row 9	Witt 2006 (c) Please note that the EQ-5D value for usual care has risen from 0.71 at 12 weeks to 0.79 at 24 weeks. This is because by this stage in the trial, the usual care group has received 12 weeks of acupuncture treatment. It can only act as a usual care comparator up to the 12-week outcomes.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	021	1 Figure 2	Witt 2006 (b) This figure nicely illustrates a difference in EQ-5D value at 12 weeks that disappears at 24 weeks. The red line from 0 to 12 weeks is similar to the blue line from 12 to 24 weeks. This is because the groups both received acupuncture over these periods. So, it is inappropriate to use the 24-week time point from this trial for calculations of long-term cost-effectiveness of acupuncture.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	025	11 Figure 3	Witt 2006 This figure nicely illustrates the dramatic drop in the EQ-5D value difference between groups from 12 to 24 weeks. This is because the usual care group received acupuncture over this period and caught up with the group that had been given acupuncture at the start of the trial. So, it is inappropriate to use the 24-week time point	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost

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				from this trial for calculations of long-term cost-effectiveness of acupuncture.	effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	026	11 Figure 4	The 24-week data from Witt 2006 should be excluded from this figure because the comparison is between two groups that had by that time both received 12 weeks of acupuncture treatment.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	028	008–012	Vickers 2018 did state that the effect size for acupuncture in neck pain appeared to reduce, whereas it was maintained in other chronic pain conditions. I investigated the papers concerned and found that the principal effect here came from one paper (Vas et al 2006) in which the effect of acupuncture on neck pain was maintained over 6 months, but the control group improved by some 40% over this period, narrowing the difference between treatment and control, and giving the false impression of a reduction in the acupuncture effect. See my research blog: https://bmas.blog/2018/10/10/the-acupuncture-trialists-collaboration-ipdm-update-2017/	Thank you for this information. The analysis you refer to is of studies of acupuncture compared to sham. The analysis using studies comparing acupuncture to no acupuncture also showed a trend for reducing effect size with time. This sentence has edited to clarify this.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	028	13 Figure 6	If the 24-week data from Witt 2006 has been included in this figure then it does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-

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					treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	032	1 Figure 7	If the 24-week data from Witt 2006 has been included in this figure then it does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	032	2 Figure 8	If the 24-week data from Witt 2006 has been included in this figure then it does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	035	1 Figure 9b	If the 24-week data from Witt 2006 has been included in this figure then it does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated.

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					Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	039	25 Table 14	The 24-week data from Witt 2006 has been included in this Table. It does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	064	Appendix A Table A1	The 24-week data from Witt 2006 has been included in this Table. It does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Acupuncture cost-effectiveness report	067	2 Appendix B Table B1	The 24-week data from Witt 2006 has been included in this Table. It does not represent a true picture of the EQ-5D gain over time, since both groups had received acupuncture treatment at this time point.	Thank you for highlighting this. The Witt 24-week data has been removed from the cost effectiveness analysis. The method for analysing post-treatment effect was also updated. Conclusions regarding the cost

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					effectiveness of acupuncture were not affected.
British Medical Acupuncture Society	Evidence review G - Acupuncture	019	3 Table 3 Row 1	The GRADE quality of evidence is downgraded for inconsistency despite the clear clinical heterogeneity you have acknowledged (see 17 above). In Guideline appendices – Methods (page 23; line 2) you state that inconsistency refers to unexplained heterogeneity. In Guideline appendices – Methods (page 23; lines 5–7) you state that the quality of evidence is downgraded only where there is no plausible explanation for heterogeneity. Therefore, the quality of evidence here should be graded as low not very low.	Thank you for your comment. The observed heterogeneity was explored with subgroup analysis (including for type of chronic primary pain and acupuncture vs dry needling) but this did not explain heterogeneity. The meta-analysis has therefore been presented as random effects and evidence downgraded for inconsistency. This is as per the statement in the methods.
British Medical Acupuncture Society	Evidence review G - Acupuncture	044	3–5	Here you acknowledge the range of different (hence clinically heterogenous) sham procedures which were pooled in the analysis of acupuncture versus sham. Under these circumstances you have acknowledged the presence of clinical heterogeneity with the comparisons that have been pooled in the analysis; therefore, statistical heterogeneity should not result in downgrading of evidence for inconsistency.	Thank you for your comment. We agree there were a range of different sham procedures used. This was not pre-specified subgroup analysis within the review, so we cannot confirm whether the difference in types of sham explain the heterogeneity. Exploration of the pre-specified subgroup analysis (including acupuncture vs dry needling and types of chronic primary pain) did not explain the heterogeneity, and

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					therefore the quality is downgraded accordingly.
British Medical Acupuncture Society	Evidence review G - Acupuncture	048	9–13	This section explains why a 'consider' recommendation was made for acupuncture rather than an 'offer' recommendation. The reasons stated are doubts about long-term effects and long-term cost effectiveness. In view of my comments above, and the fact that the data supporting an 'offer' recommendation for exercise is not better than that for acupuncture, I would ask the GDG to consider strengthening the recommendation for acupuncture to 'offer' or reducing that for exercise to 'consider'. This would seem to me to be the most equitable and unbiased outcome from the data presented. I should note in addition that whilst the efficacy of acupuncture over sham has been established, that for exercise (ie the efficacy over a sham) has not. The draft of NG59 included sham controlled data for exercise, but this was removed when it was pointed out that exercise was no better than the sham. It should not be assumed that exercise is without risk, and therefore efficacy data should be funded and sought where possible. The NICE approach continues to overlook this, and show bias in favour of exercise approaches.	Thank you for your comment. A number of factors led the committee to conclude that a stronger recommendation was warranted for exercise than acupuncture. There was evidence of benefits for longer term outcomes (>3 months) for exercise but evidence of longer terms effects was more limited for acupuncture. Exercise is also currently used as part of the management of people with chronic primary pain in the NHS unlike acupuncture and so a recommendation for acupuncture was considered a bigger change in practice that is likely to have a bigger resource impact. In addition, physical activity is well established to have benefits to health in general. It is acknowledged that there is no evidence that demonstrates a treatment-specific effect of exercise but there was not considered to be an adequate placebo

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					control for exercise that would allow this to be assessed.
British Medical Acupuncture Society	Evidence review G - Acupuncture	174–180	Figures 2, 7, 8, 35	Couto is misspelt in several Forest plots in this section	Thank you for your comment. This has now been corrected.
British Medical Acupuncture Society	Evidence review G - Acupuncture	175	Figure 8	Couto 2014 data is correctly entered; however, the narrative of this paper clearly states that acupuncture group (MDIMST) was associated with improvements in mental health. I quote from Couto 2014 discussion on page 221 of the paper: "The MDIMST group exhibited greater improvements with respect to general physical and mental health." I suspect that the authors may have inadvertently reversed the scoring system for the mental health component in their translated version of the SF-12 (the study was carried out in Brazil). You could perform a sensitivity analysis by inverting the figures for Couto 2014 (subtracting them from 100), and then I guess the results will be very similar to those of Vas 2016, and the pooled figure will have no heterogeneity. This would mean that the pooled result in the GRADE summary (page 20 row 5) should not be downgraded for inconsistency.	Thank you for your comment. The author state in the results section "At the end of the study, the physical health composite score was higher for the MDIMST and LTrP-I groups than the sham-treated group (P< 0.01), and the mental health composite score was lower for MDIMST (P <0.03; Table 2)." This is consistent with the results reported in table 2 and those analysed. It is these data that are used in the analysis in the guideline review and appear to be correct. It is likely that the statement in their discussion misreports these results.

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British Medical Acupuncture Society	Guideline	007	011	I agree that wherever possible NHS provision of acupuncture should be in a community setting; however, the BMAS has collaborated with NHS colleagues at the Royal London Hospital for Integrated Medicine (RLHIM) providing low-cost services and nurse-led group acupuncture clinics in what has become a centre of excellence for training and a potential model for service design in the community. This would be at risk if the guideline did not allow exceptions for such centres of excellence. Since this "only if" recommendation is driven by cost, perhaps more flexibility would be gained by allowing other provision at the same cost eg consider a course of acupuncture..., but only if delivered in a community setting by a band 7 (or lower) healthcare professional of no more than 5 hours of healthcare professional time OR only if treatment can be provided in other settings for the same cost.	Thank you. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.
British Medical Acupuncture Society	Guideline	General	General	Congratulations on producing this draft guideline, which represents an enormous amount of work. A single standard of evidence appears to have been applied to almost all interventions. This is a marked improvement on the two-tier evidence standard applied in NG59. There is no indication that evidence has been left out in this guideline unlike CG150, where data from direct comparisons between acupuncture and prophylactic drugs were excluded from the network meta-analysis.	Thank you for your comment.

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				The economic modelling compares acupuncture to usual care rather than to sham acupuncture. This is a sensible improvement on CG59 where economic modelling was based on comparisons of acupuncture and sham acupuncture as well as usual care. This guideline will encourage the development of community acupuncture provision, and this can be achieved at low cost. BMAS members have published a number of audits demonstrating successful provision of acupuncture in primary care, including community-based nurse-led group clinics for chronic pain.	
British Medical Association	Guideline	004	001	Shared decision aids are a good tool if they can be used properly. It is vital that clinicians have adequate time to use them effectively. This should involve a multi-disciplinary team including nursing colleagues and pharmacists as this is one of the Primary Care Network Direct Enhanced Service specifications and has been funded accordingly.	Thank you for your comment.
British Medical Association	Guideline	006	General	It is important that GPs are supported and not penalised for managing pain to reduce the number of prescriptions.	Thank you for your comment. The committee agree that GPs should be supported in implementing the recommendations.
British Medical Association	Guideline	007	001-006	A focus on trauma-based therapy is missing from the psychological therapy section.	Thank you for your comment. The psychological therapies included in the review were those prioritised by the committee as those most commonly

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					used in the management of chronic primary pain.
British Medical Association	Guideline	007	007-015	We remain unconvinced by the new evidence presented since NICE rejected support for acupuncture in CG59. We would suggest more research is needed.	Thank you for your comment. The committee were aware of the recommendation and evidence review underpinning the recommendation in NG59. The review for this guideline excluded evidence in people with low back pain and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica and was supported by a large evidence base. Consistent benefits were observed for quality of life, and pain compared to sham and usual care as well as some benefits in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective.
British Medical Association	Guideline	014 and	019-024 and general	Chronic pain management presents a significant challenge. This draft guidance seems to highlight the complexities and limitations in its management, however,	Thank you for your comment. The recommendations in the guideline

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		general		rather than offer solutions it appears to raise more questions, especially around the usefulness of pain management programmes. It also calls for research into many areas, which is welcome, but the delay in research findings will mean pressure on clinicians to continue to manage these complicated patients without adequate support and with limited treatments available.	demonstrate where there is evidence that treatments are effective for chronic primary pain. The guideline also recommends against treatments where the evidence of harm outweighs that of benefit, or there is no evidence of benefit. For pain management programmes the committee agreed the evidence reviewed did not enable a recommendation to be made for or against their use. Where the reviews of the evidence identify potential benefit from a treatment that is not sufficient to inform a recommendation, this can be highlighted by making a research recommendation on the topic. The committee agreed that was appropriate to do for a number of interventions. NICE research recommendations are reviewed regularly by the NIHR to help facilitate their funding and uptake.

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British Medical Association	Guideline	015	General	For people sitting at home doing nothing except thinking about their pain, social intervention can be powerful and loneliness and social exclusion play an important part as well. Where patient appropriate, digital connectivity / group support / online platforms, which could be regional, national or local for patients - sharing experiences and getting validation and understanding might also be helpful.	Thank you for your comment. No evidence was identified for social interventions for people with chronic pain. The committee agreed that research in this area is important and have included a research recommendation on this topic.
British Medical Association	Guideline	016-017	General	It is vital that evidence-based pain management services are widely available in the community. Access to these services across the country is variable and this must be addressed. Multi-disciplinary teams across primary and secondary care must be involved in this including nursing and pharmacy colleagues. There is also a risk that specialist pain services will be overwhelmed by referrals from GPs who need to take patients off these medications and where there are few other options. There is a need to consider the capacity of the NHS to cope with the resulting changes in clinical practice, before publishing guidelines like these.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the

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					guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the

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					guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
British Medical Association	Guideline	General	General	The lack of access to alternatives, with very long waiting times and significant thresholds for acceptance of referrals makes it currently impractical for the large number of patients who would need to access these services.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
British Medical Association	Guideline	General	General	There is no mention of group support so that people can benefit from others with same problems.	Thank you for your comment. There was no evidence identified to recommend support groups. Peer led pain management programmes were included within the review, but there was insufficient evidence to recommend these.
British Medical Association	Guideline	General and 004	General and 006	We welcome the mention of continuity of care and knowledge of the patient. This should be emphasised and made stronger.	Thank you for your comment. The committee agree these are important factors to consider. This section has been amended and where possible these points have been emphasised.
British Medical Association	Guideline	General and 009	General	Throughout the guidance, the terms chronic pain and chronic primary pain are used interchangeably. Chronic pain with an identified cause (such as significant osteoarthiritis) may exist in the same patients as chronic primary pain. We feel that this will cause significant confusion amongst health care practitioners and commissioners of services and therefore the two should be defined and used consistently throughout. In addition, the guidelines should make it clear that continued	Thank you for your comment. We agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well

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				investigation to try to identify an underlying cause is important. We welcome most of the list of what not to offer to manage chronic pain, in particular benzodiazepines, opiates and gabapentinoids. The recommendation not to offer medication or other therapies must be in the context of no other concomitant painful conditions for which there is an anatomical explanation. In our view this will be beneficial and will help clinicians when managing patients on large amounts of addictive medicines. Preventing long-term dependence is preferable to managing withdrawal which can be difficult.	as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. **Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.**
British Pain Society	Guideline	011-013	004-003	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Research: "I agree it would be great to see more research in chronic pain but we all know it just doesn't happen. Our patients are varied and complex they do not make great test subjects and randomised control trails are difficult to do."	Thank you for your comment. All NICE research recommendations are reviewed by the NIHR and help inform their future funding streams. Highlighting areas where research is required also helps inform other research funders of priority areas. The committee agree that trials on complex conditions do require some extra considerations, but are still feasible and should be highlighted where research is required.

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British Society for Rheumatology	Guideline	004-005	002	There is concern this Guideline will reduce the life expectancy and quality of life for patients with autoimmune and auto-inflammatory disease. In particular, patients with diseases which are not currently covered by other areas of NICE Guidance such as Gout, Calcium Pyrophosphate Disease, Polymyalgia rheumatica, Systemic Lupus Erythematosus, Vasculitis, Myositis, Systemic Sclerosis and the multitude of other rarer auto-inflammatory and autoimmune diseases. Such diseases can be particularly difficult to diagnose. Patients with SLE suffer significant delays to their diagnosis and their outcomes are needlessly worse. Patients with Gout similarly have poor management in Primary Care in the UK. The recommendation does not mention **diagnosis** and does not emphasise the impact upon a patient of identifying the important and treatable diseases; and providing appropriate management. The risk that undermining the diagnostic core function of the healthcare-patient relationship is huge. Missed diagnoses are costly for both the individual patient as well as the healthcare service. The costs include both financial with missed workdays, presenteeism and loss of employment. They also include death, organ-failure, dialysis and increased medication as irreversible damage accumulates for patients with untreated inflammatory disease. Litigation costs will also increase. The Guideline validates	Thank you for your comment. A recommendation has been added for when to consider a diagnosis of chronic primary pain. Specific investigations to rule out other conditions were not within the scope of this guideline and therefore the committee can't comment on these but they do note in the recommendation that chronic primary pain should be considered when there are no obvious underlying (secondary) causes.

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				Healthcare Professionals to ignore investigating for a diagnosis.	
British Society for Rheumatology	Guideline	006	001 & 011	It is surprising to see the caution about inconsistency of evidence on effectiveness of pain management programmes in contrast to the strong recommendation made for offering supervised group exercise programmes.Real world evidence from multiple Pain Management Programmes across the country demonstrate their effectiveness. Time and again, pain scores and quality of life scores move in the right direction. Employment increases after Pain Management Programmes. As is pointed out by the committee (evidence review C), pain management programme (PMP) is a very broad term and in some cases, it may not differ very much to a group exercise programme perhaps offering a combination of cardiovascular, strength and mind-body exercises) and yet the guideline appears to treat them very differently. Whilst I understand and support the call for further, better quality research it would be helpful to frame this more positively, without deterring people from using pain management programmes in the meantime.Pain Management Programmes are already commissioned and employing Health Care Professionals, often who require many years of specialist training. Much disruption would be anticipated if these services were de-commissioned	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of

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				and it is doubtful that such services could be rapidly reconstructed in a different setting There is evidence that a lot of non-evidence based practice currently takes place resulting in costly and potentially harmful outcomes for the patient (Soni et al, Hospitalization in fibromyalgia: a cohort-level observational study of in-patient procedures, costs and geographical variation in England, Rheumatology 2019) and it would be a shame to risk increasing this by discouraging the use of PMPs which are very unlikely to cause harm. There will be many patients for whom other monodisciplinary interventions have not worked and need more intensive input, who will be left with nothing if PMPs are removed from the options. It would be more useful to have a suggested hierarchy of treatment options whereby the simpler, more cost-effective are used first.	life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which

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					were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research. The committee agreed that choice of treatment should be based on a holistic assessment and shared discussion with the person to develop a care and support plan, discussing the risk and benefits and evidence for all available treatments. This should be

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					based on the person's priorities, abilities and goals.
British Society for Rheumatology	Guideline	007	007	The recommendation made in this document regarding acupuncture is potentially confusing. The first set of recommendations for low back pain (LBP) recommended acupuncture (which was highly controversial), however the take-up of this was relatively poor. The second (revised) set of LBP guidelines did not recommend acupuncture (based on very similar evidence base) because the committee did not think the evidence showed a benefit of true acupuncture over sham acupuncture. Now for chronic primary pain, the committee is recommending acupuncture. As an example, fibromyalgia will be one of the common diagnoses in this group, and axial pain (back pain) is the most common area in which people with fibromyalgia have pain. Indeed, that might be part of the initial presentation. This means that back pain acupuncture is not recommended (having previously been recommended), but when it is a feature of chronic primary pain it is recommended. This appears to lack consistency – and indeed its of note that several reviews in the literature disagree with the conclusion (e.g. Perry et al (Syst Rev 2017 May 15;6(1):972017) conclude "There was low-quality evidence that acupuncture improves pain compared to no treatment or standard treatment, but good evidence that it is no better than sham acupuncture.")	Thank you for your comment. The committee were aware of the recommendation and evidence review underpinning the recommendation in the current NICE low back pain guideline (NG59). However, the review for this current guideline excluded evidence in people with low back pain and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica and was supported by a large evidence base. Consistent benefits were observed for quality of life, and pain compared to sham as well as usual care as well as some benefits in function and psychological distress. De novo economic modelling also supported the recommendation

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				Regardless, the recommendation on acupuncture will be a challenge to implement given the lack of available resources within the NHS to provide this. It will also be difficult to deliver in the knowledge that, even for those who get may get a good response to the treatment, it will have to be restricted to a very short course of treatment. This group of patients already feel very abandoned and not well catered for by the NHS and this recommendation risks exaggerating this feeling. There is evidence that acupuncture can be safely and effectively delivered in a group setting: perhaps this format can help to mitigate the cost.	for chronic primary pain demonstrating it to be cost effective. The committee acknowledge that there will be overlap in painful conditions in many cases. Clinical judgement should be used to determine the appropriate treatment option relevant to the type of pain being treated. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation. A research recommendation has been included highlighting the need for further research on the effectiveness of repeat courses of acupuncture in this population.

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British Society for Rheumatology	Guideline	008	014	Although this recommendation is reported to be extrapolated largely on the data from the evidence on pharmacological management in fibromyalgia, it is very different in that it supports the use of antidepressants in general, across different classes and for all patients. The EULAR guidance for the management of fibromyalgia, for example, are quite different in that they are very specific about individual drugs that are recommended and in which scenarios, e.g. severe sleep disturbance or low mood, as per the holistic assessment that both guidelines are recommending, This might be confusing and risks promoting over medicalisation, depending on how the guidance is interpreted.	Thank you for your comment. Whilst it is true that a number of studies included in the review were in women with fibromyalgia, the evidence for antidepressants included other chronic primary pain populations such a chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Heterogeneity was not observed between types of chronic primary pain, so the committee agreed it provided no evidence against making this recommendation to be for all people with chronic primary pain.
British Society for Rheumatology	Guideline	009	010	We are concerned that this Guideline will reduce the quality of life of patients with chronic pain by denying them access to evidence based treatments (e.g. gabapentinoids) which have been demonstrated in high quality clinical trials to reduce pain and improve quality of life in patients with fibromyalgia. The 2019 Cochrane review for "Pregabalin for treating fibromyalgia pain in adults" found high quality evidence that pregabalin at daily doses of 300 to 600 mg produces a large fall in pain in about 1 in 10 people with moderate or severe pain. Pain reduction comes with improvements in other symptoms, in quality of life, and in ability to function	Thank you for your comment. We were aware of the Cochrane review by Derry et al. when undertaking the review and checked all of their included studies for relevance in the guideline review. This has been checked again confirming there are no studies that had been incorrectly excluded from the guideline. The primary difference for the included studies is the Cochrane review

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				Derry S, Cording M, Wiffen PJ, Law S, Phillips T, Moore RA. Pregabalin for pain in fibromyalgia in adults. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD011790. DOI: 10.1002/14651858.CD011790.pub2	includes enriched enrolment studies, which are excluded from the guideline review protocol. When setting the protocol, the committee agreed that studies with an enriched enrolment design would be excluded, due to their potential to over-estimate of an intervention effect and lack of generalisability of results to a wider population. We believe this is appropriate and a robust methodological decision for a guideline evidence review that is intended to inform population based recommendations for the NHS. The guideline outcome on the effectiveness of pregabalin therefore differs from the Cochrane review where enriched enrolment studies were included.
British Society for Rheumatology	Guideline	009	010	We are concerned that this Guideline will reduce the quality of life of patients with Complex Regional Pain Syndrome by denying them access to evidence based treatments (e.g. steroids) which have been demonstrated in randomised clinical trials and other publications to reduce pain and improve quality of life in such patients.	Thank you for your comment. No studies on the use of steroids for people with chronic primary pain (including CRPS) were identified that were relevant to the review protocol.

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				Kalita J, Vajpayee A, Misra UK. Comparison of prednisolone with piroxicam in complex regional pain syndrome following stroke: a randomized controlled trial. *QJM*. 2006;99(2):89-95. Braus DF, Krauss JK, Strobel J. The shoulder-hand syndrome after stroke: a prospective clinical trial. *Ann Neurol*. 1994;36(5):728-733. Taskaynatan MA, Ozgul A, Tan AK, Dincer K, Kalyon TA. Bier block with methylprednisolone and lidocaine in CRPS type I: a randomized, double-blinded, placebo-controlled study. *Reg Anesth Pain Med*. 2004;29(5):408-412. Munts AG, van der Plas AA, Ferrari MD, Teepe-Twiss IM, Marinus J, van Hilten JJ. Efficacy and safety of a single intrathecal methylprednisolone bolus in chronic complex regional pain syndrome. *Eur J Pain*. 2010;14(5):523-528. Christensen K, Jensen EM, Noer I. The reflex dystrophy syndrome response to treatment with systemic corticosteroids. *Acta Chir Scand*. 1982;148(8):653-655.	The review protocol only included corticosteroids administered by trigger point injections. This has been added to the recommendation to clarify that this relates to trigger point injections only. All of the references you provide have been checked for their inclusion. Kalita et al and Braus et al. were excluded from the review because the pain was not specified as being chronic. Taskaynatan et al. Munts et al. and Christensen et al. were all excluded because they were not trigger point injections. We also note 2 of these trials were stopped early due to lack of efficacy, therefore would likely not have led to a more positive recommendation.
British Society for Rheumatology	Guideline	009	010	We are concerned that this Recommendation will reduce patients' engagement with physical therapies and therefore their outcomes. For instance, one commentator's clinical practice in managing patients who	Thank you for your comment. The evidence review and expert consensus opinion of the committee did not support the effectiveness of the

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				have chronic pain relies on the use of short term analgesics to allow patients to engage with physical therapies. Denying such patients access to such therapies will reduce their engagement with physical therapies which have demonstrable benefit. A distinction should be drawn by the Guideline between the initiation of short term analgesia with education and clear objectives and withdrawal plans versus the chronic use of analgesia. Much evidence, in particular for NSAIDs and paracetamol, exists in demonstrating that analgesics are helpful in the short term for patients with acute pain. Such pain, which may have a different cause to the usual pain experienced by patients with chronic pain, can be improved with simple analgesics and therefore should be made available to the patient who has chronic pain and wishes to engage with a physical exercise program.	majority of pharmacological treatment options for management of chronic primary pain. The committee agreed that the risk of harm outweighed the benefits. The committee do not agree that there is evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The exercise recommendation and rationale highlights the need for the exercise offered to be tailored to the needs and abilities of the individual to ensure it is delivered at an acceptable level for the person.
British Society for Rheumatology	Guideline	010	014	The description of chronic primary pain is very broad and is likely to be confusing for clinicians. Further clarification of the conditions involved is needed, as clinicians may	Thank you for your comment. The committee agree this is important.

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				feel there is a lack of clarity about which conditions the guidelines apply to. A section at the beginning of the document where there is greater detail, clarifying the intended patient population would be helpful. Additionally, it is unclear why Complex Regional Pain Syndrome has been included."Chronic Pain" is MG30.0 and covers (Chronic primary visceral pain; Chronic widespread pain; chronic primary musculoskeletal pain; chronic primary headache or orofacial pain). "Complex Regional Pain Syndrome" is **not** included in Chronic Pain and has a separate code (8D8A.0). Separate UK Guidelines for the diagnosis and management of Complex Regional Pain Syndrome exist and differ from the recommendations put forward by this Guideline	Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised, but it is their view that it was appropriately categorised under chronic primary pain as although the

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					mechanisms aren't fully understood, the similarities are such that there is no reason not to consider this with other types of chronic primary pain.
British Society for Rheumatology	Guideline	011	001	In contrast to ICD-10, ICD-11 does not include a specific code for fibromyalgia. It would fall under the category of chronic widespread pain. This may be confusing for people who are not aware of the relatively recent changes and as FM is common, it may be worth adding an explanation to this effect.	Thank you for your comment. We have added fibromyalgia as an example of a condition that is included in the ICD-11 definition of chronic primary pain in the 'terms used in this guideline' section.
British Society for Rheumatology	Guideline	011	004	We have concerns that restricting the 'Recommendations for Research' limits the research agenda. Topics such as bariatric oxygen, anti-oxidants, and autoimmune therapies, for example, may be equally as valid as laser therapy or transcranial magnetic stimulation.	Thank you for your comment. The recommendations for research specifically relate to areas that have been reviewed within the guideline where the committee agreed more research may be able to better inform future updates of the guideline. They cannot be made for interventions that have not been considered within the guideline reviews.
British Society for Rheumatology	Guideline	013	012	There is a wealth of information available as to what psychological, biological and social factors predict unsuccessful pain management. The guideline as it stands fails to recognise that social factors (e.g. housing, finances, education, literacy) are associated with chronic pain on epidemiological studies and have been found to	Thank you for your comment. The guideline reviewed the evidence for psychological, biological and social factors. There was a lack of good quality evidence that had undertaken

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				be demonstrable in large cohort studies have not been documented. It is unclear why psychological factors and mental health (e.g. anxiety, depression, catastrophisation, low self-efficacy, emotional regulation) have not been promoted as associated with chronic pain as demonstrated in epidemiological and large cohort studies. It is unclear why biological factors (e.g. severity of injury, sex, age) have not been included as to be associated with chronic pain in epidemiological studies and cohort studies.	multivariate analysis adjusting for confounders. This is required to demonstrate which factors are independent predictors of poor outcome rather than just showing an association between the two factors.
British Society for Rheumatology	Guideline	014	009-010	"…the evidence suggested that this is valued by people with chronic pain. Evidence showed that discussions about self-management often happen late in the care pathway, or not at all." We have concerns this evidence is not sufficiently robust, and perhaps anecdotal. It is important to be evidence-based and publish this evidence to retain validity of the Guidelines and retain engagement for implementing them. Indeed, it is recommended that such transparency be followed in the Development Guidelines.	Thank you for your comment. The evidence for this statement was from the qualitative review detailed in Evidence review B. Confidence in the evidence was assessed according to methodology set out in the methods chapter for qualitative evidence. There was low confidence in this finding, but the committee note in the discussion of the evidence in the review chapter that despite concerns regarding data adequacy, they decided that this was particularly

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					important to highlight as initiating this type of discussion early on and at subsequent consultations can make a difference to how people are able to manage their pain.
British Society for Rheumatology	Guideline	019	003-006	We have concerns that patients with chronic pain will have poorer outcomes, including quality of life and sleep due to the phrase "the committee decided not to make a recommendation for sleep hygiene". It is likely that sleep hygiene will help patient outcomes when they have chronic pain and I cannot think that this will be harmful. This is a low-cost intervention (often simply including education and literature) and aligns well with patient's "care plan" focusing on "their priorities, strengths, preferences, interests and abilities." (point 1.1.5, page 5, lines 7-8). We would urge the Guideline group to reconsider their negative views on this recommendation as we believe that it will be confusing and contradictory in practice.	Thank you for your comment. The committee discussed the evidence for sleep hygiene and agreed that although some benefits were observed, this was only from 1 small study. They considered that sleep hygiene is also a component of CBT for insomnia where they had made a recommendation for further research. This is summarised in the rationale, highlighting that there were limited benefits observed. The committee agree this is an accurate reflection of the evidence, and the inclusion of a research recommendation is not overly negative. The committee's full considerations are detailed in the discussion of the evidence in Evidence review F.

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British Society for Rheumatology	Guideline	General	General	We are pleased that an attempt has been made to provide a definitive overview that can be widely disseminated with appropriate resources from a body such as NICE. The Guidelines are to be commended for an emphasis on the scale of the problem; the complexity of individual care; the time and resources that this cohort of patients consume; and the focus on individual doctor-patient relationships.	Thank you for your comment.
British Society for Rheumatology	Guideline	General	General	Overall there is a lack of recognition that often patients cycle through episodes of acute pain, which may require management with medications including steroids and gabapentinoids, especially when therapies such as exercise, CBT etc. have not been effective in controlling symptoms.	Thank you for your comment. We have now added recommendations to the assessment section to include considerations when there are flare ups of pain.
British Society for Rheumatology	Guideline	General	General	In general, the application of these guidelines will require much more resource for managing this patient group than is currently available. Therapies will need to be better funded in order to be confident that patients will be able to access high quality psychological, physiotherapy input in a timely fashion. In addition, clinicians assessing patients will need to be able to allow the time and follow up needed to assess and manage patients appropriately. In addition, there isn't a network in place to ensure that these changes are communicated to relevant parties efficiently. Initiatives such as the MSK champions by	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain

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				Versus Arthritis could help here, but this programme is new and has only just started.	will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
British Society for Stereotactic and Functional Neurosurgery (BSSFN)	Guideline	022	011	With respect to Peripheral Electrical Nerve Stimulation (PENS) it is stated that since the technique is not widely used in current practice for chronic primary pain, no further research is warranted. PENS is a relatively new but fast developing field which is increasingly used for the management of patients with secondary pain syndrome. Its role in the management of chronic primary pain has not been consistently and systematically studied and therefore there is a need to generate clear evidence through well conducted research, and this should be endorsed in this document.	Thank you for your comment. Research recommendations are made based on those most likely to be high priority to the NHS and to inform future updates of the guideline. The committee agreed that as at present this is being explored as an option for secondary chronic pain rather than chronic primary pain, it was not a priority area for a research recommendation within the guideline.
British Society for Stereotactic and Functional Neurosurgery (BSSFN)	Guideline	General	General	The remit of the guideline is acknowledged throughout the document as chronic primary pain, yet the title does not reflect this and gives the impression that the guidelines apply to all forms of chronic pain, both primary and secondary. To avoid confusion, it is prudent to include the term "primary" in the title.	Thank you for your comment. The title has been amended to clarify that chronic primary pain is a focus of this guideline.

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British Society for Stereotactic and Functional Neurosurgery (BSSFN)	Guideline	General	General	ICD-11 definition of chronic primary pain encompasses a wide variety of conditions. Whilst these have many commonalities, there also significant differences. Thus as an example, there is ample evidence that complex regional pain syndrome (CRPS), does have significant neuropathic elements and therefore the neuromodulation strategies eg spinal cord stimulation or dorsal root ganglion stimulation can confer significant benefit to the patients. We therefore strongly recommend including such neuromodulation techniques as an option in selected patients with chronic primary pain as judged appropriate by the pain multidisciplinary team.	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised, but it is their view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there is no reason not to consider this with other types of chronic primary pain.
British Society of Clinical & Academic Hypnosis (BSCAH)	Guideline	005	005	We feel that it is vitally important at the same time to acknowledge that there are ways that the person can use to help themselves and to never take away hope.	Thank you for your comment. The committee agree that self management plays an important role. A recommendation has been included

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					to discuss the person's strengths, and the skills they have to manage their pain and what helps when the pain is difficult to control. The committee also agreed it was important to consider this when developing a shared care and support plan.
British Society of Clinical & Academic Hypnosis (BSCAH)	Guideline	018	026	These statements are incorrect. It depends, of course, upon one's interpretation of 'limited' and 'little', but we argue that there is a considerable and growing body of evidence demonstrating that hypnosis has a clinically significant impact upon pain. The evidential strength is now such that an international body of research scientists and medical experts has just made representation to the World Health Organisation, in a white paper entitled *Hypnosis for Pain Relief*(De Benedittis, *et al.*; 2020). Hypnosis has been employed, with apparent success, in a variety of therapeutic domains, but it is precisely because its impact upon pain is now so well documented that the decision was taken that this specific use should be presented to the WHO, in the hope that the body will see fit to endorse the use of hypnosis in this field. Evidence for the effectiveness of hypnosis comes from a number of directions. Thus, there are clinical studies and laboratory-based research findings. The latter have used a variety of scanning techniques (PET, SPECT, fMRI) to examine brain behaviour in response to pain, with or	Thank you for your comment. It is important to note that the reviews for specific interventions included in this guideline, and the relevant recommendations, are for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that

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				without a hypnotic intervention. Results reveal a clear impact of hypnosis upon activity in the 'pain matrix', a circuit which includes the anterior cingulate cortex, insular and relevant somatosensory regions (e.g. Valentini, *et al.*; 2013). Before the advent of scanning technologies, subjective reports could be dismissed as just that – subjective, although with pain it is, after all, the subjective element which is important. Now it is clear that the levels of pain reported by experimental participants correlate very closely with observed neural activity – activity which is modulated by hypnosis. There is a further observation which demonstrates the specific impact of hypnosis. The extent of pain reduction correlates with hypnotic susceptibility. If that were not the case it could be argued that hypnosis was an irrelevance. A recent review and meta-analysis of 85 research papers (Thompson, *et al.*; 2019) concluded that clinically meaningful reductions in pain ratings were achieved in people scoring high for hypnotic susceptibility (a 42% reduction in pain rating) and also those scoring medium (29% reduction). Those scoring low on hypnotisability did not achieve useful levels of pain reduction, but it should be noted the majority of people score medium or high. Clinically, hypnosis is used to offer relief from both acute and chronic pain. Although the acute situations are not directly relevant here, any successes in this field are	chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The rationale text refers to the evidence that was identified relevant to the review protocol to inform the recommendations. In this case there was only 1 relatively small study for hypnosis in people with chronic primary pain. The references provided have all been checked for their relevance to the review protocol. Of those that are primary studies, none are in chronic primary pain and therefore do not meet inclusion criteria for the guideline review.

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				further evidence that hypnosis modulates pain. A meta-analysis by Montgomery, DuHamel and Redd (2000) is of particular interest. These authors compared studies examining the impact of hypnosis on healthy volunteers taking part in experimental pain research, with studies that used clinical samples receiving hypnosis for pain management. The results revealed that 'hypno-analgesia' was equally effective in the laboratory and clinical settings, producing a medium to large effect, depending upon hypnotic susceptibility. Elkins, Jensen and Patterson (2007) reviewed thirteen controlled prospective trials of hypnosis for the treatment of chronic pain, that compared outcomes from hypnosis to either baseline data or a control condition. The findings indicate that hypnosis interventions consistently produce significant decreases in pain associated with a variety of chronic-pain problems. Also, hypnosis was generally found to be more effective than nonhypnotic interventions such as attention, physical therapy, and education. Many studies report improvements in other ratings impacted by pain, such as better sleep and reduced use of analgesics. Moreover, at three-month follow-up the improvement is often described as being better maintained following hypnotic intervention. This effect was reported by Tan *et al.*(2014) who conducted a randomised control trial comparing hypnosis with biofeedback. The trials contained another variable: the	

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				number of hypnosis sessions. Some participants received 8 sessions (matching the number of biofeedback sessions), but for others the number of training sessions was reduced, instead providing patients with appropriate recordings to listen to at home. In the most 'impoverished' group only two hypnosis sessions were offered. Nevertheless, while the hypnosis conditions significantly outperformed the 8 sessions of biofeedback, there were no statistical differences in outcome across the various hypnosis groups. This is an important indication that the clinical use of hypnosis need not demand a large investment in time. Rather than describing further clinical trials and meta-analyses (a MEDLINE search using 'hypnosis + pain' reveals 579 publications in the last decade) we conclude by pointing out that our organisation (BSCAH) does not admit those who are not qualified health professionals. We are academic researchers and health professionals (dentists, GPs, surgeons etc.) who, when appropriate, make use of hypnosis to benefit our patients. We find it to be clinically effective and cost effective, and urge that NICE recommends its use as a safe, beneficial alternative to opioid analgesics. De Benedittis G, Abrahamsen R, Fabre C, Fang X, Malafronte M, Naish P, Ruysschaert N, Shahidi E &	

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				Jensen M. (2020). *Hypnosis for Pain*. A White Paper submitted to the WHO. Valentini E, Betti V, Hu L & Aglioti S. (2013) Hypnotic modulation of pain perception and of brain activity triggered by nociceptive laser stimuli.*Cortex*. Vol 49p 446–462 Thompson T, Terhune D, Oram C, Sharangparni J, Rouf R, Solmi M, Veronese N & Stubbs B. (2019) The effectiveness of hypnosis for pain relief: A systematic review and meta-analysis of 85 controlled experimental trials. *Neuroscience and Biobehavioral Reviews*. Vol 99 p 298-310 Montgomery G, DuHamel K & Redd W.(2000) A meta-analysis of hypnotically induced analgesia: how effective is hypnosis? *International Journal of Clinical and Experimental Hypnosis*. Vol 48 (2) p138-53 Elkins G, Jensen M & Patterson D. Hypnotherapy for the Management of Chronic Pain (2007) *International Journal of Clinical and Experimental Hypnosis*. Vol 55 (3) p 275–287 Tan G, Rintala D, Jensen M, Fukui T, Smith D & Williams W. (2014). A randomized controlled trial of hypnosis	

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				compared with biofeedback for adults with chronic low back pain. *European Journal of Pain* 19 (2) 271-80	
British Society of Clinical & Academic Hypnosis (BSCAH)	Guideline	018	030	A major reason for hypnosis not being widely used is that it is not NICE recommended. Thus, this is a circular argument: we do not recommend a treatment now because people are following our past decision not to recommend it. This is not a sound basis for evaluating the value of a treatment. Rather it is a dismissal, on the grounds that it will not impact many people either way. That approach carries the risk of locking out a treatment that is both medically effective and cost effective (as we argue it is), and prevents the general benefits that would accrue if it were increasingly widely used. Where hypnosis is used it is found to be effective, and every effort is being made to promote its use by medical professionals. For example, the Royal Society of Medicine's two sections *Pain*and *Hypnosis & Psychosomatic Medicine*are together organising a series of webinars to increase awareness of the use of hypnosis in this field. A significant factor in the decision to take this action is that the President of the *Pain*section, an anaesthetist, uses hypnosis to treat chronic pain in her professional work. It is unfortunate that the NICE stance on hypnosis serves as a continual break upon attempts to make its benefits and applications more widely known.	Thank you for your comment. The decision on whether or not to recommend an intervention is based on the evidence reviewed. The committee agreed there was insufficient evidence available to recommend hypnosis for chronic primary pain. The decision on whether to include a research recommendation is based on whether there is promising evidence to suggest that research would add value, but also whether this is an area of importance to the guideline topic and feasible to carry out. It was the committee's opinion that although hypnosis may be used in other types of chronic pain, it was not widely considered for chronic primary pain (as likely reflected by the evidence based). They consequently agreed that further research for hypnosis in this specific population was not likely to add value.

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Chronically Awesome	Guideline	004 - 005	002 - 016	These recommendations will be challenging to implement within current appointment times. Achieving shared decision making such as that described in 1.1 through discussions of benefits, risks, uncertainties, expectations, experiences etc, as well as providing advice and information requires longer appointment times than are currently provided, particularly where needs and illnesses are complex.	Thank you for your comment. We acknowledge the challenges of appointment times. However the assessment of people with chronic pain is central to their management and the committee agree it is important that all of these factors are incorporated in appointments where relevant.
Chronically Awesome	Guideline	005	015	Feedback from our membership felt that the proposals overall invalidated their experiences of pain, and their experiences of currently offered treatments, but welcomed raising awareness of the potential to invalidate experiences in the specific context of giving negative or normal test results.	Thank you for your comment. The committee agree it is very important not to invalidate people's experiences of pain. This is not their intention with the recommendations, these are intended to reflect best practice and direct towards those interventions with evidence of effectiveness to improve patient care overall.
Chronically Awesome	Guideline	006	011 - 014	It is unclear how these classes will work in practice. Is it proposed that patients will be grouped randomly for classes, or will classes be arranged so that patients are grouped by ability and mobility, or type of need etc.? How these classes are arranged and provided will make a significant difference not only to the potential to benefit patients, but also to the ability to keep patients safe.	Thank you for your comment. Delivery and set up of these services can be determined by local commissioners and service providers.

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Chronically Awesome	Guideline	006	015 - 017	Research by Chronically Awesome has shown that patients with chronic illnesses face multiple barriers to accessing exercise, including financial, physical and psychological barriers, as well as the ability to access exercise professionals qualified or trained to manage clients with complex needs. Solely recommending and encouraging continued exercise is unlikely to be successful because these barriers have not been addressed.	Thank you for your comment. The recommendation for supervised group exercise is for provision within the NHS. The committee were mindful of people's different physical abilities and psychological barriers that may exist and noted that people are more likely to continue with exercise if the programme offered suits their lifestyle and physical ability and addresses their individual health needs. They agreed that the choice of programme as well as the content should take into account people's abilities and preferences. This might include providing individual exercise advice for different members of a group. This was highlighted in the recommendation and in more detail in the rationale underpinning the recommendation. The committee agreed it is important to recommend that people remain physically active beyond the end of the group programme because there are long

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					term general health benefits. They have now highlighted in the rationale this does not necessarily have to incur a cost.
Chronically Awesome	Guideline	007	002 - 004	How will waiting times and/or capacity building be managed for CBT and ACT. In many NHS trusts there are long waiting times to access psychological support services, and adding a large number of additional patients without additional capacity is likely to lead to even longer waiting times. Without this capacity building there is a risk that patients suffering with chronic pain are left without psychological support services for extended periods of time.	The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Chronically Awesome	Guideline	007	008 - 015	Chronic pain is, by definition, long-term. Offering a maximum of five hours of treatment is short-term in the extreme. It is accepted that the benefits of acupuncture do not last over the medium to long term, so this element	The committee agree that chronic primary pain requires long term management. The evidence base for

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				of proposed care feels incongruous and insufficient against the need of patients. Acupuncture is also best used for targeted areas of soft-tissue tension or damage. Where patients are experiencing widespread muscular or skeletal pain, acupuncture is unlikely to be a beneficial or appropriate treatment, further limiting treatment options proposed in these guidelines.	all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments. The evidence reviewed for acupuncture included a number of studies in people with fibromyalgia where pain is widespread which did demonstrate benefit. The committee agreed it was appropriate

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					to recommend acupuncture for all types of chronic primary pain. The type of acupuncture may vary according to type of chronic primary pain, but the committee agreed this would be determined by clinical judgement.
Chronically Awesome	Guideline	008 - 009	013 - 002	The communication of prescribing anti-depressants for chronic pain needs to be managed carefully. There is a risk that patients feel that their experiences are invalidated or they are made to feel like it is 'all in their heads' if they are offered antidepressants as a primary treatment pathway for chronic pain.	Thank you for your comment. We agree that good communication between the healthcare professional and person with chronic pain is central to good chronic pain management. The recommendations in section 1.1 of the guideline intend to help address this and including being sensitive to the risk of invalidating the person's experience of chronic pain. Antidepressants are recommended for their effects on symptoms of chronic primary pain and benefits observed on patient reported outcomes related to this. A recommendation has been added to highlight this is not for depression but because they may help

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					with quality of life, pain, sleep and psychological distress.
Chronically Awesome	Guideline	008 - 009	013 - 002	Patient experience tells us that the side effects of antidepressants can be as devastating as those of opioids. If patients feel that antidepressants are not appropriate for them, these proposals would leave them no other pharmacological treatment options.	Thank you for your comment. We acknowledge that there are side effects experienced by some people and include a recommendation to discuss the problems associated with withdrawal, as well as noting in the rationale that the risk of withdrawal symptoms should be discussed. The evidence reviewed did not support the use of any other pharmacological option for chronic primary pain, however other non-pharmacological options recommended in the guideline can be considered.
Chronically Awesome	Guideline	009	010 - 024	Instructing doctors not to offer any of the following removes the ability for patients to use these tools if they are appropriate for them. If shared decision making is the aim, and doctors are encouraged to communicate potential risks and benefits, then these treatments should be make available. Removing options removes autonomy. Instead, patients should be able to make informed decisions based on discussion with their doctor. This would be in line with page 5, line 9-11 "Discuss the possible benefits, risks and uncertainties of **all**	Thank you for your comment. The evidence review and expert consensus opinion of the committee did not support the effectiveness of the majority of pharmacological treatment options for management of chronic primary pain. They therefore agreed they should not be recommended as they are not demonstrated to benefit

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				management optionsfor the person's condition when first developing the care plan and at all stages of care."	most people. The committee agree people should be able to make informed decisions on which treatment to use, but that this should be based on those treatments demonstrated to be effective for chronic primary pain. The committee note that there are suggestions that small subgroups of people with chronic primary pain may benefit from some treatment. These guidelines provide recommendations for the population with chronic primary pain. Unfortunately research to date does not enable this group of responders for different interventions to be identified and therefore recommendations for more targeted prescribing are not possible. The committee agreed it was inappropriate to recommend trying medicines for which there is no good evidence that most people will benefit from or to risk exposing all of the

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					chronic primary pain population to medicines with a potential for harm, without evidence on how to determine the small subgroup that may benefit.
Chronically Awesome	Guideline	010	001 - 002	We question why patients already on these medications are able to stay on them with an explanation of the risks of continuing, while new patients will be denied these treatments. We believe all patients should be given the right to access these treatments alongside the risks of continuing.	Thank you for your comment. The committee acknowledge that following this guidance may lead to different treatment options being available to those newly presenting with chronic primary pain, or those not having yet started pharmacological treatment. However the evidence reviewed indicated these will not be of benefit to the majority of people as on the whole beneficial effects were not observed and there was evidence of harms. The committee agreed the risk of harms outweighed the benefits.
Chronically Awesome	Guideline	016	009 - 017	It is of concern that while other treatments have been ruled out due to a lack of evidence, group exercise has been recommended despite studies being limited to women with fibromyalgia and chronic neck pain. It is also of concern that there is limited evidence around types of exercise. Without detailed information, it is unclear how	Thank you for your comment. The committee agreed there was a large body of evidence in favour of supervised group exercise. The committee acknowledge that the

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				group exercise would be used across a wide variety of people and chronic primary pain symptoms. It is unclear how classes would work, how long the service would be offered for, and how a patient would be assessed for suitability. Much more research, information and guidance should be developed before this becomes a valid and useful part of the treatment toolbox.	evidence informing the exercise review was largely from populations with fibromyalgia or chronic neck pain. The committee considered that response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions. However it was also considered that the most appropriate type of exercise may depend on the type of pain condition and it should therefore be tailored to individual needs and preferences. This is detailed in the committee's discussion of evidence in the evidence review and has been added to the rationale in the guideline for clarity.
Chronically Awesome	Guideline	024	017 - 025	Studies mentioned in this section are flowed (non-randomised) but the committee falls back on their 'experience' when making the decision about opioids. We do not feel this is an appropriate approach, particularly when it is made by non-clinical staff, and is not applied consistently across other treatment options.	Thank you for your comment. When setting the review protocol for this question it was agreed that non-randomised studies were acceptable to inform safety of these medicines as long term follow up data is rarely available from RCTs and these

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					questions are more likely to be answered by observational data. The studies do have greater risk of bias associated than a well conducted RCT, but this is accounted for in the rating of the quality of the evidence. Guideline recommendations are made by a committee of healthcare professionals and lay members, all with expertise in the area. They take into account the evidence presented to them together with their clinical and personal experience and expertise. The technical team who undertake the evidence reviews do note vote on recommendations. Methods followed to form recommendations are consistent across reviews and follow the processes detailed in Developing NICE guidelines: The manual.
Chronically Awesome	Guideline	024	017 - 025	The number of people who become reliant on or addicted to opioids is in the minority, while many more benefit. Instead of penalising the majority, can doctors not be better trained to identify addiction at an early stage, and	Thank you for your comment. This recommendation is specifically for people with chronic primary pain. The committee note that there are

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				patients be monitored closely as they would be if a medication risked damage or organs etc.?	suggestions that small subgroups of people with chronic primary pain may benefit from some treatment, however there is no research to identify who this subgroup of people are. These guidelines provide recommendations for the population with chronic primary pain for which the evidence did not indicate there is benefit for the majority of people, but there is evidence of harm. The committee also consider that is possible the number of people addicted is underestimated due to the stigma associated with coming forward with help for dependence to a prescribed medicine. The committee agreed it was inappropriate to recommend trying medicines for which there is no good evidence that most people will benefit from or to risk exposing all of the chronic primary pain population to medicines with a potential for harm, without evidence

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					on how to determine the small subgroup that may benefit.
Chronically Awesome	Guideline	025	004 - 009	NSAIDs are prescribed with great regularity and with positive effects for patients. Like opioids, NSAIDs have been rejected based on lack of evidence and potential harm. However, all medical and pharmacological interventions carry a risk of harm, and we feel the decision to exclude NSAIDs is arbitrary.	Thank you for your comment. There was some, albeit limited, evidence available for the use of NSAIDs for chronic primary pain. This evidence demonstrated no difference between NSAIDs and placebo for quality of life, pain or psychological distress and worse outcomes for function. This is detailed in the rationale accompanying the recommendation. The committee agreed this was consistent with their experience of the use of NSAIDs for chronic primary pain, and taken with the knowledge of potential harms, agreed it was appropriate to recommend against its use.
Chronically Awesome	Guideline	026	003 - 011	Paracetamol is a widely recommended medication for all types of pain, and a lack of evidence is contrary to recommendations across the NHS, 111 and pharmacies. They are widely available over the counter so it feels impractical to withdraw this as a treatment option. Again it is felt that 'possible' harms are used as a reason for withdrawing these medications despite potential harm	Thank your comment. There is no evidence that paracetamol is beneficial for chronic primary pain which is why it's use has been recommended against. Recommendations in other NICE

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				existing for all pharmacological options including antidepressants.	guidelines for chronic pain conditions have also recommended against its use (NG59 Low back pain and sciatica in over 16s).
Chronically Awesome	Guideline	026	026 - 029	It is of concern that the recommendation is to reduce the use of pharmacological approaches in the treatment of chronic primary pain, as this leaves CBT or ACT as the sole long-term solution, acupuncture and group exercise both being offered on short-term basis. This of grave concern where waiting times can be several months if not longer to see a specialist in order to obtain a diagnosis that would result in appropriate treatment for the individual.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in

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					this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee also recommend that people remain physically active after an exercise programme ends, and have also included a priority research recommendation for repeat courses of acupuncture. The committee agree that there is not good evidence to support the use of pharmacological treatment options for chronic primary pain. These are also associated with harms, particularly with long term use.
Chronically Awesome	Guideline	General	General	The approach that this document takes is questionable in that, rather than expanding the toolkit available to both doctors and patients when managing chronic pain, the proposals laid out remove a broad range of tools from the kit and replaces them with others. We question why the toolkit cannot be added to, rather than changed. If the NHS goal of achieving shared decision making is to be met, doctors and patients must be able to look at a full range of options and be able to discuss each option before deciding together on the most appropriate treatment pathway for each individual. By removing treatment options as is proposed in this document, the ability of patients and healthcare professionals to make	Thank you for your comment. The recommendations in the guideline demonstrate where there is evidence that treatments are effective for chronic primary pain. The guideline also recommends against treatments where the evidence of benefit outweighs that of harm, or there is no evidence of benefit. The committee agree people should be able to make informed decisions on which

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				shared decisions is severely limited, going against the target of the NHS and against patient autonomy and welfare.	treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain.
Chronically Awesome	Guideline	General	General	It is felt that decisions made by the committee are inconsistent across this report. For some treatment options, treatments are disregarded on be basis of insufficient evidence or evidence of limited quality. But other treatment options have been recommended despite limited evidence or evidence of limited quality. It is unclear why the committee have felt that some evidence can be extrapolated or used despite limitations, while others cannot.	Thank you for your comment. Recommendations were made in accordance with Developing NICE guidelines: The manual as well as the methods chapter for this guideline. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. Their discussion of how the evidence informed the recommendations is detailed briefly in the rationales in the guideline and in more detail in the discussion of the evidence sections in the review chapters. The view of the committee

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					is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant for all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS).

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Chronically Awesome	Guideline	General	General	It is important for us to say that we welcome the use of counselling, acupuncture and in particular exercise, as part of the management of chronic pain. All have the potential to be a valuable part of the treatment toolbox shared by doctors and patients. We also welcome continued review of the way chronic illnesses are managed in order that they reflect the most up-to-date science and treatments, and of course we welcome new guidance where none has previously existed. We also applaud the recognition that the guidelines make around things like how patients experience communicating with doctors, and the potential for normal or negative results to make patients feel dismissed. Finally, we hope that the recommendations for further research into things like relaxation therapy, social interventions, laser therapy, transcranial magnetic stimulation and cannabis-related medicinal products.	Thank you for your comment and support for the guideline.
Chronically Awesome	Guideline	General	General	Despite the positive aspects of the draft guidance, we have some serious concerns and questions. You are welcome to use (or ignore!) any of the points below when making your submission to a stakeholder organisation or to NICE directly (see below). **Fostering collaborative partnerships** – Right at the start of the draft guidance, NICE recommends that doctors "Foster a collaborative supportive relationship" by	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				"knowing the patient as an individual, enabling patients to actively participate in their care, including communication, information, shared decision making, and [recognising] that chronic pain can cause distress." To do this it is recommended that doctors: • Ask the person to describe how pain affects their life, and how their life may affect their pain. • Ask the person about their understanding and acceptance of their condition, and that of their family, carers and significant others. • [Acknowledge] the fact that the pain may not improve or may get worse. • Develop a care plan with the person with chronic pain. Explore their priorities, strengths, preferences, interests and abilities to inform the plan. • Discuss the possible benefits, risks and uncertainties of all management options for the person's condition when first developing the care plan and at all stages of care. • Provide advice and information relevant to the person's individual preferences, at all stages of care, to help them make decisions about managing their condition.	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.

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				To those who have lived with chronic illnesses for any length of time, these recommendations feel almost laughable. In order to implement all of the above, to really foster collaborative partnerships, two things need to happen. First, appointment times need to be extended beyond 5-10 minutes, or multiple back-to-back appointments should be made available to chronically ill patients to allow for these discussions to take place. Current appointment times just do not allow for the above list to take place. Instead, appointments are rushed and patients often feel they have missed things they wanted to say or query in the rush of the appointment – especially where cognitive impairment from brain fog, fatigue etc. play a part. Second, more interdisciplinary collaboration needs to happen. It is extremely difficult to make collaborative partnerships that enable effective and informed care plans to be made when it is so difficult for doctors to talk to each other. Currently the GP tends to be the hub of contact from what can be a variety of specialist consultants who typically don't communicate directly with each other, and this lack of collaborative partnerships between doctors greatly limits the ability for doctors to create collaborative partnerships with patients.	
Chronically Awesome	Guideline	General	General	**Expanding the toolbox** – While we welcome the recommendation to make exercise, acupuncture and counselling part of the chronic pain management toolbox, we feel that it is better to 'add to the toolbox, not just change the tools'. The guidance talks of "shared decision	Thank you for your comment. It is important to note that the reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather

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				making" when it comes to treatment, but by taking painkillers, anti-inflammatories and steroids off the table, NICE are taking the ability to take some decisions away from patients. If treatment plans are to be tailored to each individual as the guidance says it should, we need to have every option open to patients who can then work with their doctors to find the right short, medium and long term management plans for them. Linked to this are the limited approaches suggested when it comes to psychological and emotional support. The guidance is limited to CBT and ACT, both "talking therapies" designed around accepting circumstances and better dealing with negative thoughts and behaviours. However, alternative therapies such as EMDR are already being used by the NHS in conditions such as PTSD and post-natal psychosis, and it is starting to be used successfully to assist chronic pain patients for whom talking therapies are not suited. Here again we would like to see NICE giving guidance that includes a wide range of approaches so that patients and doctors can find an approach that suits each individual.	than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should

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					be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain.
Chronically Awesome	Guideline	General	General	**Treatment pre-diagnosis** – the guidelines don't lay out how patients should be treated pre-diagnosis. Should chronic pain be treated as chronic primary pain until otherwise diagnosed? If it is suspected that they have a condition like endometriosis or IBS, should they be treated as having chronic primary pain until the diagnosis is confirmed, or should they be treated as they would be once diagnosed? These questions could have a significant impact on the thousands of people who are on (often lengthy) waiting lists to see consultants in order to get a diagnosis, who risk not get the treatment most appropriate to their situation. This is even more so the case where a patient is suffering from a less well-known conditions where diagnosis can take years. For example, research has shown that the	Thank you for your comment. The assessment section has been amended to include more clearly some recommendations for the assessment when considering the diagnosis. We note a holistic assessment is important and an individualised approach required. Each person's individual symptoms and presentation will be different and require different consideration and investigations as appropriate. This guideline should also be used alongside other NICE guidelines,

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				average time from first symptoms to diagnosis for EDS patients is 19 years. EDS is known to cause widespread chronic pain, and patients typically see a number of consultants before diagnosis is reached. Will these patients be limited in their treatment options over this extended period of time or will doctors be able (or even encouraged) to change the way they treat patients over time to reflect their healthcare journey towards diagnosis?	including CG138 Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. This covers more recommendations on assessment of people using services in general, including when they don't yet have a diagnosis.
Chronically Awesome	Guideline	General	General	**Waiting times** – Just like the waiting times for diagnosis, current waiting times for the treatments being recommended like CBT are often long, and in many areas ACT, acupuncture and group exercise is not yet offered by NHS Trusts. The guidance does not outline how pain should be managed while a patient waits for access to the recommended treatments, potentially causing weeks or even months or years of unmanaged pain.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. It is hoped that this

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					guideline will help increase provision and waiting lists would reduce. The recommendations also include highlighting the importance of giving information on self-management.
Chronically Awesome	Guideline	General	General	**Short-term solutions for a long-termproblem** – by definition, chronic pain of any sort is not short-term. Yet it seems that at least two of the four recommended treatment paths are only short-term. The guidelines specifically state that only five hours of acupuncture should be available. When talking about exercise, the guidelines do not state how long the free NHS group exercise programmes would last, but they make clear that despite advising patients to continue to exercise long-term to help continue to manage pain, it will not be a funded provision. Our 2019 research showed that 37% of respondents said cost was a barrier to accessing movement and exercise, and it is therefore imperative that further planning is put in place to support patients to continue to exercise.	Thank you for your comment. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform

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					future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments. In respect of exercise, the committee noted that physical activity continued beyond an exercise programme does not necessarily have to incur a cost.
Cochrane Pain, Palliative and Supportive Care Review Group	Evidence review A-Factors	general	general	In the evidence review of risk factors, what is called 'comorbid psychiatric disorder' consists of anxiety or depression scores on non-diagnostic questionnaires. It is inaccurate and misleading to refer to this as psychiatric disorder. Misunderstanding of use of common psychiatric scales designed for and standardised on physically well populations is noted on p55 in relation to discussion by committee, but appears to have been ignored in the summary.	Thank you for your comment. Comorbid psychiatric disorder was considered as a potential risk factor and also a confounder that should be adjusted for as detailed in the protocol. Studies were excluded from the analysis if they had not adjusted for at least 2 of the pre-specific confounders within the review. Study definitions of risk factors or confounders that were related to this heading were included here, but the full details of the study factor or confounder were stated instead to acknowledge that they were not in fact the desired factor for example of' 'comorbid psychiatric disorder'. As you

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					note, this was acknowledged and considered by the committee in their interpretation of the evidence and was stated in the discussion of the evidence. A footnote has been added to the summary of included studies table to explain why these are listed under this heading.
Cochrane Pain, Palliative and Supportive Care Review Group	Evidence review C-Pain management programmes and F Psychological therapies	general	general	Pain management programmes (PMPs) are always psychologically informed, with direct psychological content and other therapeutic components, most often physical activity, but also including analgesic reduction, occupational therapy, and sleep promotion, and are delivered in ways consistent with psychological methods and content. For this reason, it makes little sense to distinguish pain management programmes from psychological interventions – usually cognitive behavioural therapy (CBT), acceptance and commitment therapy (ACT), or mindfulness – that are rarely delivered without any other components alongside except in trials where the pain management package is 'dismantled' to attempt to identify unique effects of particular components.	Thank you for your comment. The committee's opinion was that it was important and appropriate to review psychological therapies as a standalone intervention as well as when included as part of a pain management programme. This was in part because the two reviews were in different sections of the guideline scope; the pain management review covered all types of chronic pain, whereas the guideline was also covering specific pharmacological and non-pharmacological interventions for chronic primary pain only. It was agreed important to include

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					psychological therapies within these interventions. The definition of pain management programme agreed by the committee for the review protocol was 'any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two'. This was deliberately not too specific to exclude too many studies, but the committee agreed there needed to be a physical component as well as psychological.
Cochrane Pain, Palliative and Supportive Care Review Group	Evidence review C-Pain management programmes and F Psychological therapies	general	general	It seems that many trials were sifted out at an early stage by the review teams, so that the guidelines group never had the chance to discuss whether they should be included or not. Sifting appears to have been rather insensitive to the varied ways in which psychological and other pain management content is described in many trials. PaPaS have just published a systematic review and meta-analysis of psychological interventions for chronic pain in adults (Williams et al. 2020), but during the guidelines process, Prof Amanda Williams, a member of our editorial board and a co-opted member of the guidelines group, raised a number of times the	Thank you for your comment. The technical team undertaking the reviews are skilled and trained in evidence based medicine and systematic review methodology. They undertake the sifting of the evidence at title and abstract stage, and again at full text, according to the agreed review protocols. At the title and abstract stage, if there is uncertainty

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				discrepancies between the 2020 review which was in process and the 2012 review of which it was an update, and the output of the search and sifting, using very similar PICOs and search terms, for the NICE guidelines. Some of the trials that Williams et al. (2020) included appeared in exclusion lists for the NICE review of PMPs, with reasons, in the NICE documents, and this has allowed PaPaS to check. Most exclusions were because trial interventions were not deemed to be a PMP, defined by the committee in the protocol as any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two. Exclusions were said to be usually because the intervention was either psychological or physical but not both, or included psychological and physical components but delivered in parallel with no interaction or coordination between them. A thorough check of the included and excluded trials for Williams et al. 2020 against the NICE review included and excluded trials showed very little overlap. Two examples of trials incorrectly excluded as not pain management programmes, both found in Appendix I among the excluded trials follow. Here we provide the elaboration of reasons provided by NICE when Professor Williams queried the decisions. One is by Bliokas et al., published in 2007, whose title specifies "multidisciplinary	as to whether an item should be included, the full text is ordered. If uncertainty remains on review of the full text, this is discussed with members of the committee as appropriate, and included checking some inclusions with our co-opted expert members where required. Any potential missing items or queries of inclusion raised by committee members, or co-opted members, are checked by the technical team. This includes all of those raised by Prof Amanda Williams as mentioned in your comment. Responses were provided and these were discussed with the committee where any further query remained. There do remain some differences between the associated Cochrane reviews and the guideline reviews. These are because of the differences in the scope and purpose of the

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				chronic pain management groups", and whose objectives in the Abstract also mention that the basis of the trial was a pain management programme to which a specific extra psychological component was added. The second is by Kole-Snijders et al., published in 1999, whose title and abstract do not mention pain management programmes, but were excluded on the basis of no physical intervention when participants each had 50 hours' individual treatment by physical therapists. These are just two examples where the rationale provided by NICE for exclusion does not seem clear or appropriate and they reflect a broader issue with this NICE review with numerous trials of interventions that might reasonably be considered to be PMPs excluded. Further there are a number of examples of trials that were included by NICE but were excluded from the Cochrane review on the basis that they were too small or that the psychological component was delivered by non-psychologist professionals (10 trials) or laypersons (1 trial). Psychology is not common sense, and psychological therapy is not just talking. There are many studies showing the unsatisfactory nature of much communication between healthcare staff and patients (some reviewed in these guidelines), so to assume that any staff can teach psychology, when there is no suggestion that anyone could deliver medical care or physiotherapy or pharmaceutical advice, is problematic. It	guideline compared to the Cochrane reviews and the criteria set out in the review protocols agreed with the committee, in accordance with the scope. The committee's opinion was that it was important and appropriate to review psychological therapies as a standalone intervention as well as when included as part of a pain management programme as these two reviews covered different populations. In some cases this required agreement by the committee as to whether the elements were sufficient to include in either review. The psychological therapies review protocol was specific to chronic primary pain (excluding conditions already covered by NICE guidelines) whereas the pain management programme review protocol was for all types of chronic pain.

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				means that many of the NICE-included studies of psychological therapy, and of pain management programmes, are underpowered in terms of authentic delivery. The 2020 Cochrane review (Williams et al. 2020) required that a psychologist delivered the psychological content of the intervention, because there is very poor evidence that it can be adequately implemented without some training and this would reasonably be expected to impact effectiveness. The overall result is that NICE excluded for incorrect reasons a large number of relevant trials. Many of these trials represent the kind of multicomponent pain management programmes delivered in many pain clinics and a few community settings in the UK. NICE instead included some trials that were underpowered either because of their size or the lack of suitable training of personnel. Where processes, particularly around early sifting of eligible studies, may not have been entirely transparent the result is that the committee is asked to make best sense of what was presented to them, without knowing what had been discarded or discounted at an earlier stage, having to take on trust that those presented were the most suitable trials on which to evaluate effectiveness.	The definition of pain management programme agreed by the committee for the review protocol was 'any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two'. It was agreed the multidisciplinary aspect should focus on the components, not the person / people delivering it. As stated above, where there was uncertainty in the inclusion status from the title or abstract, the full paper was ordered. This was the case for both Bliokas et al. 2007 and Kole-Snijders et al. 1999. Both were discussed with the committee and agreed that the physical component was not sufficient to be deemed to meet the protocol criteria of a pain management programme. In Bliokas et al. people were encouraged to

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					identify activities that they avoided and those that led to movements of concern. These did form part of their graded exposure pain management, but not as an active intervention. The committee did not consider the level of this physical activity as enough to be considered a multidisciplinary intervention. Although Kole-Snijders states physical therapists provided 50 hours of treatment, it states that patients were taught to increase their sitting and standing tolerance and developed a daily activity schedule according to operant principles to be used at home. This is the only description of the physical component provided, and again the committee did not agree this was sufficient to meet the protocol criteria.
Cochrane Pain, Palliative and Supportive	Evidence review C- Pain manageme	gene ral	general	The guideline says: "1.3.3 Consider acceptance and commitment therapy (ACT) or cognitive–behavioural therapy (CBT) for pain for people aged 16 years and over with chronic primary pain". The data on ACT are directly	Thank you for your comment. We believe robust criteria were followed when conducting the review. We note

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Care Review Group	nt programmes and F Psychological therapies			contradicted to the findings of the Williams 2012 review which comprehensively found that there was insufficient evidence to make such a claim and a recommendation for future research was only possible. Although there is significant enthusiasm for ACT based treatments in chronic pain that enthusiasm is not matched by the evidence. Perhaps of note is the reason for the difference. When robust criteria are applied the putative effects are missing. To illustrate this, in our recent review Williams (2020) reported: "For ACT, the finding of no evidence of efficacy or safety is at odds with several non-Cochrane reviews. Veehof 2011 combined 22 studies of ACT and mindfulness-based meditation, including non-randomised trials, and reported ACT to be "promising." In 2016, they updated this to 25 studies, all RCTs, and concluded "...that individuals with pain, in general, respond rather well to acceptance-and mindfulness-based interventions and that beneficial effects are retained after treatment"(Veehof 2016). Twenty-two of the studies included in that review did not meet our inclusion criteria. Twelve of the 25 are ACT studies. Nine of the 12 are not included here, seven because of small size, one because it was not delivered face-to-face, and one because it had no suitable control. One 2017 review included 11 RCTs (Hughes 2017). Their primary outcomes were acceptance of pain, quality of life and functioning. Their conclusions were for a positive effect of ACT on acceptance of pain and on functioning. Eight	that one of the key reasons stated for the difference between the Williams review and other systematic reviews is the latter's inclusion of studies of small sample size. We do not agree this is reason alone to exclude a study from a systematic review, as with meta-analysis the sample size can be accounted for in weighting and risk of bias assessment. Smaller studies can add to a body of evidence to give a better estimate of the true effect across trials than would be available from those small studies in isolation, taking into account the quality of that evidence. Sample size is therefore not considered as an exclusion criteria in this review protocol. The committee agree that the evidence reviewed in the guideline does support a positive recommendation to consider ACT. The committee took great care to ensure that there was consistency in decision

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				of the 11 are not included here, five because of small size, two because they were not delivered face-to-face, and one because it was a non-inferiority trial. A different 2017 review included 10 studies, had no accessible protocol, attempted no meta-analysis and simply reported on investigator-chosen endpoints (Simpson 2017). Their conclusions were positive for an effect on pain acceptance. Seven of the 10 were not included here, four because of small size, two because they were not delivered face-to-face, and one because it was a non-inferiority trial."	making across the level and amount of evidence underpinning recommendations. They agree this was also consistent with levels of evidence for other interventions in the guideline where 'consider' recommendations were made.
Cochrane Pain, Palliative and Supportive Care Review Group	Evidence review C- Pain management programmes and F Psychological therapies	general	general	For those commissioning psychologically-based interventions for chronic pain in adults, or including such interventions in policy determinations, it is important to recognise that not all psychological treatments are the same. There is variety in the content, delivery, and clinical intentions of treatments, depending on their theoretical provenance. Interventions aim to reduce distress and disability, with or without a reduction in pain. The largest body of evidence we have supports the use, by trained psychologists, of CBT to produce benefits immediately after treatment and at follow-up of at least six months, rather than providing no treatment. The evidence is sufficient (i.e. large and of moderate quality) and unlikely to change with future studies. The overall effects are small or very small, meaning that the population benefit may be large, but more work is needed to identify which patients will individually benefit. There is development in	Thank you for your comment. The committee agree these are important factors to consider. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also

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				other treatments such as ACT, emotional expression, and psychodynamic psychotherapy, but these remain experimental and ongoing rigorous evaluation and monitoring of positive and negative outcomes is advisable.	be considered by NICE where relevant support activity is being planned.
Cochrane Pain, Palliative and Supportive Care Review Group	Evidence review G-Acupuncture	General	General	The recommendation to consider acupuncture is interesting in that it deviates from the recommendations of the most recent NICE guidance on osteoarthritis and low back pain, both of which gave a "do not offer" recommendation on the basis of evidence of a lack of efficacy. It is notable that the certainty of the evidence around the efficacy of acupuncture (vs sham) for pain (visual analogue scale (VAS)) is very low in the largest analysis. The studies that comprise this comparison are generally small and at risk of multiple important biases that might be expected to exaggerate any true effect. There are major threats to clinician and patient blinding in the included studies (participant blinding is frequently suboptimal and from the clinician perspective most studies are effectively open-label, though reasonable double-blind methods are available for many acupuncture approaches) as well as issues with randomisation and allocation concealment, selective outcome reporting, incomplete outcome data and very high statistical heterogeneity (inconsistency). Similar issues of study quality impact the other comparisons. With the focus	Thank you for your comment. The committee were aware of the recommendations in the low back pain and sciatica and osteoarthritis guidelines. These are a result of the different evidence bases informing the recommendations in the guidelines The imprecision in the VAS pain acupuncture versus sham analysis was taken into account in the interpretation of the evidence, as were other areas of uncertainty or concerns in the quality of evidence. This is reflected in the committee's discussion of the evidence in the evidence review. For pain reduction in the sham comparison the committee particularly noted that the imprecision was marginal, crossing the MID by 0.3. The committee agreed that overall the

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				(appropriately) on subjective self-reported outcomes these multiple biases have great potential to create falsely positive results. It is also here that the scope may have an influence as the exclusion of studies in some conditions (for example in low back pain where numerous larger scale trials exist) introduces a study-level selection bias that broadly limits the analysis to smaller poorer quality studies. Contrasted with recent more inclusive synthesis of the efficacy of acupuncture (Vickers et al 2018) which include larger and more rigorous trials and found very small, clinically trivial differences between acupuncture and sham acupuncture, notwithstanding similar blinding issues, these results are incongruous and should be considered very carefully. There is no theoretical reason to explain this contrast. The effect sizes seen in some of the included studies are extreme for this clinical field against any benchmark. Examples here include a number of studies which present mean differences in pain intensity of greater than 3 points on a 0-10 numeric rating scale (NRS). While that might superficially appear to be a positive, it should raise concerns regarding the veracity of those results that go beyond issues of blinding. Results from the multiple analyses for HRQoL are highly inconsistent. Some detailed comments indicate that the conclusions as presented to the committee may not be reliable, including	body of evidence was demonstrating a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. The risk of bias elements highlighted have been taken into account for in the risk of bias rating, and subsequently in the quality ratings which were discussed with the committee. The quality of the evidence is reflected in the strength of the recommendation (see NICE guideline manual). Here the recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. Comparison with the conclusion of Vickers et al. is not appropriate, as the

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				the fact that only 379 participants were in larger studies with group sizes above 50. • Not all the treatments called acupuncture are necessarily deliverable. Couto 2014 used "deep dry needling combined with paraspinal deep intramuscular stimulation with needle rotation". Also, from this study, actual pain scores at 4 weeks were available in Figure 2, and better than the 4-week averages used in the calculation. This may be relevant to some other forms of acupuncture described. • In Harris 2005, the week 9 timepoint chosen happened to be the point at which pain scores in the acupuncture group were lowest. • Lee 2011 is problematical on two counts. Firstly, the initial pain scores were so low as to make for an insensitive assay of analgesia (note that moderate or severe initial scores are needed for sensitivity). Secondly, Lee 2011 is a republication with additional data from Lee 2008, but the data on pain is inconsistent between the two. • Vas 2016 uses data of percentage change in pain score as if they were the change in pain in absolute measures. They are not. By calculating the actual changes, they should	two systematic reviews have included a different evidence base. Vickers et al. covers all types of chronic pain. It is possible that when separated into different types of chronic pain, differing effects could be observed. Vickers et al. includes chronic headache, back pain, neck pain, OA, and shoulder pain. No studies are specifically in fibromyalgia syndrome which is a common type of chronic primary pain which is the focus of this guideline review and recommendation. NICE guidelines exist for some of the separate types of pain included in Vickers et al. and have come to different conclusions based on the separate populations (for example acupuncture is also recommended in the NICE headaches guideline). Nevertheless, Vickers conclude 'that acupuncture is effective for the treatment of chronic pain, with treatment effects persisting over time'. While we agree, the scope

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				be reductions of 3.2 and 2.1 (not 4.1 and 2.7), and the mean difference (MD) would be 1.1 not 1.4.The largest trial (Molsberger 2011) is a large study comparing acupuncture with sham acupuncture and conservative orthopaedic therapy. It has broadly good methods, though did not blind clinicians and did not evaluate the success of participant blinding raising a substantial risk of performance bias. Attrition was substantial and imbalanced across groups at the primary endpoint of 3 months with 45% of the sham group lost and counted as non-responders compared to 17% in the verum group though surprisingly NICE rated the study at low risk of bias for incomplete outcome data for this timepoint. The recommendation to consider acupuncture is therefore made using a highly uncertain evidence base and in the context of a broader, more robust and relevant evidence base that offers a substantially different answer with little uncertainty. While the committee offer reassurance that that they "took into account the low quality in their interpretation of the evidence" this does not solve the problem that when we aggregate poor quality studies they cannot lead us to a reliable answer.	has had an influence on the outcome of the review (by its definition of the population), that does not mean the outcome for this population is incorrect. In relation to the specific points highlighted in your comment: We do not exclude studies based on sample size, as they still add to the body of evidence but are aware of the care that must be taken when interpreting the evidence. The limitations of such studies are accounted for in GRADE in the risk of bias and quality ratings. In the meta-analysis smaller studies will typically have wider confidence intervals and less weight (influence) in the overall effect than larger studies, but the overall power may be increased by their inclusion in a meta-analysis to give a better estimate of the true effect.

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					It is not possible to accurately extract the precise effect or variance reported in the graph in Couto et al. 2014. For this reason the data reported in the narrative has been extracted. The committee did consider the variety in types of acupuncture and methods of delivery included in the studies. They note in the rationale that the type of acupuncture or dry needling should depend on the individual needs of the person with pain, rather than specifying details of acupuncture delivery. For Harris et al. 2005 the time points chosen for extraction were consistent with those stated in the review protocol: the closest time point less than 3 months, and longest timepoint greater 3 months. The fact that this is the lowest pain value for acupuncture at 9 weeks (reported as less than 3 months in the review) is coincidental.

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					The pain outcome measures reported in Lee et al. 2008 and Lee et al. 2011 are different, hence the different values. As detailed below. Lee 2008 reports the Brief Pain Inventory as median and standard deviation. Lee 2011 reports VAS pain, as mean and SD. We note that the baseline pain values reported in Lee 2011 are relatively low, however it was not a protocol criteria to exclude below a certain level of pain. Vas et al. 2016 has reported percentage pain reduction. Although it is possible to calculate the absolute decrease in pain from the data they provide, it is not possible to report the variance around that change therefore this data could not be used. For that reason the mean percentage reduction and its standard deviation have been reported so that the data

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					could be considered fully in the analysis and quality assessment. Regarding Molsberger et al. 2010 the lack of clinician blinding is accounted for in the risk of bias assessment. Thank you for highlighting that attrition was not accounted for. This has been updated in the report and the risk of bias rating changed accordingly. The outcome this study contributed to in the meta-analysis was already rated as very low quality, and this has reinforced the rating but does not change the interpretation of the results. The problem of aggregating poorly conducted small studies is well known and is addressed in part by GRADE and in the complex decision making made by guideline committees when making recommendations (taking into account all factors from the review for example, economic evidence, trade-

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					off between benefits and harms). With this in mind the committee offers their reassurance that they have taken your methodological concerns into account alongside the many other factors when making the recommendations for acupuncture.
Cochrane Pain, Palliative and Supportive Care Review Group	Evidence review J-Pharmacological management	general	general	These are comments restricted to the pharmacological interventions that may be made in treating people with primary chronic pain, as defined by this guideline. Most of the comments concern fibromyalgia, which affects many people [global mean prevalence of potential cases of fibromyalgia estimated as 2.7% (range 0.4% to 9.3%), usually older women]. The condition is associated with very considerable disability and reduced quality of life, as well as severe and long-lasting pain that is difficult to treat. The few treatments known to be effective help no more than about 10% of people with the condition, but reduced pain is associated with improvements in associated symptoms, much improved quality of life, and ability to work. **Pregabalin** The guideline combines gabapentin, pregabalin, and (possibly) mirogabalin together under the generic term 'gabapentinoids'. It is not entirely clear why this is. The	Thank you for your comment. When agreeing the protocol for the review of pharmacological interventions, the committee agreed it was appropriate to pool pharmacological interventions included in the review by class (with the exception of antidepressants which were separated by sub-class). This included antiepileptics. The only evidence identified in this class was for gabapentinoids, and so they appear pooled in the review. The committee agreed this was appropriate because they are currently considered to be part of the same group of drugs and act similarly. The committee do not agree that

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				drugs ***may***have similar mechanisms of action, but based on animal experiments that is increasingly being questioned. Moreover, the evidence on gabapentin is relatively weak, and the excellent evidence on mirogabalin demonstrates that it is ineffective at the doses used. This commentary therefore sticks to a specific drug, and mostly a specific dose, specific patient-valued outcomes, and specific duration of trial. **Exclusions** The guideline has chosen to exclude a number of large, high-quality, randomised, double-blind trials that have been used to judge evidence of pregabalin efficacy and safety in fibromyalgia by, inter alia, the FDA, EMEA, and Cochrane reviews. There are four: Arnold 2008, Mease 2008, and Pauer 2011 were excluded because they had "incorrect study design (placebo run-in phase)". Entry criteria for these studies was as follows (from Arnold, but they were all very similar designs): "*Patients were considered eligible for the study if they were at least 18 years of age, male or female (were nonpregnant and nonlactating), met the American College of Rheumatology classification criteria for fibromyalgia, 34 and had a pain score of at least 40 mm on the 100-mm pain visual analog scale (VAS) at screening (visit 1) and random*	evidence from animal models are reliable to predict human responses as mechanisms that occur in animals are not necessarily as important in humans. Please note that mirogabalin was not included within the review as it does not have a license in the UK for any indication. **Exclusions** The exclusion of studies with an enriched enrolment design / placebo run in phase was agreed when setting the protocol for this review. Placebo run in studies: The committee do not agree that a placebo run in phase is the same as requiring a minimum baseline level of pain prior to study entry. The intention of this placebo run in phase (as stated in Arnold 2008) is to exclude placebo responders (those who had

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				assignment (visit 2). ***In addition, patientsalso had to complete a minimum of 4 of 7 daily entries inpain diaries during the 1-week, single-blinded run-in period,with average mean pain score ≥4."*** The placebo run in was used to ascertain that these participants genuinely had moderate or severe pain at baseline. This is not only not an incorrect study design, but rather essential in establishing a sensitive assay. The requirement of moderate or severe pain in ascertainment of analgesic efficacy has been established for at least 75 years. In these trials, the ascertainment of at least moderate pain was even better established than usual. Almost all trials have a one-week assessment period for establishing initial pain and when current treatments have been discontinued. For example, Arnold 2019, which is included, says that participants should have "ADPS of ≥ 4 on the 11-point numeric rating scale (NRS) over the past 7 days prior to randomization (based on completion of at least 4 daily pain diaries during the 7-day baseline period prior to randomization)". There is little or no difference between a week on no drugs or a week on no dugs plus placebo. These three trials, with data on almost 2,250 people with fibromyalgia, have been erroneously excluded. Crofford 2005 was excluded because "Not review population. Excluded known non-responders". The	≥30% reduction in pain when receiving placebo). While this can be a useful methodology employed in a proof of concept study, it does not provide a generalizable estimate of the efficacy of the medicine in the general population. There are two main concerns: 1 - Such trial designs will likely increase the observed magnitude of effect of the medicine compared to the placebo group as placebo responders are removed. Whilst the placebo response in pain is known to be high, this is reflective of how the general population are likely to respond, and so excluding these gives a biased estimate of effectiveness gained from these trails compared to those without a placebo run in phase. 2 – The side effect profile of many of these medicines (including pregabalin) are notable. Having a placebo run in phase can effectively unblind study participants as they are able to notice

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				exclusion was actually: "Those who had failed to respond to previous treatment with gabapentin at dosages ≥1,200 mg/day for pain associated with FMS were excluded." But this was a trial of pregabalin, not gabapentin, and the discussion admits that "prior beneficial response to gabapentin was not systematically recorded, so it is not possible to determine whether these participants were more likely to respond to treatment with pregabalin." Not only was this not an exclusion of known non-responders, and certainly **not**an exclusion of non-responders to pregabalin (the drug under test), but also the evidence is that this sort of partial enrichment has no effect on analgesic efficacy assessment with pregabalin, where the maximum enrichment was by about 12% (Straube 2008). As a result, we consider that this trial, with over 500 people with fibromyalgia, has been erroneously excluded. Crofford 2008 was excluded on the grounds: "Not review population. Only responders". That is not exactly true: the participants screened and entering the initial open label phase of the study were exactly the same in terms of the inclusion and exclusion criteria used as participants in other trials, fulfilling American College of Rheumatology (ACR) criteria for fibromyalgia, and having at least moderate pain at screening and baseline visits. After a six-week open label phase to determine whether participants could both get adequate pain relief, and those with "≥50% reduction in pain VAS score from OL	the difference between tablets received. This again biases the results of the study, generally in favour of the active intervention when in a clinical trial setting. Enriched enrolment design: The committee considered that including enriched enrolment design studies would not provide the committee with an overview of the effect of pharmacological interventions for people with chronic primary pain and would not support their decision making for this population as a whole. By including studies that only recruit known responders there are difficulties with interpreting the data for a patient population, particularly for people that have not been prescribed the drug of interest previously. By the nature of these studies people that don't respond (but are diagnosed with chronic primary pain) are not

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				baseline and a self-rating of overall improvement on the PGIC scale of "much improved" or "very much improved" were then randomised to continuing with their established dose, or placebo, for a six-month period. This trial is an exemplar of how enriched enrolment randomised withdrawal (EERW) trials should be done (Pain 2015 156:1382–1395) and mimics real world conditions. Although EERW designs cannot be combined with studies of conventional design, they can inform in just the same way. This trial, with over 1,000 people with fibromyalgia, has been erroneously excluded. In total five large, high-quality, randomised and double-blind trials of pregabalin in fibromyalgia have been erroneously excluded: totalling information on over 3,700 people. A consequence of this policy is that most of the analyses performed for antiepileptics have data from only a few, rather small, trials for pain. Figure 4 has about 500 participants in total, Figure 5 54, and only Arnold 2007 and Arnold 2019 contribute data for fibromyalgia, the former with 117 participants and the latter with 1,903 participants, but only a single (different) pain outcome with each. **Duloxetine**	included. The effect of this is to likely increase the observed magnitude of effect of the medicine in a population when it is known not to be effective for some people. It does not provide a generalizable estimate of the efficacy of the medicine in the general population. In addition, the concerns re the side effect profile stated above (in our discussion about placebo run in studies) also apply here. The committee also note and agree with your comment number 152 that these trials would be very useful if it could be determined from them which characteristics identify responders compared to non-responders, to enable targeted prescribing. Crofford 2005 was excluded because as stated above the committee believe there is no good clinical rationale that gabapentinoids cannot be pooled as appropriate because

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				Exclusions and inclusions Arnold 2004 is excluded because it had a one-week placebo run in to establish minimum pain requirement. As already explained, that is an error, and it leads to the improper exclusion of data from 205 people with fibromyalgia. However, Arnold 2012 is included. This trial used a suboptimal dose of 30 mg pregabalin daily, at least half that used in all other trials, and used clinically. Including this trial (with zero treatment effect) in an analysis of effective doses was an error. **Outcomes analysed** Good clinical trials are data rich, and Cochrane reviews of pregabalin in fibromyalgia and neuropathic pain, and those on duloxetine in a range of pain conditions, offer many different ways of expressing analgesic results. Often forgotten is the patient perspective – what do participants with pain want of therapy? The answer is consistent across all acute and chronic pain, and headache – large degrees of pain relief, and quickly. A recent systematic review demonstrates this clearly (Moore 2013a). Another demonstrates that people with pain rate their pain very differently from their carers, who typically downgrade the patient experience, roughly by	they are currently considered to be part of the same group of drugs and act similarly. Hence in accordance with the review protocol, this exclusion is correct. Regarding Crofford 2008, the committee maintain that the exclusion reason provide is appropriate. You state this is not exactly true, however the authors state 'As the trial was designed to assess the durability of response to pregabalin monotherapy, only those patients who were responders to pregabalin at the conclusion of the 6-week OL [open label] treatment phase were eligible for the 26-week DB phase…. Those who completed the OL, but did not meet responder criteria, were assessed as non-responders and were ineligible to enter the

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				the magnitude of some of the best analgesics known (Seers 2018). This is why pain studies have moved significantly in reporting, so that at least 50% (or at least 30%) pain intensity reduction has become the standard. These values are available in the excluded, and in at least one of the included studies (though neither sought nor used in this evidence assessment). Importantly with this form of outcome analysis, patient response is bimodal – either very large benefit is seen, or very little, with very few participants experiencing an 'average' response; this has important consequences for other symptoms. **An alternative analysis of pregabalin and duloxetine trials** Using outcomes important to participants with pain, our Senior Editor Andrew Moore has for fibromyalgia performed an analysis combining the data in the Cochrane review of pregabalin 300 mg daily for fibromyalgia with the three studies in Arnold 2019 using WebPlotDigitizer to abstract the relevant numbers from graphs for the three Daiichi trials. Pregabalin results from seven trials and 3,278 patients using 300 mg daily for at least three months are shown in Figures 1 and 2, for at least 50% and at least 30% pain intensity reduction respectively. The magnitude of the risk difference is 8% and 9% respectively, significantly	DB phase of the trial." The full description of the open label phase that precedes the double blind period of the trial also clearly states the intention is to identify responders. The committee's opinion remains that the description provided in the study is consistent with only including responders in the double-blind study phase for which study data is reported. As stated above, the committee agreed such studies do not provide generalizable evidence to inform decisions for patient populations. These trials do not give any further information about which people with fibromyalgia (in this case) benefit and can also not be used to inform targeted prescribing. **Duloxetine** Regarding Arnold 2004, our response is consistent with that stated above, that we believe exclusion of studies

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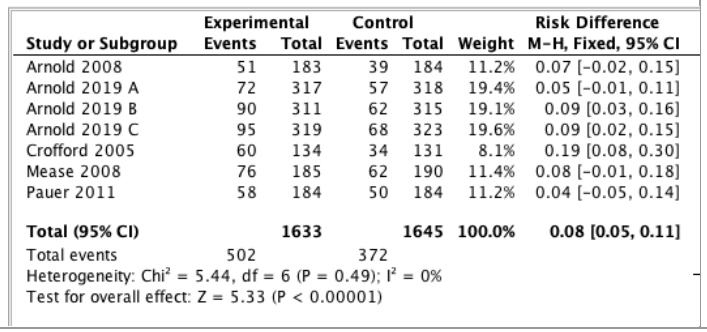
				better than placebo, and with no measurable heterogeneity in these large, high-quality, long duration studies. Moreover, a large (1,000 patient) EERW trial lasting six months confirms the degree of benefit, and that it continues in the long term for pregabalin. **Figure 1: Pregabalin 300 mg daily: at least 50% pain intensity reduction**  Experimental / Control / Risk Difference Study or Subgroup — Events — Total — Events — Total — Weight — M-H, Fixed, 95% CI Arnold 2008 — 51 — 183 — 39 — 184 — 11.2% — 0.07 [-0.02, 0.15] Arnold 2019 A — 72 — 317 — 57 — 318 — 19.4% — 0.05 [-0.01, 0.11] Arnold 2019 B — 90 — 311 — 62 — 315 — 19.1% — 0.09 [0.03, 0.16] Arnold 2019 C — 95 — 319 — 68 — 323 — 19.6% — 0.09 [0.02, 0.15] Crofford 2005 — 60 — 134 — 34 — 131 — 8.1% — 0.19 [0.08, 0.30] Mease 2008 — 76 — 185 — 62 — 190 — 11.4% — 0.08 [-0.01, 0.18] Pauer 2011 — 58 — 184 — 50 — 184 — 11.2% — 0.04 [-0.05, 0.14] **Total (95% CI) — 1633 — 1645 — 100.0% — 0.08 [0.05, 0.11]** Total events — 502 — 372 Heterogeneity: Chi² = 5.44, df = 6 (P = 0.49); I² = 0% Test for overall effect: Z = 5.33 (P < 0.00001)	with a placebo run in phase is appropriate. Regarding Arnold 2012, duloxetine is not licensed for use in chronic primary pain in the UK. Consistent with all reviews of medicines used off license we have included studies of any dose if the study otherwise meets the review protocol. Furthermore, we note in the FDA approval of duloxetine the starting dose is noted as 30 mg, with a recommended dose of 60mg, although they note some patients respond at the starting dose. We also note in the included studies of amitriptyline, benefit is seen from a study of 5mg. We believe that particularly in medicines used off license if benefit is observed at lower doses this is useful information to inform the use of these medicines and should not be excluded from the review, but do agree it's important to consider in decision making and discussion of the evidence.

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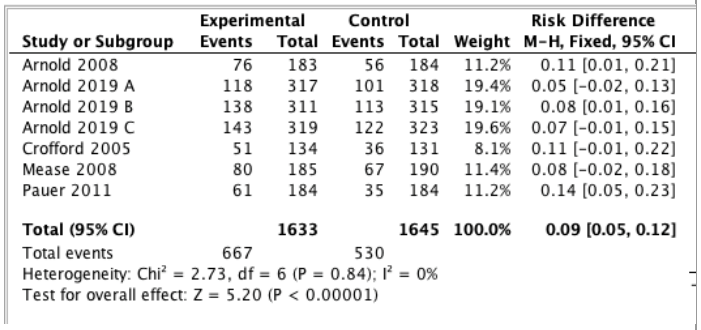
				Figure 2: Pregabalin 300 mg daily: at least 30% pain intensity reduction  Duloxetine results from six trials and 2,246 patients using 60 or 120 mg daily for at least three months are shown in Figures 3 and 4, for at least 50% and at least 30% pain intensity reduction respectively. The magnitude of the risk difference is 9% and 11% respectively, significantly better than placebo, and with limited heterogeneity in these large, high-quality, long duration studies.	**Outcomes analysed** We agree that patient important outcomes are vital to informing recommendation making. The IMMPACT core outcome set was used when forming this review protocol. In terms of reporting pain, we are aware that trials of pain are encouraged to report number of responders (30 or 50%) as well as the continuous outcome data. When setting the review protocol we agreed that dichotomising continuous outcomes loses some important information on the variation in response and we advise against reporting it *instead* of the continuous data. To avoid double counting of information in decision making we therefore note that this should be a secondary outcome to the continuous data (only reported if the continuous data wasn't available). This is still consistent with the IMMPACT recommendations.

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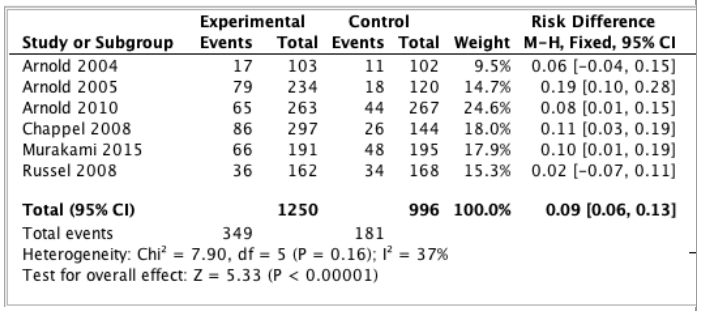
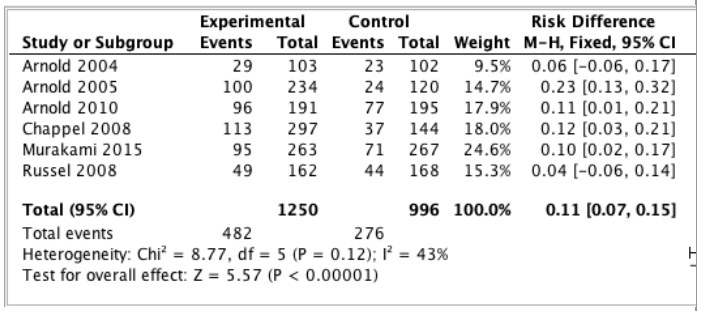
				Figure 3: Duloxetine 60/120 mg daily: at least 50% pain intensity reduction  **Figure 4: Duloxetine 60/120 mg daily: at least 30% pain intensity reduction**  **Comparing efficacy with pregabalin and duloxetine**	**Alternative analysis** Thank you for providing your reanalysis of this data, however for the reasons stated above, we believe the methodology followed in the guideline is robust and appropriate for reviews informing recommendations for national guidance.

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				Table 1 shows the comparison between the summary analyses of these two interventions for fibromyalgia. Each uses: • the same dose of the drug under test in a comparison with placebo, • using essentially similar patient populations with at least moderate pain relief (typical mean initial pain scores were in the range 6 to 7.5 out of 10, indicating most had severe pain), • the same study duration of around three months, • the same or very similar methods of ascertainment of pain by the patient, • the same patient-centered outcomes, • the same method of analysis, • using all available data (at least all immediately available at short notice). The table includes data on over 5,500 participants, and, for each of the two outcomes, percentages with treatment and placebo achieving the outcome is very similar. For each outcome, about 10% more of the participants treated had the outcome with treatment than with placebo. **Table 1: Comparison between analyses of pregabalin and duloxetine**	

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				Number of / Percent wit Drug daily dose / Trials / Patients / Active At least 30% pain intensity reduction Pregabalin 300 mg 7 3278 41 Duloxetine 60/120 mg 6 2246 40 At least 50% pain intensity reduction Pregabalin 300 mg 7 3278 31 Duloxetine 60/120 mg 6 2246 28 Comparison of the responses between the two drugs at each outcome indicates no significant difference in effect size, using 2-tailed z-test. The committee found that duloxetine had no benefit on pain in the long term, despite this overwhelming evidence, far larger in quantity and longer in duration than data for other antidepressant drugs. The committee found little or no benefit of antiepileptic drugs in terms of pain in shorter or longer term, and that "*there was insufficient evidence to justify the routine use of gabapentinoids for chronic primary pain.*"	

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				As presented here, for fibromyalgia there is a large amount of high-quality data with little uncertainty, and with confidence intervals that include the threshold of absolute difference of ≥10 set as a limit by NICE. The evidence presentation to the committee omitted very large amounts of directly relevant evidence, by failing to follow established evidence for patient-centred outcomes, and by presenting the evidence in a way that precluded the committee from making a proper, evidence-based decision. **The individual patient experience** Clinical trials of pregabalin used for the treatment of fibromyalgia have examined the individual experience of pain, and have linked their pain experience to the experience of concomitant symptoms (fatigue, depression, sleep, etc). The experience of people with fibromyalgia who are successfully treated – their pain is reduced by a satisfactory degree – is similar to those with other pain conditions. Those who have good pain relief experience significant clinical benefit in all the other symptoms, and their quality of life improves dramatically. **Pain** How participants express their experience in terms of a global impression of change is associated with their pain	

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				at the end of a three-month trial, as shown in Figure 5. Those much or very much improved typically have low pain scores (at worse mild pain), while those reporting minimal change, no change, or worsening report typically moderate or severe pain. **Figure 5: PGIC experienced by 1,858 participants with fibromyalgia completing 8-14 week trials (PGIC: Patients' Global Impression of Change; VAS PI: visual analogue scale pain intensity)**	

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				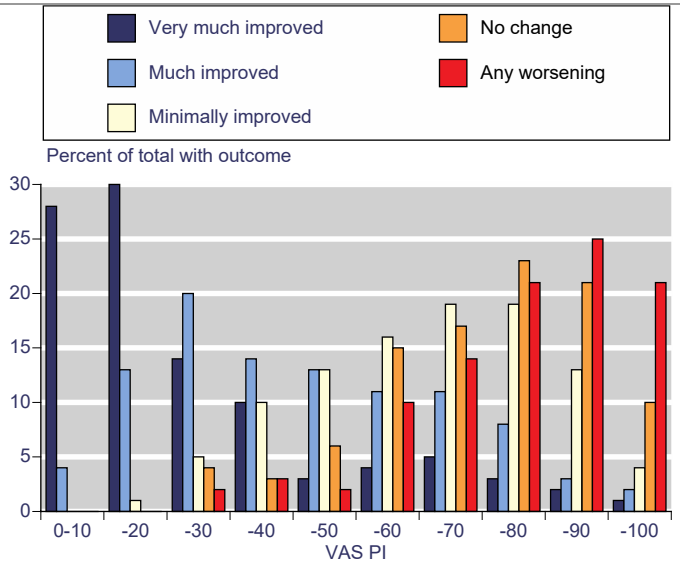 The pain experience at the end of these trials is typically determined early in the trial and then sustained. One trial used a 1-100 mm VAS scale with intermediate reporting at 5 and 9 weeks. Figures 6-8 show the pain scores in the individual participants according to their pain intensity reduction at the end of the trial. Most of those who did not respond never responded at any time, though there were some who had an early response but who withdrew from the trial principally	

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				because of intolerable adverse events. This was the largest group of participants, about 50%. Their pain scores throughout the trial were predominantly in the range of severe pain. Most of those who had an intermediate response, between 15% and 50% pain intensity reduction had a similar response throughout the period. This was the smallest group, about 20%. Their pain scores throughout the trial were predominantly in the range of moderate pain, though some were severe and some were mild at the end of the trial. Most of those who had a good response responded early, typically maintained that response throughout the trial, and had final pain scores of mild pain at the end of the trial. This was about 30% of the total. **Figure 6: People with pain intensity reduction 0-15% at end of trial, where withdrawal uses initial pain score (VASPI: visual analogue scale pain intensity; PIR: pain intensity reduction; N: number of participants)**	

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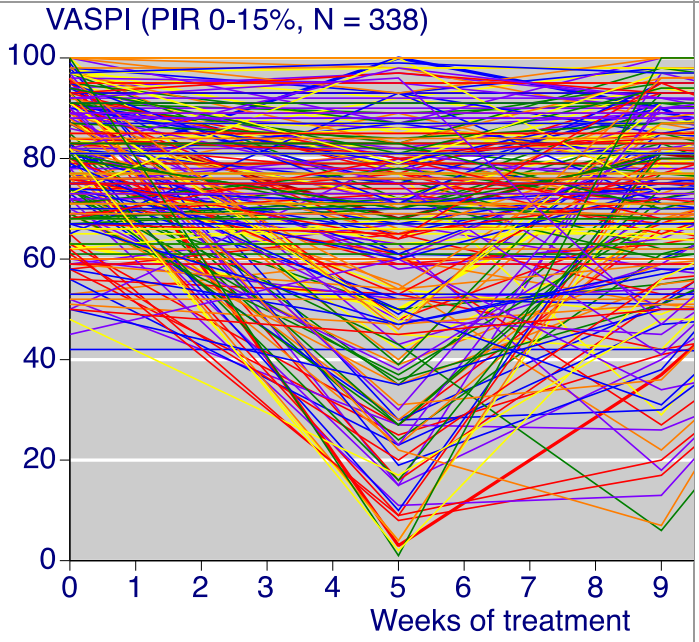
Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	**Developer's response** Please respond to each comment
				 **Figure 7: People with pain intensity reduction 15-49% at end of trial (VASPI: visual analogue scale pain intensity; PIR: pain intensity reduction; N: number of participants)**	

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				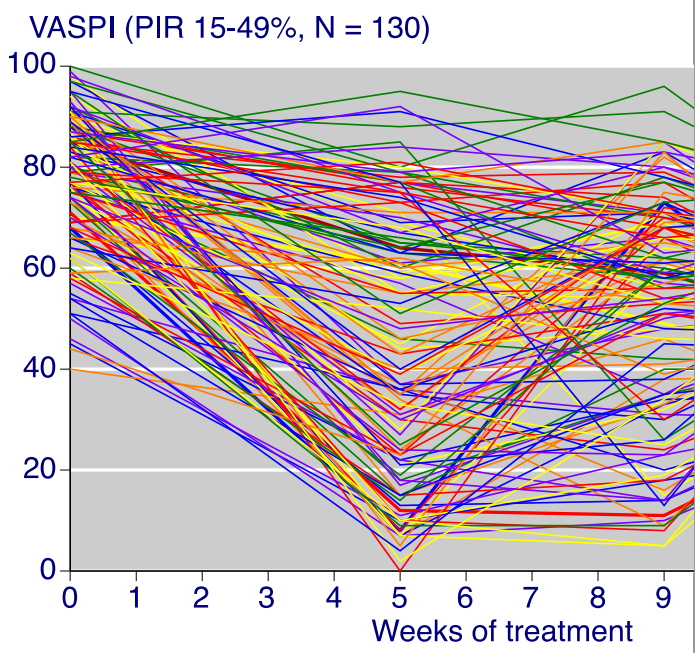	

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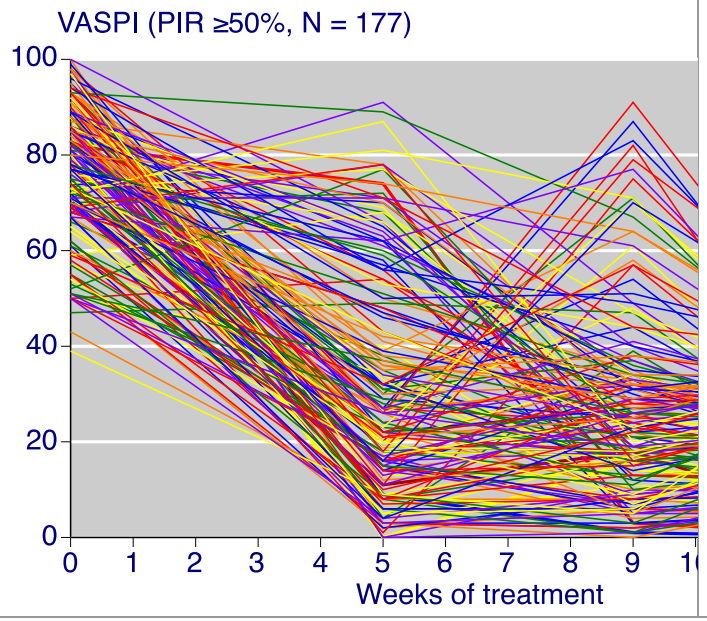
				Figure 8: People with pain intensity reduction ≥50% at end of trial (VASPI: visual analogue scale pain intensity; PIR: pain intensity reduction; N: number of participants)  	

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				Stopping rules This information can be used to test the potential for a "stopping rule" of value for clinical practice. A "stopping rule" is a point where we can be pretty sure that further treatment is futile. A stopping point is reached when: • a patient stops treatment because of adverse or another event • a patient experiences an inadequate level of pain relief to justify further treatment, *in the knowledge that further treatment will NOT bring good pain relief* Stopping treatment prevents treatment when there are risks and costs, but no benefit. Using the data from the 645 participants described above, and using a pain intensity reduction of less than 30% from that at the beginning of treatment at 5 weeks as a stopping rule, we can test how efficient it would be. Figure 9 shows that 86% would not have achieved any useful pain relief, 14% may have achieved ≥30% pain intensity reduction, and 8% ≥50% pain intensity reduction. **Figure 9: End of trial result in participants with pain intensity reduction of less than 30% after five weeks of treatment**	

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				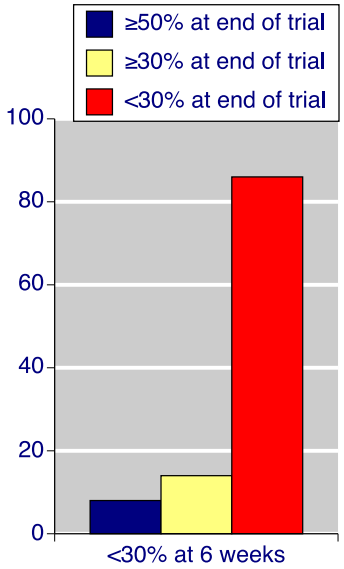 **Quality of Life** The committee rightly identified throughout the document that quality of life was of key importance. However, the presentation of evidence was such that only ***average***quality of life data were presented. It is obvious that when the magnitude of a difference in effect size in pain is small, there is unlikely to be much benefit in concomitant measures such as quality of life or sleep. For	

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				pain there is abundant evidence that large degrees of pain relief are associated with large benefits in concomitant areas, especially in terms of quality of life. For fibromyalgia there is good evidence from individual patient-level analysis that those with good pain relief have large benefits in quality of life and concomitant symptoms (sleep, depression), and their ability to work. For example, analysis by degree of pain relief demonstrates stepped benefits in terms of quality of life (Figure 10) and days missed from work (Figure 11) (Straube 2011a) using data from almost 2,000 participants enrolled in clinical trials of fibromyalgia. Even better results are obtained for those with at least 50% pain intensity reduction and pain score below 3/10 at the end of the trial, in whom almost four days per week of work are gained (Straube 2011b). **Figure 10: Quality of life and pain (QALY: quality-adjusted life year)**	

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				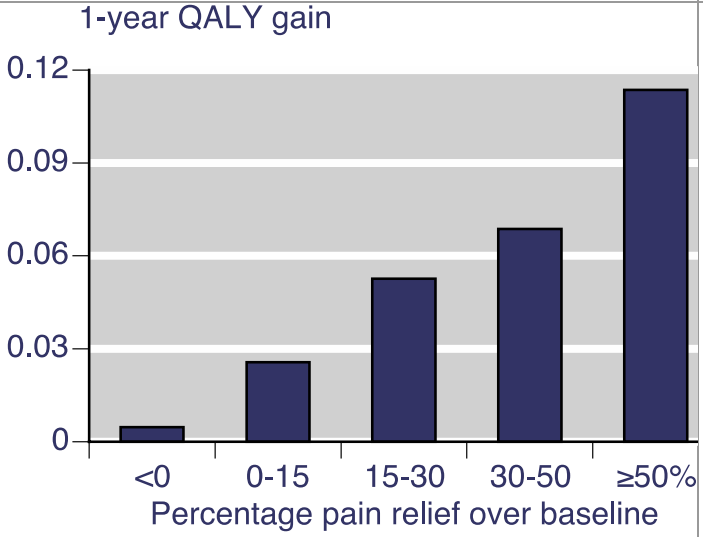 **Figure 11: Days lost from work and pain (FIQ: Fibromyalgia Impact Questionnaire)**	

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				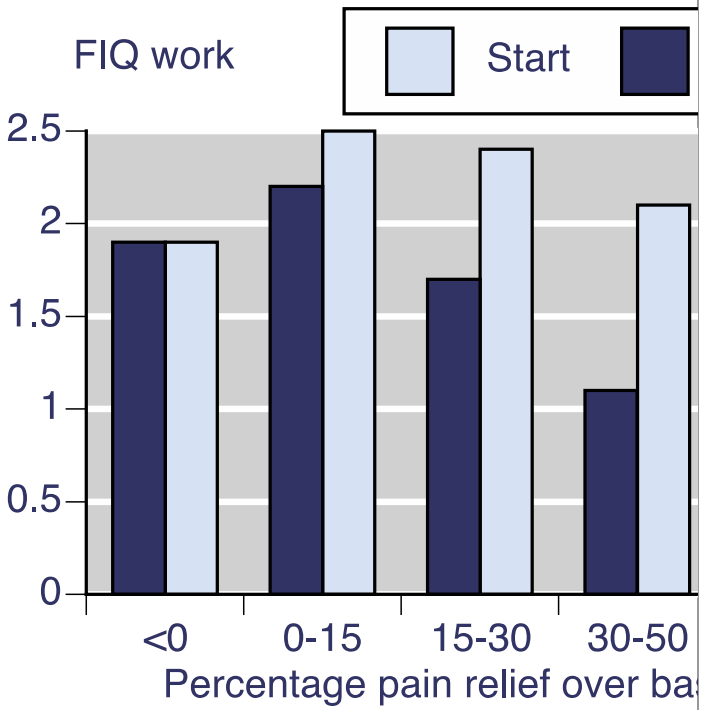 Benefits go further, and include fatigue (Figure 12), sleep disturbance (Figure 13), depression (Figure 14), disability (Figure 15), or all components of the SF-36 (Figure 16).	

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				All show large benefits in those people with the greatest degree of pain relief. **Figure 12: Fatigue measures from Global Fatigue Index (GFI) according to pain intensity reduction**	

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				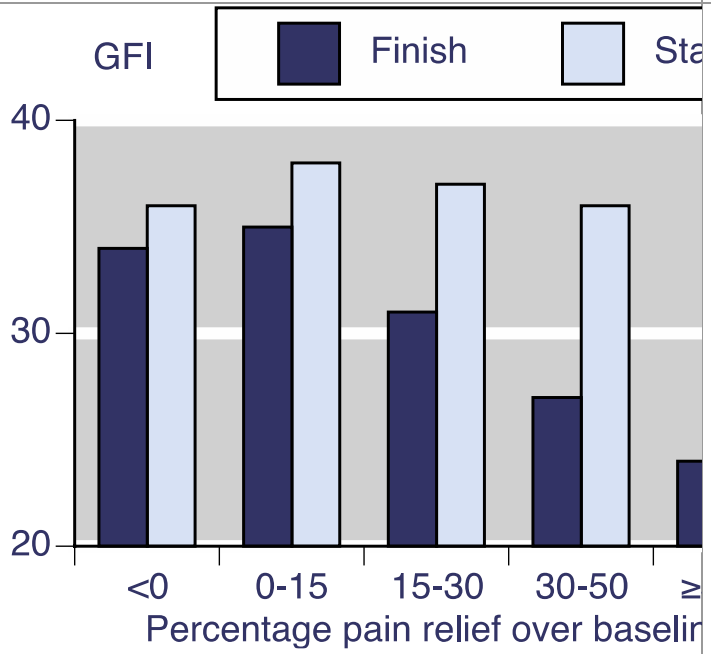	

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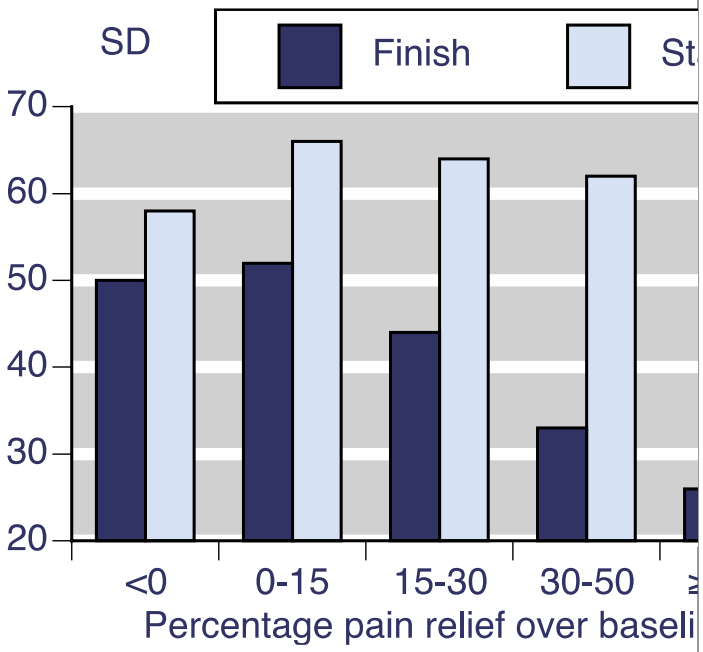
				Figure 13: Sleep disturbance (SD) according to pain intensity reduction  	

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				Figure 14: HADS score accordingto pain intensity reduction (HADS: Hospital Anxiety and Depression Scale)	

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				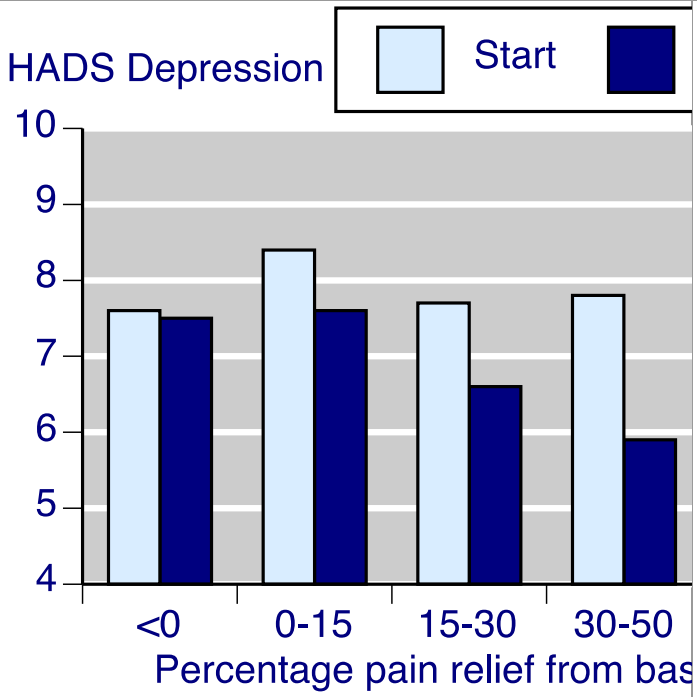	

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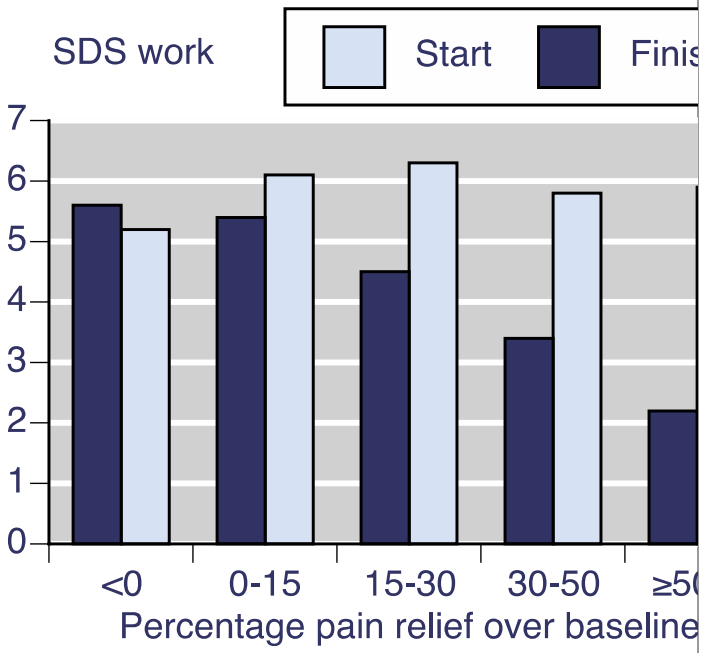
				Figure 15: Work disruption from Sheehan Disability Scale (SDS) accordingto pain intensity reduction  	

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				Figure 16: Individual components of SF-36 accordingto pain intensity reduction	

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				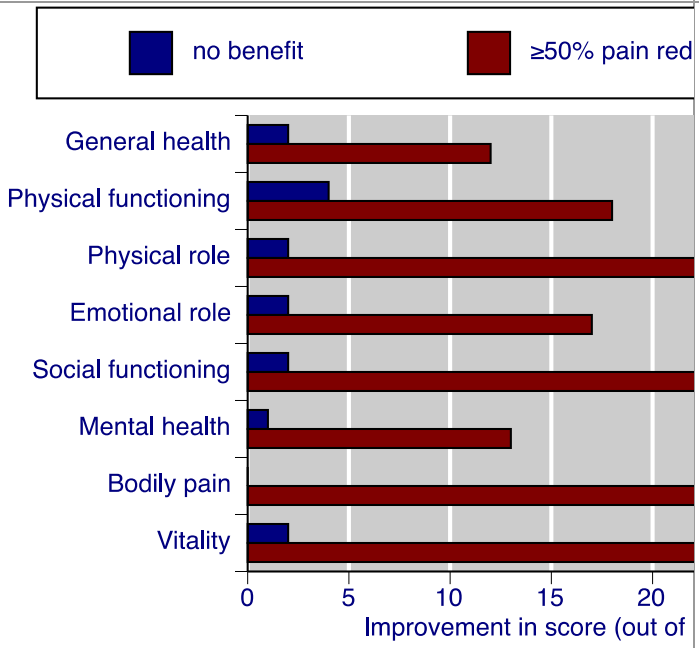 This evidence undermines the conclusions of the guideline that there is little or no quality of life benefit from the use of antiepileptics in these pain conditions. On the contrary, those few with good pain relief have values for quality of life that approach normal, including the ability to work.	

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				Conclusion These comments relate only to some aspects of pharmacological therapy for one pain condition in this guideline. The conclusion is that the methods of evidence collection, analysis, and presentation used in the guideline were flawed, consequently undermining the committee's ability to make an informed judgement. There is an established evidence base demonstrating that, for fibromyalgia at least, there is good evidence that pregabalin not only has a similar effect size for pain as duloxetine, but also that those patients with good pain relief derive large benefits across all their concomitant symptoms, their quality of life, and their ability to work.	
Cochrane Pain, Palliative and Supportive Care Review Group	General	General	General	The points made in Comments 4 and 7 of this document also apply to the pain management programme section: about synthesis (splitting to an extreme rather than combining similar trials with similar outcomes for analysis), and about the prominence given to MID, a far more arbitrary quantity than is acknowledged by NICE, in evaluating efficacy.	Thank you for your comment. Please see our response to your comments 4 and 7.
Cochrane Pain, Palliative and Supportive Care Review Group	General	General	General	Bliokas VV, Cartmill TK, Nagy BJ. Does systematic graded exposure In vivo enhance outcomes in multidisciplinary chronic pain management groups? Clin J Pain 2007;23(4), 361-74. Brinck EC, Tiippana E, Heesen M, et al. Perioperative intravenous ketamine for acute postoperative pain in adults. Cochrane Database Syst Rev.	Thank you for your comment. All of the references you provide have been double checked for their relevance to the guideline review protocols. Details are as follows:

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				2018;12(12):CD012033. Published 2018 Dec 20. doi:10.1002/14651858.CD012033.pub4 Dechartres A, Trinquart L, Boutron I, Ravaud P. Influence of trial sample size on treatment effect estimates: meta-epidemiological study. BMJ 2013;346: f2304 Fanelli D, Costas R, Ioannidis JP. Meta-assessment of bias in science. Proc Natl Acad Sci U S A. 2017 Apr 4;114(14):3714-3719. doi: 10.1073/pnas.1618569114. Flather MD, Farkouh ME, Pogue JM, Yusuf S. Strengths and limitations of meta-analysis: larger studies may be more reliable. Control Clin Trials. 1997 Dec;18(6):568-79. IntHout J, Ioannidis JP, Borm GF, Goeman JJ. Small studies are more heterogeneous than large ones: a meta-meta-analysis. J Clin Epidemiol 2015;68:860-9. DOI 10.1016/j.jclinepi.2015.03.017. Kole-Snijders AMJ, Vlaeyen JWS, Goossens MEJB, Rutten-van Mölken MPMH, Heuts PHTG, van Breukelen G, van Eek H. Chronic low-back pain: what does cognitive coping skills training add to operant behavioral treatment? Results of a randomized clinical trial. J Cons Clin Psychol 1999;67(6):931-44.	Bilokas et al. was excluded from the pain management programmes due to having an insufficient exercise component to meet the protocol definition of a pain management programme. It was excluded from psychological therapies due to not being chronic primary pain. Brinck et al. was not relevant for the pharmacological review because it was for acute postoperative pain, not chronic primary pain. Dechartres et al., Fanelli et al., Flather et al. and IntHout et al are methodological studies relating to your previous comment about sample size which we have responded to above. Kole-Snijders et al. was excluded due to having an insufficient exercise component to meet the protocol definition of a pain management

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				Moore RA, Gavaghan D, Tramèr MR, Collins SL, McQuay HJ. Size is everything – large amounts of information are needed to overcome random effects in estimating direction and magnitude of treatment effects. Pain 1998;78:209-16. Moore RA, Eccleston C, Derry S, Wiffen P, Bell RF, Straube S, et al. ACTINPAIN Writing Group of the IASP Special Interest Group on Systematic Reviews in Pain Relief, Cochrane Pain, Palliative and Supportive Care Systematic Review Group Editors. "Evidence" in chronic pain-establishing best practice in the reporting of systematic reviews. Pain 2010;1 50: 386–9. Moore RA, Straube S, Aldington D. Pain measures and cut-offs - 'no worse than mild pain' as a simple, universal outcome. Anaesthesia 2013a;68(4):400-12. Moore RA, Derry S, Aldington D, Cole P, Wiffen PJ. Amitriptyline for neuropathic pain in adults. Cochrane Database of Systematic Reviews 2015, Issue 7. CD008242. Moore 2015b, Moore RA, Derry S, Aldington D, Cole P, Wiffen PJ. Amitriptyline for fibromyalgia in adults. Cochrane Database of Systematic Reviews 2015, Issue 7.CD011824;	programme. It was excluded from psychological therapies due to not being chronic primary pain. Moore et al. 1998, Moore et al. 2010, Moore et al. 2013a are all methodological studies. Moore et al. 2015 was not relevant to the pharmacological review population as the systematic review I for neuropathic pain rather than chronic primary pain. There is existing NICE guidance for pharmacological management of neuropathic pain (CG137). References for Moore et al. 2015b were checked for any relevant studies for the pharmacological review. Nguyen et al. and Nüesch et al. are methodological studies.

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				Nguyen TL, Collins GS, Lamy A, Devereaux PJ, Daurès JP, Landais P, Le Manach Y. Simple randomization did not protect against bias in smaller trials. J Clin Epidemiol. 2017 Apr;84:105-113. Nüesch E, Trelle S, Reichenbach S, Rutjes AWS, Tschannen B, Altman DG, et al. Small study effects in meta-analyses of osteoarthritis trials: meta-epidemiological study. BMJ 2010;341(7766):241. Oberoi S, Yang J, Woodgate RL, et al. Association of Mindfulness-Based Interventions With Anxiety Severity in Adults With Cancer: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2020;3(8):e2012598. Published 2020 Aug 3. doi:10.1001/jamanetworkopen.2020.12598 Pogue J, Yusuf S. Overcoming the limitations of current meta-analysis of randomised controlled trials. Lancet. 1998 Jan 3;351(9095):47-52. Roberts I, Ker K, Edwards P, Beecher D, Manno D, Sydenham E. The knowledge system underpinning healthcare is not fit for purpose and must change. BMJ 2015;350:h2463.	Oberoi et al. is not relevant to the guideline population. Pogue et al., Roberts et al. Sawyer et al., Seers et al, Straube et al. (x3), Thorlund et al. And Turner et al. are all methodological or background relating to other comments you have submitted which we have responded to in the relevant comment row. All references in Vickers et al. had been checked for relevance to the acupuncture review and Williams et al for the pain management programmes and psychological therapies reviews. Zhang et al. is a methodological study.

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				Sawyer SM, Azzopardi PS, Wickremarathne D, Patton GC. The age of adolescence. Lancet Child Adolesc Health. 2018 Mar;2(3):223-228 Seers T, Derry S, Seers K, Moore RA. Professionals underestimate patients' pain: a comprehensive review. Pain 2018;159(5):811-818 Straube S, Derry S, McQuay HJ, Moore RA. Enriched enrollment: definition and effects of enrichment and dose in trials of pregabalin and gabapentin in neuropathic pain. A systematic review. Br J Clin Pharmacol;66(2):266-75 Straube S, Moore RA, Paine J, Derry S, Phillips CJ, Hallier E, McQuay HJ. Interference with work in fibromyalgia - effect of treatment with pregabalin and relation to pain response. BMC Musculoskeletal Disorders 2011a; 12, 125 Straube S, Moore RA, Paine J, Derry S, Phillips CJ, Hallier E, McQuay HJ. Interference with work in fibromyalgia - effect of treatment with pregabalin and relation to pain response. BMC Musculoskeletal Disorders 2011;12:125 Thorlund K, Imberger G, Walsh M, Chu R, Gluud C, Wetterslev J, Guyatt G, Devereaux PJ, Thabane L. The number of patients and events required to limit the risk of overestimation of intervention effects in meta-	

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				analysis--a simulation study. PLoS One. 2011;6(10):e25491. Turner RM, Bird SM, Higgins JP. The impact of study size on meta-analyses: examination of underpowered studies in Cochrane reviews. PLoS One. 2013;8(3):e59202. doi: 10.1371/journal.pone.0059202. Vickers AJ, Vertosick EA, Lewith G, et al. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. Journal of Pain 2018; 455-474 Williams AC de C, Fisher E, Hearn L, Eccleston C. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database of Systematic Reviews 2020, Issue 8. Art. No.: CD007407. DOI: 10.1002/14651858.CD007407.pub4. Zhang Z, Xu X, Ni H. Small studies may overestimate the effect sizes in critical care meta-analyses: a meta-epidemiological study. Crit Care. 2013 Jan 9;17(1):R2. doi: 10.1186/cc11919	
Cochrane Pain, Palliative and Supportive Care Review Group	Guideline-research recommendations	11	General	In key recommendations for research in the main guidelines document, p11, is the suggestion that optimum characteristics – by implication, the same for all chronic pain patients, an untenable assumption – of pain management programmes can be defined? There is an extensive empirical literature which has tried to do just	Thank you for your comment. On consideration of stakeholder comments the research recommendation for pain management programmes has been removed as it is considered that there

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				that, using modelling, regression, dismantling trials and other methods. There is no 'one size fits all', as has been evidence for at least a decade. Encouraging further empty attempts to identify such a 'one size' is unhelpful. Similarly, there is a body of existing literature which aims to identify risk factors that may represent barriers to successful management of chronic pain and on relaxation as a stand-alone treatment. Encouraging further simple attempts to answer these questions may lead to research waste (Glasziou & Chalmers 2018).	has already been extensive research in this area. The guideline reviewed the evidence for psychological, biological and social factors. There was a lack of good quality evidence that had undertaken multivariate analysis adjusting for confounders. This is required to demonstrate which factors are independent predictors of poor outcome rather than just showing an association between the two factors.
Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	Clinical guidelines for the management of chronic primary pain have the potential to improve the quality and consistency of care for a group who commonly feel neglected by a healthcare system that does not work for them and as such we at Cochrane Pain, Palliative, and Supportive Care Review Group (PaPaS) welcome such an initiative in principle. As a group we have extensive experience of synthesising evidence in this field and through that experience we are very aware of the many substantial difficulties that can arise when trying to draw conclusions and develop workable recommendations from what is often a rather messy evidence base. This area is affected by challenges	Thank you for your comments. We agree that saying 'specific' conditions in this context may be misleading and this has been reworded in the overview section for the guideline. The committee acknowledge the overlap with low back pain and the ICD-11 definition of chronic primary pain. Its exclusion was to avoid having overlapping recommendations for a population appearing in two NICE guidelines. This decision was made

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				of clinical heterogeneity (in populations and interventions), diagnostic ambiguity, difficulty in capturing an elusive outcome (pain), heterogeneity in treatment response, the highly variable quality of relevant clinical studies and generally small average treatment effects. These challenges result in substantial uncertainty and leave the findings of evidence reviews prone to being unhelpfully influenced by specific methodological choices and open to varied interpretations. In offering our feedback we hope to constructively raise concerns of this nature for the committee to consider. **Concerns with the scope:** The draft guideline states that it covers "….assessing and managing chronic pain in people aged 16 years and over" and should be used alongside existing NICE guidance for "specific conditions" that cause pain, including headaches, low back pain and sciatica, rheumatoid arthritis, osteoarthritis, spondylarthritis, endometriosis and irritable bowel syndrome. It includes recommendations on managing chronic primary pain (as defined in International Classification of Diseases ICD-11) for which there is no other NICE guidance. The use of the word "specific" is worthy of attention here as some of the above listed conditions will include people	during scoping which informed the population for all the reviews of interventions for management that may otherwise contradict with existing guidance. Amendments have been made to the supporting text and presentation of the guideline to improve clarity and direct people to related NICE guidelines where that population was excluded. The committee consider the quantity, quality and subsequent limitations of the evidence in their interpretation of the evidence when forming recommendations. Their considerations are detailed in the discussion of the evidence in the review chapters. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider

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				who fit the ICD-11 definition. This is particularly true of low back pain, where non-specificity and diagnostic uncertainty is the norm; many people would fit the ICD-11 definition and also where there is the largest evidence base for clinical interventions. One possible unintended consequence of pragmatically excluding studies in populations for which there is existing NICE guidance is that it may exclude highly relevant evidence that may be of better quality than what is actually included. The evidence base for many of the conditions that remain within the scope is relatively small and immature. As such the resultant evidence reviews for NICE mainly include small and relatively exploratory studies. This can have an important impact on the resulting evidence reviews and subsequent recommendations by introducing a study-level selection bias where larger more robust trials are selectively excluded. The opposing risk of the scope is that of pooling data from heterogenous clinical populations and interventions which may result in failure to identify a uniquely effective intervention in a broader class or one that is that is effective for a specific patient group. The decision to include people under 18 in the guideline raises issues. Although many children's hospitals cease intake of patients over the age of 16, many pain clinics continue to treat people as children beyond the age of 16. In fact, childhood was recently redefined as	evidence to apply for all types of chronic primary pain unless evidence suggest otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe evidence reviewed suggested that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). During scoping, stakeholder feedback suggested that the guideline should start at age 16 because some adult services start from 16. The evidence base identified was all for people aged 18 and over. The committee

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				continuing to the age of 24 in 2018 (Sawyer 2018). Certainly, children between 16-18 years are often included in paediatric studies. Chronic pain presents challenges to children who are less autonomous, continue to live at home and rely heavily on their parents. Starting the guidance at 16 years results automatically in a void of evidence as children of this age-range are included mostly in paediatric studies. Clearly decisions regarding scope were made a priori and cannot be changed at this stage but a clear recognition of how they may impact the evidence reviews is vital when drawing conclusions and forming recommendations.	considered that in many cases the recommendations could equally apply to 16-17 year olds, but they add details where this does not apply (most notably for antidepressants). The committee have also added a recommendation for considerations during the assessment of young adults with chronic pain.
Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	Pain is a field in which the choice of methods can profoundly affect the results obtained. At PaPaS we have produced a suite of high-quality systematic reviews across the full range of interventions that pertain to the population of interest and should inform clinical decision making. Due largely to the unique and restrictive scope of this guideline many of these were excluded or not considered, despite being highly relevant. Cochrane reviews, including PaPaS reviews, were excluded from consideration in the evidence reviews for pharmacological, psychological, manual therapy, exercise, acupuncture, electrophysical modalities (transcutaneous electrical nerve stimulation (TENS)) and pain management programmes. It is disappointing and inefficient that many of these were not formally considered in the process.	Thank you for your comment. We do agree that where possible high quality systematic reviews such as Cochrane reviews should be used within guidelines and can help reduce duplication by doing so. The population overlaps between chronic primary pain, other types of chronic pain, and existing NICE guidelines made it particularly challenging to do so in many cases in this guideline however.

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Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	Defining clinical importance in the field of persistent pain is a difficult question that has received a lot of attention and some, though not total, consensus. For within-person change it is encouraging to see the use of widely accepted "responder" thresholds, though disappointing to see them take a low priority, and of course disappointing to see how little of such data there was available. We recognise the need to apply thresholds to aid consistent decision making. In persistent pain it is clear that nothing works well for most people but for some interventions a small number of people may derive important benefit. As such the threshold applied of ≥10 absolute risk difference (Number-Needed-to-Treat (NNTB) 10) presents a risk of excluding an intervention that may offer important benefit to a small number of people with pain. An example of where this may have occurred is presented below in our discussion of pregabalin and duloxetine . For average between-group differences in pain the decision to base judgement thresholds of clinical benefit as a function of baseline variance is more problematic as variance in the measurement of outcomes is not a function of clinical importance.	Thank you for your comment. When setting the protocols, thresholds for clinical importance were discussed at length with the committee. The committee agree that there is not total consensus on values for chronic pain. Responder criteria for pain were discussed and included for pain, however this was agreed only to be used when continuous data were not reported by the study for that outcome. This has been clarified in the methods chapter. Number of responders was very rarely reported in studies, with the exception of the pharmacological studies where it was more commonly reported. It would therefore not have been possible to apply consistent thresholds for different interventions had this been used as a basis of determining clinical importance.

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					We agree that different approaches to determining thresholds each have their own pros and cons. All decisions about clinical importance in the guideline were made in discussion with the committee, including consideration of the absolute effect. Clinical importance was only one of the factors taken into account when making recommendations. The quality of evidence, imprecision and balance of benefit and harms are all considered before recommendations are made. No intervention was excluded purely on an assessment of the absolute effect of a single study. The committee note that there are suggestions that small subgroups of people with chronic primary pain may benefit from some treatment. These guidelines provide recommendations for the population with chronic pain. Unfortunately research to date does not enable this group of responders

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					for different interventions to be identified and therefore recommendations for more targeted prescribing are not possible. The committee agreed it was inappropriate to recommend trying medicines for which there is no good evidence that most people will benefit from or to risk exposing all of the chronic primary pain population to medicines with a potential for harm, without evidence on how to determine the small subgroup that may benefit.
Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	Synthesis: The separation of analyses of pain by different measurement tools, and health related quality of life (HRQoL) into the multiple subdomains/ scales of the included measures, creates a significant issue of multiple comparisons. The predominance of single or 2 trial analyses throughout is not the best use of the data and sacrifices the potential precision that can be afforded by pooling. There is nothing in the Appendix: Methods 2.3.2 on Methods of combining clinical studies that explains why there is so little combination of similar studies with similar or the same outcomes, generating instead tens of single trial meta-analyses that jettison the power of meta-analysis.	Thank you for your comment. We follow the guidance from the SF36 manual (regarding subdomains of health related quality of life scales). Ideally where available we report the physical and mental component summary scores, but if not, the individual subscales are reported as they are validated if all reported individually. Where studies have reported these in the same way, they

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				Beyond the issue of precision, the size of studies may have a profound impact on their results that this might lead to an overly positive picture for some interventions (Dechartres 2013; Nüesch 2010). Dechartres (2013) demonstrated that trials with fewer than 50 participants, which reflects the majority of studies included in this review, returned effect estimates that were on average 48% larger than the largest trials and 23% larger than estimates from studies with sample sizes of more than 50. Similarly, in Cochrane Reviews of amitriptyline for neuropathic pain and fibromyalgia (Moore 2015a; Moore 2015b), smaller studies were associated with substantially lower numbers needed to treat for an additional beneficial outcome (NNTBs) for treatment response than larger studies. In their recommendations for establishing best practice in chronic pain systematic reviews, Moore (2010) suggest that study size should be considered an important source of bias, as have others (Fanelli 2017; Flather 1997; IntHout 2015; Ioannidis 2005; Moore 1998; Nguyen 2017; Pogue 1998; Roberts 2015; Thorlund 2011; Turner 2015; Zhang 2013).Recent examples of how small study size can influence results include a commentary to a recent JAMA paper (Oberoi 2020), and in postoperative pain (Brink 2018). The bottom line is that conclusions based only on small studies are often or usually incorrect, especially where methodological considerations indicate significant risk of	are pooled, but if the summary scores are reported in some studies, and individual subscales in others, they cannot be pooled. Whenever possible outcomes have been pooled in meta-analysis. This can be done where similar continuous outcomes are reported on the same scale (reporting either final values or change scores) but if different scales are reported, these can only be poled if all data are either final values or change scores. This level of methodological detail is not usually provided in the methods chapter for the guideline reviews, but is detailed in the Cochrane handbook and is best practice systematic review methodology. Where outcome measures are assessing different aspects of an outcome, they are not pooled. We agree that sample size is an important factor to consider when

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				bias. That situation applies to several parts of the evidence presented to the committee. These dual issues of multiple comparisons and study size raise the risk of multiple false positives but more broadly a serious problem of imprecision. In this instance small differences in methodological approach and interpretation are prone to producing quite different conclusions which may influence the recommendations of the committee and, in turn, patient care.	interpreting the results. We do not exclude studies of smaller sample size as it may be possible to pool these with other studies in the meta-analysis increasing the body of evidence for that outcome. The sample size will be taken into account by the study's weight in the meta-analysis. Where studies of small sample size cannot be pooled, this is one of the factors the committee takes into account in their decision making to inform recommendations.
Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	The approach taken to the application of GRADE (Grading of Recommendations Assessment, Development, and Evaluations) may result in overestimating the certainty of the evidence for some comparisons with potential impacts on the decisions of the guideline development group (GDG). Imprecision judgements were based on whether the effect sizes and 95% confidence intervals overlapped the minimally important difference (MID) threshold. This approach arguably undervalues the importance of study size in determining the certainty of evidence and a more cautious approach would be to consider any analysis based on a small number of participants to be downgraded on the basis of imprecision. As an example,	Thank you for your comment. The confidence interval is widely agreed to account for sample size to a large extent. For example, the Cochrane handbook states 'The width of the confidence interval for an individual study depends to a large extent on the sample size. Larger studies tend to give more precise estimates of effects (and hence have narrower confidence intervals) than smaller studies.' In the example you give, it is likely that the

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				the approach taken by NICE would allow a single small study with poor randomisation and at subsequent risk of serious bias to be rated as offering moderate-quality evidence, which would be inappropriate.	single small study would have had wide confidence intervals around the effect, leading it to be rated as low or very low quality evidence, depending how wide. To reassure you, GRADE is only one part of the complex decision making process. The committee take a number of factors into account when making recommendations, including the net clinical benefit over harm (clinical effectiveness) alongside the magnitude of the effect (or clinical importance), quality of evidence (including the uncertainty) and amount of evidence available.
Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	In both the evidence review on psychological treatment and on pain management programmes (1.7.12) is a statement about downgrading all trials for lack of blinding. While blinding is important in randomised trials (but rarely checked, only assumed by the nature of design even for drugs with well-known side effects that unblind participants), where it is clearly not possible, as in psychological treatment trials, methodological features that partly mitigate it have been investigated and used:	Thank you for your comment. We do note that blinding is not possible in all circumstances, and some trials attempt to mitigate this where possible. However, it can still lead to a risk of bias with subjective outcome measures. Studies with an attention control were also included and should

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				assessment by staff blind to treatment allocation; expectations of improvement taken from all participants at baseline; an attempt at equipoise in those who deliver control and comparison conditions, rather than clear therapist allegiance expressed in some publications. These design features were discussed in committee, but appear to have been ignored. Simply marking down all trials for lack of blinding, and therefore lowering the overall quality, is not a helpful approach to the problem. Nor was there recognition that some trials used some outcomes that were not self-report: a feature that could have been identified better as positive and recommended to future trials.	be accounted for differently in risk of bias to unblinded studies. We disagree that the committee have ignored this factor. This was discussed and considered when determining recommendations, as was the subjectivity of the outcome measure.
Cochrane Pain, Palliative and Supportive Care Review Group	Methods	General	General	In the light of the low confidence expressed about self-report, not without reason, it is surprising to see the weight put on exact calculation of change in scales for minimally important difference. None of this took account of unreliability of scales, often around the same size as the MID identified. Additionally, a quantum improvement in outcome scale has different meaning according to the baseline, which is why pain reduction is usually expressed in percentages rather than absolute values. For those with high baseline levels of pain, small reductions can be trivial; for those with low scores at baseline, they may represent substantial change. None of this appears to be recognised.	Thank you for your comment. Baseline values are taken into account for all continuous outcomes where they are available. The baseline values for the outcomes are reported in the evidence tables with the results and were used to inform committee discussion.
Crohn's & Colitis UK	General	General	General	In summary, we would recommend that:	Thank you for your comment. The guideline covers the assessment of all

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				• IBD is specifically listed as being covered by the guideline given the significant impact of pain on people with Crohn's and Colitis • Pain is included in NICE guidelines on Crohn's Disease and Ulcerative Colitis and the quality standard on Inflammatory Bowel Disease • The section on medications is framed more clearly to avoid potential confusion and recognises the role that medication can play in treatment for pain • Research recommendations for chronic primary pain are extended to include chronic pain to address the pressing unmet need in this area • More training and sharing of good practice in the multidimensional aspects of pain management and greater understanding of the likely causes of ongoing pain are supported.	types of chronic pain, but the specific management recommendations are for chronic primary pain only. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines (including Irritable bowel syndrome) to enable more easy navigation between the recommendations for different topics. We will pass your comments re. adding pain to topics considered in the Crohn's disease and Ulcerative Colitis

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					guidelines to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Crohn's & Colitis UK	Guideline	1	8	Pain is experienced by up to 70% of patients with Crohn's or Colitis in active disease and 20-50% of patients in remission (Ng SC et al, 2017) and has a significant and highly debilitating impact on people's quality of life, ability to work and psychological wellbeing. For example, Lucy, who has Crohn's Disease, said: "*My pain is exhausting, and it's rarely just pain. If not accompanied by diarrhoea, fatigue, or other debilitating symptoms, it's accompanied by a spiral of anxious, ruminative thoughts about what the pain means…I was constantly at doctors and hospital appointments, but I was rarely asked about my pain."* The complex interrelationship between pain and other symptoms and associated complications and conditions and their combined impact for individuals with Crohn's or Colitis is further illustrated by this quote from James, who also lives with Crohn's Disease: *"Over the years my Crohn's symptoms have often shown up as pain- related with fatigue following, not always diarrhoea present. I have often wondered why a short bout of pain can leave me so fatigued. Furthermore, Crohn's and the later*	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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				diagnosis of Primary Sclerosing Cholangitis (PSC) have had a major impact on my working life." Despite this impact, pain is not currently covered within the current NICE guidelines on Crohn's Disease or Ulcerative Colitis or quality standard 81 on Inflammatory Bowel Disease (IBD). In IBD, there are two linked types of pain: inflammatory and post-inflammatory. Management of the inflammatory component with for instance biologics may have a bearing on the development of post-inflammatory pain although this influence also needs further study. Additionally, complications and extra-intestinal manifestations of IBD such as strictures, fistulas and joint pain can change the quality of pain making it more widespread and life limiting. Abdominal pain in IBD can also have a severe direct impact on nutrition which can then have a confounding effect on physical and mental health. Existing data (e.g. Sweeney el al, 2018) suggest that a range of clinical and psychosocial factors are associated with pain in IBD, with active coping and perceived social support associated with less pain. In addition to psychosocial factors, causes of pain may include co-existing irritable bowel syndrome, visceral hypersensitivity, fibromyalgia and bacterial overgrowth.	We will pass your comment regarding the inclusion of pain in the Crohn's Disease and Ulcerative Colitis guidelines to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

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				It is therefore important that a detailed assessment of the causes of pain is undertaken in IBD patients before treatment is initiated and that a holistic approach is taken to explore potential interventions. Discussing options should be part of shared decision-making with the patient. Also, that pain is considered in those who are not experiencing active disease, as part of care planning and ongoing review/monitoring as these patients are more likely to be suffering in silence. Currently, pain is often not addressed as part of consultations and reviews, with clinicians caring for patients with IBD focusing predominantly on the control of active disease in the bowel. This is likely to be because of i) lack of true understanding of the likely causes of ongoing pain despite healing of inflammation and ii) inadequate training for clinicians in the multidimensional aspects of chronic pain management. In a UK-wide IBD Patient Survey carried out by the IBD UKalliance, just over half (53%, 5,405/10,224) agreed or strongly agreed with the statement "During appointments, I am asked about pain and treatment options are discussed to manage this", while 27% (2,778/10,224) disagreed or strongly disagreed. The 2019 IBD Standardsdeveloped by the 17 professional and patient organisations, including the	

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				British Society of Gastroenterology, Royal College of Nursing and Royal College of Physicians, state that: "Pain and fatigue are common symptoms for IBD patients and should be investigated and managed using a multidisciplinary approach including pharmacological, non-pharmacological and psychological interventions where appropriate." (Statement 7.4) Pain is included in Patient Reported Outcome Measures, such as the IBD Control Questionnaire. The British Society of Gastroenterology consensus guidelines on the management of Inflammatory Bowel Disease in adultsrecommend that: "Patients with IBD and pain should be investigated for stricturing disease, abscesses or uncontrolled inflammation. In the absence of an obvious cause of pain, other factors should be considered including adhesions, visceral hypersensitivity, functional bowel disorder or dysmotility, depression and/or anxiety, sleep disturbance, stress and psychosocial factors (Recommendation 22). **We would therefore strongly urge the Committee to include IBD within the list of conditions specifically mentioned as being covered by the guideline and to include pain when reviewing and updating existing guidance for IBD.**	

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Crohn's & Colitis UK	Guideline	11	4	We welcome the Committee's focus on the need for further research in this area but are concerned that this is mostly framed around research recommendations for chronic primary pain, for example, regarding psychological interventions. Participants in a qualitative study exploring the experience of pain in Inflammatory Bowel Disease expressed the need for better psychological support and assessment of pain in clinical practice (Sweeney et al, 2019). Cognitive Behavioural Therapy may help alleviate stress and anxiety caused by and contributing to pain. Acceptance has been widely recognised in the chronic pain literature (e.g. MCracken and Morley, 2014). Further research in the role of psychological techniques in pain management interventions would be valuable for patients with Crohn's or Colitis. There is a significant unmet research need to understand risk factors for the development of chronic pain in IBD so that chronic pain can be prevented. Developing a thorough understanding and optimising management of IBD symptoms, predominantly pain and fatigue, were among the top 10 questions raised in a James Lind Alliance research priority setting by patients and clinicians (Hart et al, 2017).	Thank you for your comment. The reviews for specific interventions included in this guideline, recommendations and research recommendations arising from them, are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. The title has been amended to reflect that chronic primary pain is also a focus of this guideline as well as adding clarity in other areas of the guideline.

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				For this reason, Crohn's & Colitis UK has established a global IBD pain networkto further our understanding of pain in IBD through stimulating research and opportunities for collaboration. We are currently funding four research projects in this area focusing on: - Mediators that activate pain nerves (specifically MMP12) - Visceral hypersensitivity of pain nerves in chronic inflammation - Risk factors linked to the development of pain in IBD - Acceptance Commitment Therapy (ACT) to determine effectiveness in treating chronic pain in IBD **We support the Committee's recommendation for further research in pain management programmes, psychological and relaxation therapy and social interventions, but would strongly urge the Committee to extend these recommendations to apply to chronic pain as well as chronic primary pain given the significant unmet need and highly debilitating impact of pain for people with IBD as outlined above.**	
Crohn's & Colitis UK	Guideline	9	10	We are concerned that there could be confusion in relation to this section which refers specifically to chronic primary pain but could be understood to relate to chronic pain as well. We think this needs to be made much	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are

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				clearer – and there may also be cases where there could be some overlap. For example, for patients with IBD, this could be when the original cause of pain can no longer be considered the cause of ongoing pain. It is important to treat every patient as an individual and to recognise that trials of medication have a role. In chronic secondary pain such as IBD-related pain, there is a role for opioids in the treatment of acute, severe pain associated with exacerbation of chronic disease, although long-term use should be avoided (BSG consensus guidelines on the management of Inflammatory Bowel Disease in adults, 2019). **We would urge the Committee to consider how this section can be made much clearer to avoid any potential confusion and to acknowledge that trials of medication have a role in treatment for pain and the importance of treating every patient as an individual.**	relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Crohn's & Colitis UK	Guideline	General	General	Crohn's & Colitis UKwelcomes the opportunity to comment on this draft guideline. The two main forms of Inflammatory Bowel Disease (IBD), Crohn's Disease and Ulcerative Colitis are lifelong conditions affecting at least 300,000 people in UK, with recent research suggesting the numbers affected could be double this. While those	Thank you for your comments. We have responded to your individual comments below.

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				of all ages are affected, diagnosis is most often when people are in their teens or twenties. In Crohn's and Colitis, the gut periodically becomes swollen, ulcerated and inflamed in an unpredictable relapsing-remitting pattern, causing debilitating symptoms including acute abdominal pain, weight loss, diarrhoea (sometimes with blood and mucus) and severe fatigue. In many people pain becomes chronic, persisting despite apparent remission of inflammation. There are also a wide range of extraintestinal manifestations, which can affect the joints, skin, bones, eyes, kidneys and liver, and a significant psychological impact as well as chronic pain. People living with the conditions often face a lifetime of medication and, in many cases, major surgery. If poorly controlled, complications from Crohn's and Colitis can be fatal. The pattern, severity, impact and prognosis of symptoms among patients with Crohn's or Colitis vary substantially but frequently lead to deterioration in quality of life.	
Crohn's & Colitis UK	Questions	General	General	**What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** More training and sharing of good practice in the multidimensional aspects of pain management and	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment,

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				greater understanding of the likely causes of ongoing pain would make a significant difference to the 70% of people with Crohn's or Colitis experiencing chronic and debilitating pain. Pain services also need to be resourced and supported appropriately to meet the need. **The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.** Covid-19 has impacted face-to-face appointments and monitoring, reducing access to the IBD team and resulting in delays and cancellations of tests, procedures and surgery, as shown by the results of Crohn's & Colitis UK's recent Life in Lockdown survey. For example, 26% of respondents either had to wait longer than usual or were unable to speak to an IBD specialist and 43% of respondents were unable to access tests and procedures as usual. It is therefore highly likely that people with Crohn's or Colitis have been experiencing increased inflammatory and post-inflammatory pain over this period, with less opportunity for support with management and treatment than pre-Covid.	such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. Thank you for your information regarding the effect COVID-19 has had on patient care.

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Derby and Derbyshire CCG	General	General	General	Local specialist opinion: It should be clarified that proposed NICE guidelines do not necessarily apply to existing patients suffering from various types of "chronic pain" (as we understand it).	Thank you for your comment. That is correct, the reviews for specific interventions included in this guideline and related recommendations are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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03/08/2020 – 14/08/2020

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Derby and Derbyshire CCG	General	General	General	Miscellaneous queries • What to do in chronic pain management when all options have been explored – do prescribers then revert to management with drugs???? Or best supportive care? • Resources for de-prescribing- regional hub support?	Thank you for your comment. The committee agree that a care and support plan should be developed with the person and regularly reviewed. This should include providing advice about and supporting self-management. Recommendations have been added to highlight this. The evidence for helping people stop medicines has not been reviewed within this guideline. The committee agree that additional support may be required and highlight the recommendations on stopping or reducing antidepressants in the NICE guideline on depression in adults as well as the upcoming guideline on medicines associated with dependence or withdrawal symptoms.
Derby and Derbyshire CCG	Guideline	004	002	Assessing all types of chronic pain Local specialist opinion: Agree with much that is in the assessment aspect of the manuscript, but it does not seem to be evidenced based.	Thank you for your comment. These recommendations were informed by evidence from a qualitative review on effective communication between people with chronic pain and

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				Also it is presumably for the assessment of Chronic Primary Pain?	healthcare professionals. The rationale section linked to at the end of this section explains how the committee used this evidence to inform the recommendations. This section is for all types of chronic pain (both chronic primary pain and chronic secondary pain). Headings in the guideline have been amended to clarify that, and a visual summary of what is covered in the guideline has been included.
Derby and Derbyshire CCG	Guideline	004	015-017	Local specialist opinion: Psychological and social factors do play a role in chronic pain/CPP but there are underlying biological mechanisms in almost every case, regardless of whether or not it is understood. One should not attribute all chronic pain/CPP to psychological and social factors only	Thank you for your comment. This recommendation is intended to highlight factors that may impact on the pain, or vice versa, rather than attributing the pain to these factors. The recommendation has been revised to include some additional factors to consider.
Derby and Derbyshire CCG	Guideline	005	009-011	Local specialist opinion: It is possible that patients with CPP (who don't have any identifiable cause) may have co-existing condition where interventions/analgesics are likely benefit and improve quality of life e.g. focal lower back pain may benefit from radiofrequency.	Thank you for your comment. We agree that chronic primary pain can coexist with other conditions. A recommendation has been added to highlight this and it is also included in

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					the definitions at the beginning of each section. Where recommendations in other guidelines apply for these conditions, they should be followed.
Derby and Derbyshire CCG	Guideline	006	001-004	Non-pharmacological management Pain management programmes Local specialist opinion: • Social interventions and pain management programmes should not be treated in isolation. • NICE review looked at chronic pain in this area and not chronic primary pain. • The evidence presented by NICE shows improved quality of life with professional PMP compared to usual care, however, NICE seems to discount PMPs with a psychological component in it.	Thank you for your comment. No evidence was identified for social interventions for people with chronic pain. The committee have recommended further research on this topic. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the

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					guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.
Derby and Derbyshire CCG	Guideline	006	010-017	EXERCISE Local specialistopinion: • There is no strong evidence for NICE recommended supervised exercise program and Acupuncture/dry needling for CPP. • However there is evidence that exercise in itself can reduce pain states particularly in fibromyalgia	Thank you for your comment. The committee agreed that there was a large body of evidence in favour of both supervised group exercise and acupuncture for chronic primary pain. For exercise, consistent benefits were observed for pain and quality of life from a large number of studies. This

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					was consistent across different types of exercise and benefit was seen for both short- and long-term follow up. For acupuncture overall the evidence demonstrated a benefit of acupuncture, for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendations for both acupuncture and exercise demonstrating them both to be cost effective.
Derby and Derbyshire CCG	Guideline	007	002-006	Psychological therapy for CPP Local specialistopinion: • The evidence looked at chronic primary pain in this domain. • Evidence showed that ACT was of benefit for quality of life and psychological distress and there is benefit for ACT for pain reduction and sleep *JAPC opinion – ACT and CBT are good non-pharmacological recommendations. As a commissioner we would need investment for these alternative therapies, to ensure*	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				equitable availability for the whole of the Derbyshire population. Currently we do not have complete coverage across Derbyshire. Further any structural changes to commissioned services will require a period of transition	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Derby and Derbyshire CCG	Guideline	007	007-015	ACUPUNCTURE Local specialist opinion: • The guidelines looked at the benefit of acupuncture in chronic primary pain- the evidence base for this is of very low quality. There is good balance of effect for chronic neck pain but should be done in the community (Band 7 or below delivering 5 hours or less of acupuncture). • A major flaw of the review is the lack of differentiation to individual states. e.g. vulvodynia and neck pain are not comparable. • Acupuncture is controversial. There may be small populations for whom use can be justifiable but it is widely inappropriately used. There should be a requirement to keep any provision to a small well	Thank you for your comment. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic

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				defined group with good outcome measures before repeat. *Overall JAPC opinion acupuncture – JAPC feels this recommendation is based on weak evidence, but similar to ACT/CBT, we would need investment for this alternate therapy. More specific guidance for initiation for eligible patients, continuation and how many treatment cycles and when to discontinue, i.e. service specification.*	primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost effectiveness evidence supporting the recommendation. The committee noted that the majority of evidence was based on women with chronic neck pain or fibromyalgia. However, the committee agreed that for interventions such as acupuncture, response to treatment

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					would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions. The committee noted that the type of acupuncture may vary according to type of pain, but that this would be determined by clinical judgement. The recommendation details specific guidance for delivering acupuncture, including the length of the course of treatment. Due to the uncertainty in the effectiveness of repeat courses of acupuncture, a research recommendation was also included.
Derby and Derbyshire CCG	Guideline	008	001-006	ELECTRICAL THERAPIES Local specialistopinion: • Evidence base is for chronic primary pain, and the Majority of TENS evidence comes from one study only.	Thank you for your comment. The committee agree the evidence for TENS was very limited. Two studies were included, one of which had a very small sample size.
Derby and Derbyshire CCG	Guideline	008	013	Consider an antidepressant Local specialist opinion: • Medications like sertraline, fluoxetine, paroxetine and citalopram- although do help with depression, do not	Thank you for your comment. The recommendation for antidepressants was based on a systematic review of the evidence for people with chronic

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				have evidence of any beneficial action on pain pathways. Thus NICE is assuming that depression is the main causative factor for CPP and there are no underlying biological pain mechanisms. Depression in chronic pain patients often presents as a consequence of chronic pain or a co-existing condition rather than sole cause of chronic pain itself. For SSRIs, SNRIs and tricyclics the quality of evidence is low.	primary pain. Benefit was demonstrated in outcomes for health related quality of life, pain, function as well as psychological distress. This evidence is therefore supportive of these drugs having a beneficial effect on patient reported outcomes for people with chronic primary pain and is not based on any assumption on the causative factor for chronic primary pain. The committee's views are that the mechanisms are not fully understood. A recommendation has been added to highlight that these are recommended for their effects on the symptoms of chronic primary pain.
Derby and Derbyshire CCG	Guideline	009	010	Pharmacological management - do not offer any of the following .....Opioids, NSAIDs, anti-epileptic, local anaesthetics, by any route, unless as part of a clinical trial for complex regional pain syndrome, local anaesthetic/corticosteroid combinations, paracetamol, ketamine, corticosteroids and antipsychotics. Local specialist opinion: • In patients with true primary pain it is acceptable to not offering the above treatments option, however,	Thank you for your comment. The committee agree that the evidence does not support the effectiveness of these medicines for chronic primary pain. The committee acknowledge that there can be overlap with other conditions. Clinical judgement should be used to determine the appropriate treatment option relevant to the type

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				in reality patients come in complex mixes and clinicians would have to be careful about classification. e.g. people with very severe fibromyalgia would benefit from local anaesthetics (lignocaine) and ketamine infusions. Under the draft proposals, these treatments options would not be a viable choice. • Aim of pharmacological therapy in chronic pain is not to cure the condition but to make it more manageable so that patients can engage with rehabilitation. Pharmacological agents used in pain clinic are almost always started on trial basis to check their effectiveness in specific patients, side effects and reviewed regularly. Most of pharmacological agents are used as a course for a period of time and then weaned down once patients start adopting rehabilitation and self-management strategies. • The evidence if for chronic primary painand only 33 studies were included in this review where 19 studies are from fibromyalgia. There are more evidence/ studies available which have not been included in the review. • There is no attempt to differentiate between pain states in the assessment of therapies for chronic primary pain; this means that pain states as different as fibromyalgia, headache CRPS and facial pain research are treated together from a research and evidence point of view. This is bad practice and	of pain being treated according to the relevant NICE guideline. The committee agree that the primary aim of management chronic primary pain is relief of symptoms. The systematic review looked for evidence of effect on a range of patient reported outcomes. Where evidence was available the committee agreed this was not demonstrating effectiveness of these medicines. The committee therefore do not agree they should be trialled in this population. Their experience is that it is often the case people are started on these medicines, perhaps with the intention of this being a trial, but they are then continued long term despite lack or efficacy and often with harms. As there is no evidence these benefit the majority of people with chronic primary pain the committee agree they should not be recommended, even for short term use.

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				assumes that these pains states are the same, when clearly they are not. • Some opioids like tramadol and tapentadol have evidence of anti-neuropathic action and help some patients with neuropathic pain. Criticism for NICE - several excellent Cochrane reviews available which address the issue of chronic primary pain in the chronic pain states included in this review (most notably fibromyalgia and analgesic adjuncts). The conclusions of these Cochrane reviews are far more tailored, thorough and robust for these states. The NICE review ignores the value of these Cochrane reviews and discounts the studies within them, often for spurious methodological reasons; i.e. run in period for placebo. The NICE guidance will therefore leave a large group of patients with second tier, or no treatment, compared to previously and also compared to individuals with Chronic Secondary Pain.	The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider this evidence for all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. Where there was reason to suggest that different considerations applied, this was acknowledged in the recommendations, for example the research recommendations for gabapentinoids and local anaesthetics for CRPS.

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					Neuropathic pain is included in the NICE guideline for neuropathic pain in adults. A visual summary has been added to the guideline to highlight which recommendations apply to which population. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The Cochrane reviews were fully considered when undertaking this review and all of their included studies were checked for relevance for inclusion in this guideline review. There are some differences between the methods followed by the Cochrane reviews and the NICE guideline. The NICE methods are as per the methods chapter in this guideline and Developing NICE guidelines: The manual. These are robust methods for developing

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					evidence based guidelines. The two primary reasons for the difference in included studies and consequently the conclusions in the review are; the inclusion of enriched enrolment studies in the Cochrane reviews, which are excluded from the guideline review protocol, and the populations of the reviews. When setting the protocol, the committee agreed that studies with an enriched enrolment design would be excluded, due to their potential to over-estimate of an intervention effect and lack of generalisability of results to a wider population. We believe this is appropriate and a robust methodological decision for a guideline evidence review that is intended to inform population based recommendations for the NHS. The guideline outcome on the effectiveness of pregabalin therefore differs from the Cochrane review where enriched enrolment studies

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					were included. Another reason that led to differences with the Cochrane reviews is the population as this guideline review of pharmacological treatment is for chronic primary pain only. A number of the Cochrane reviews were for chronic pain more generally, or for specific types of chronic secondary pain, which were excluded from the scope of this guideline for the management reviews.
Derby and Derbyshire CCG	Guideline	009	013 & 021	NSAIDS/paracetamol Local specialist opinion: • Only few studies included in the review No evidence was identified for paracetamol	Thank you for your comment. There was a very limited amount of evidence available relevant to the review protocol for NSAIDs specific to people with chronic primary pain, and none for paracetamol, as you highlight.
Derby and Derbyshire CCG	Guideline	009	015	Gabapentinoid Local specialist opinion: • Very small number of studies included in the review and benefit showed in subgroup analysis. The two Cochrane reviews looking at pregabalin and gabapentin/duloxetine were not included (the pregabalin studies from Cochrane discounted due to	Thank you for your comment. The committee were aware of the relevant Cochrane reviews and their conclusions. They were fully considered when undertaking this review and all of their included studies were checked for relevance for

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				run in time of placebo, which lead to discounting all of the studies in this Cochrane review)	inclusion in this guideline review. A key difference was the inclusion of studies with an enriched enrolment design / placebo run in phase. When setting the review protocol for the pharmacological review included in this NICE guideline the committee agreed these should be excluded, the reasons are set out below. Placebo run in studies: While this can be a useful methodology employed in a proof of concept study, it does not provide a generalizable estimate of the efficacy of the medicine in the general population. There are two main concerns: 1, such trial designs will likely increase the observed magnitude of effect of the medicine compared to the placebo group as placebo responders are removed. Whilst the placebo response in pain is known to be high, this is reflective of how the general

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					population are likely to respond, and so excluding these gives a biased estimate of effectiveness gained from these trails compared to those without a placebo run in phase. 2 – the side effect profile of many of these medicines (including pregabalin) are notable. Having a placebo run in phase can effectively unblind study participants as they are able to notice the difference between tablets received. This again biases the results of the study, generally in favour of the active intervention when in a clinical trial setting. Enriched enrolment design: The committee considered that including enriched enrolment design studies would not provide the committee with an overview of the effect of pharmacological interventions for people with chronic primary pain and would not support their decision making for this population as a whole. By including studies that only recruit known

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					responders there are difficulties with interpreting the data for a patient population, particularly for people that have not been prescribed the drug of interest previously. By the nature of these studies people that don't respond (but are diagnosed with chronic primary pain) are not included. The effect of this is to likely increase the observed magnitude of effect of the medicine in a population when it is known not to be effective for some people. It does not provide a generalizable estimate of the efficacy of the medicine in the general population. In addition, the concerns re the side effect profile stated above (in our discussion about placebo run in studies) also apply here. The committee are aware this has resulted in the exclusion of some studies of pregabalin in people with fibromyalgia. For the reasons stated above, they believe this is appropriate when making evidence based

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					medicine for a population with chronic primary pain.
Derby and Derbyshire CCG	Guideline	010 - 011	014-021 001-003	The ICD-11 definition of chronic primary pain – Local specialist opinion: • There is a conflation of chronic pain and chronic primary pain- this is a major flaw. The majority of the pain that seen in specialist pain clinics or in the community is chronic secondary pain. There is then no discrimination between chronic primary pain states: vulvodynia, fibromyalgia etc. • The ICD-11 definition for chronic primary pain does not include the below classifications of pain: o Chronic cancer related pain o Chronic post-surgical or post traumatic pain o Chronic secondary musculoskeletal pain o Chronic secondary visceral pain o Chronic neuropathic pain o Chronic secondary headache or orofacial pain • Disagrees with chronic regional pain syndrome being a form of Primary Pain- as it nearly always results from trauma or another stimulus. • Similarly for fibromyalgia it can often be both primary and secondary (symptoms rising after an initial disease process e.g. RA or OA). • Blanket labelling of patients with new definition/ classification and withdrawal of pain treatments has	Thank you for your comment. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with

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				potential to cause distress and serious harm to huge group of chronic pain patients. • The review discounts 47 Cochrane reviews and also seems to discount most of the studies that made up these reviews. *Overall opinion from JAPC – we do not agree with NICE's definition of chronic primary pain which includes chronic widespread pain, complex regional pain syndrome, chronic primary headache or orofacial pain, chronic primary visceral pain and chronic primary muscolosketetal pain which includes fibromyalgia. As highlighted above there are some significant omissions in the inclusion definition.*	subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised,

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					but it is their view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there is no reason not to consider this evidence with other types of chronic primary pain. All relevant Cochrane reviews were considered in the development of the evidence reviews and the included studies were reviewed for their relevance to the guideline review protocols and included where appropriate. This is detailed in the evidence reviews.
Dystonia UK	Guideline	004-005	001-016	We agree with the recommendations. Not only are there differing types of dystonia which can affect people in a number of different ways, the condition effects people of all ages and at all stages in life. It is important that the individual and their experiences are properly understood to treat the resulting pain.	Thank you for your comment.
Dystonia UK	Guideline	005-10	017-010	We are in agreement with the recommendations. We would, however, query why the use of physiotherapy was	Thank you for your comment. Physiotherapy was considered where

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				not considered while forming these guidelines? We support further research in the areas detailed in the draft consultation.	the interventions provided by those healthcare professionals fell within the reviews, for example, exercise and manual therapy.
Endometriosis UK	Guideline	001	006	We welcome the recommendation to ensure Individualised care when managing chronic pain. The chronic pain experienced by those with endometriosis will vary, for example depending on the location and extent of the endometriosis, and different individuals will have different priorities for their care including pain management.	Thank you for your comment.
Endometriosis UK	Guideline	001	007	We welcome the recommendation to ensure patients are supported to and able to actively participate in their care and care planning. Feedback from the endometriosis community has shown those with endometriosis are keen to understand their condition and symptoms, and want to play an active role in managing their chronic pain. However, lack of information and lack of opportunity to discuss their options for this is often cited.	Thank you for your comment. The committee note in the rationale for the recommendation that longer appointment times may be required to fully implement these recommendations.
Endometriosis UK	Guideline	001	011-012	We welcome the recognition that experiencing chronic pain can cause distresses, and the need to foster a collaborative and supportive relationship. With the average length from symptom onset to diagnosis taking 7.5 years in the UK, many with endometriosis have experienced challenges getting their symptoms along with the severity and impact of their chronic pain	Thank you for your comment. The committee agree this is an important factor in the management of chronic pain.

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				understood, or sometimes even believed. They may have concerns about discussing their pain and related experiences if they have previously felt not believed or listed to, and fostering a collaborative supportive relationship will be key.	
Endometriosis UK	Guideline	001 and 002	General	We welcome the focus on good communication, shared decision making and care plan development taking account of individual priorities and preferences, and understanding the impact of pain on the individual. These are all themes that are reported as important to those with endometriosis.	Thank you for your comment.
Endometriosis UK	Guideline	005	018-020	Whilst section 1.2 refers to the NICE guideline on endometriosis for guidance on this as a specific condition, the NICE Guidelines on Endometriosis (NG73) provides extremely limited guidance on non-pharmacological pain management. The only statement that NG73 under Non-pharmacological management is: 1.9.1 Advise women that the available evidence does not support the use of traditional Chinese medicine or other Chinese herbal medicines or supplements for treating endometriosis. We request an explicit statement is added to the draft Chronic Pain Guideline on the benefits to all those with chronic pain of exercise, psychological therapy and acupuncture.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations

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				Endometriosis can cause chronic secondary pain, and is not chronic primary pain. However, section 1.3 emphasises the benefits of exercise programs and psychological therapies for chronic primary pain. We consistently hear that those with endometriosis are not offered pain management, despite being recognised as a chronic pain condition. In a recent survey undertaken this year (results confidential until 20th October 2020) of over 10,000 respondents with endometriosis, 90% said they would have like to access psychological support but were not offered this. The impact of the chronic pain of endometriosis symptoms is demonstrated by the 95% of respondents saying pelvic pain affected their ability to lead their lives as they wanted to either negatively or very negatively.	are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. We will pass your comment regarding the inclusion of pain in the Endometriosis guideline to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Endometriosis UK	Guideline	011	004	We are supportive of the recommendations for research. There is the need for research on pain management programmes and social interventions – robust evidence relating to these can only be of benefit for those with any kind of chronic pain.	Thank you for your comment. On consideration of stakeholder comments regarding the extensive amount of research there has been to date on pain management programmes however, the committee have decided not to recommend further research. The research recommendation for social interventions remains.

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Endometriosis UK	Guideline	General	General	The Guideline highlights the variety of factors that can contribute to chronic pain and its management, and the importance of individualised care. This is all welcomed. To enable this to happen there needs to be the time in appointments to for the good communication and personalised care planning. We request that the need to schedule longer appointments is explicitly added to the guidance.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Endometriosis UK	Guideline	General	General	It takes on average 7.5 years from onset of symptoms to get a diagnosis of endometriosis. Whilst some may achieve a quick diagnosis in a year less, for others diagnosis may take 15+ years. During this time, many suffer from chronic pain that is not attributed to a specific condition, and may be considered by healthcare practitioners as chronic primary pain. Whilst it may be	Thank you for your comment. The committee agree this is important to state within the guideline and have added recommendations for the assessment to include investigating underlying causes, and also to

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				considered implicit, there is no explicit statement in the guidance about healthcare professionals supporting the individual to identify if there is an underlying cause for their chronic pain. To support use of the guideline by people with chronic pain, we request that at an appropriate point In section 1.1 a statement is included about supporting a diagnosis of a condition that cause pain, if there are indications of symptoms of these.	acknowledge that the initial diagnosis may change with time.
Faculty of Homeopathy	Acupuncture cost-effectiveness report	019	011	Beyond simply delivering a symptom relieving acupoint protocol, Traditional Chinese medicine treats deeper causes of symptoms. For example, a classical diagnosis might find organ chi/qi energy disturbances. Acupoint selection may therefore tonify organs that had become deficient. Acupuncture is not simply a symptom relieving intervention, but may be used curatively, and therefore patients may continue to improve for long periods after the initial treatment course. Furthermore, many traditional clinics would supplement the treatment with Chinese herbal prescriptions. Even though acupuncture alone could be curative, the history of Chinese medicine typically incorporates herbal medicine for this purpose. The research trials may not have included enough data analysis as to whether patients were also on herbs.	Thank you for your comment and for this information. This sentence has been revised.
Faculty of Homeopathy	Acupuncture cost-effectiveness report	025	007	This is not strictly a true statement, in that self-acupressure can be taught to patients to continue stimulating key trigger points between sessions, and for ongoing future benefit after the course of acupuncture is	Thank you for your comment. This sentence has been revised here and elsewhere in the report where it appears.

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				completed. There are a few dozen acupoints that are powerful means of symptom control when pressed for even a few minutes. examples include Lung-1 Zhong-fu for cough, asthmatic wheeze etc, Large Intestine-4 Hegu for general pain relief, and Pericardium-6 (Neiguan) for nausea (especially pregnancy nausea).	
Faculty of Homeopathy	Acupuncture cost-effectiveness report	043	008	I would argue increased benefit to keeping follow-up sessions to at least 30 minutes, as for initial consultations, for at least two reasons. One is that adequate time is still needed at the beginning of each appointment to review any changes to symptoms, clarify any new symptoms, and re-assess the Chinese medicine diagnosis. Classical or Traditional Chinese medicine may seek to go further into deeper causations, probing the patient's chronology for clues on the onset of the disease. Renewed pulse and tongue diagnosis should take place to assess any changes, these are vital examination findings for a classical practitioner. Furthermore, more time is often needed to provide further advice to patients, on how to prevent relapse, on lifestyle issues, or explaining the causations to their disease process. A follow-up appointment is not simply a repetition of the acupoint needling protocol of the first consultation.	Thank you for your comment. This sensitivity analysis was intended to explore uncertainty in the costing of acupuncture based on the studies given than some studies did not specify how long sessions were. The wording has been edited in this section.
Faculty of Homeopathy	Acupuncture cost-effectiveness report	043	012	I recommend the NHS should have clearly defined payment/fee levels for any subcontracted acupuncture services where there is a group setting for multiple patients receiving needling across cubicles etc. I have seen situations where private acupuncture practitioners	Thank you for your comment. The committee agrees that it will be important to ensure payment levels are appropriate but this is beyond the remit of a NICE guideline.

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				have invoiced the contracting authority a full fee based on an individualised consultation when treatment was instead in synchrony. Really the payment should be set to a lower threshold for such services. Also, typical working arrangements in synchrony group clinics is for acupuncture trainees/students or junior staff to take case histories, follow-up reviews, and prepare the patients, whilst the lead practitioner moves from cubicle to cubicle in rapid succession. Although there is nothing inherently wrong with this approach, there is little expert involvement for each individual patient. I recommend there should be enough of a range of acupuncture services so that very complex patients, especially those with long-term conditions that have been resistant to response, should have at least some phase of individualised appointments with competent acupuncture practitioners.	
Faculty of Homeopathy	Comment form question 1	N/A	*N/A*	*Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.* One challenge in implementing acupuncture services is the ideological resistance and antagonism towards the complementary-alternative medicine sector, from several directions – such as sceptical campaign groups, members of funding bodies and within conventional medicine. There are entrenched ideas that acupuncture has no physical basis, and/or that the concepts of Traditional Chinese medicine have no place in a modern scientific approach. This latter belief system has even stifled the	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				proper use of classical acupoint protocols within western medical acupuncture. Including acupuncture within this guideline would go some way towards addressing the disparity between public interest and lack of NHS commissioning. Surveys consistently show significant proportions of the population seek complementary-alternative treatment and are mainly self-referred and self-financed (Sharp et al 2018). Hence the challenge is for the medical profession to adopt an Integrative Medicine model of healthcare more widely, or at least initially within chronic pain management. There is already an infrastructure of Integrated Medicine hospitals or clinics (such as the Royal London Hospital for Integrated Medicine) as a platform for implementation of increased acupuncture, psychological and other complementary medicine services. Debbie Sharp et al. Complementary medicine use, views, and experiences: a national survey in England. BJGP Open 2018; 2(4). doi: 10.3399/bjgpopen18X101614	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Faculty of Homeopathy	Comment form question 2	N/A	*N/A*	*Would implementation of any of the draft recommendations have significant cost implications?* Complementary approaches such as acupuncture have the potential to significantly reduce further tertiary referrals, conventional treatments, and even reduce further diagnostic work-up and investigation where a clear route to treatment using holistic principles is	Thank you for your comment. The committee considered whether to incorporate downstream effects on resource use due to acupuncture in the economic evaluation however as suggested this was not done due to a

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				apparent (after excluding red flag symptoms of deeper serious pathology that would require further management). The economic analysis has not included or evaluated this as a cost saving for acupuncture, and this is perhaps a calculation to be made after further research upon implementation of the service. More research would eventually be needed on this economic evaluation. For example, Wye et al (2009) found only poor-quality audit data to evaluate any favourable impact of NHS based primary care complementary therapy on health outcomes and NHS costs, but results suggested at least moderate impacts. The impact of integrative medicine (including acupuncture) on pain management significantly found an average of 55% reduction in pain levels and advocated further work to determine reduction in total health costs and pain medication usage (Dusek et al 2010). Jeffery Dusek et al. The Impact of Integrative Medicine on Pain Management in a Tertiary Care Hospital. Journal Patient Safety. Vol 6 (1), March 2010. doi: 10.1097/PTS.0b013e3181d10ad5 Lesley Wye et al. The Impact of NHS based primary care complementary therapy services on health outcomes and NHS costs: a review of service audits and evaluations. BMC Complementary and Alternative Medicine. 2009, 9:5. doi: 10.1186/1472-6882-9-5	lack of evidence. This is discussed in section 2.2 of the model report.

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Faculty of Homeopathy	Comment form question 3	N/A	*N/A*	*What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)* Another challenge is the risk of a disparate and fragmented acupuncture service if this NICE guideline advocates acupuncture but without further standards of practice. I strongly urge an incentive to collaborate with acupuncture partners (such as regulatory/registering organisations and other acupuncture stakeholders) for the purpose of writing a Code of Practice for Acupuncture in Chronic Pain (e.g. a possible title '*Into Practice Guide: Acupuncture for Chronic Pain*.'). This document should include explanations of specific acupuncture management for a wide variety of regional and local pain syndromes, syndrome diagnoses, acupoint protocols, Traditional Chinese medicine and western acupuncture approaches. I would be interested in being involved in such a project. It is pertinent that the World Health Organisation has now included a supplementary chapter 26 of Chinese medicine diagnostic syndromes in the latest International Coding of Disease ICD-11. This has the potential to boost research, reporting and case management when using acupuncture as part of an Integrative approach to chronic pain and I recommend any future Acupuncture for Chronic Pain industry specific guideline incorporates ICD-11 chapter 26 coding.	Thank you for your comment. It is beyond the remit of NICE guidelines to develop standards of practice for specific interventions. The review of acupuncture for this guideline was for chronic primary pain only. The committee agreed that the review included a variety of different types and intensities of acupuncture, but it was not possible to determine from this review whether one was more effective than another. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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				It stands to reason to utilise existing resources when implementing acupuncture for chronic pain, such as allocating funding and referral for acupuncture within existing NHS Pain clinics, Integrative Medicine clinics and relevant outpatient clinics. In order to encourage this, it is necessary to unblock Clinical Care Commissioning (CCG) funding that has been withheld from acupuncture services over the past several years, sometimes for no real economic reason other than bias and prejudice towards anything to do with complementary medicine. I would suggest a large enough budget is stipulated for acupuncture services in order promote the service equitably. This would certainly also require a change to the PoLCE strategy within CCG groups. CCG funding should also not be reliant on acupuncture clinics having to make individual applications for patient funding but should commission generically for chronic pain. World Health Organization ICD-11 browser available at www.who.int/classifications/icd/en/	recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Faculty of Homeopathy	Comment form question 4	N/A	*N/A*	*The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.* There are clear policies (as well as Codes of Practice) in place from acupuncture registering bodies, which inform on how acupuncture practitioners may safely re-start	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing

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				their clinics and treat patients during the Covid-19 pandemic. This includes use of personal protective equipment PPE, safe methods of pulse and tongue examination, touch assessment of acupuncture meridians and trigger points and safe needling techniques. Such policies could be incorporated in the guideline, perhaps as an addendum to the acupuncture section. A modified policy could be created through partnership with existing acupuncture stakeholders. For example, some change to acupuncture clinics will likely be necessary, such as a preference for individualised clinics rather than group synchrony acupuncture of multiple patients in one session (to facilitate social distancing).	where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
Faculty of Homeopathy	Evidence review A	056	023	Despite low quality of evidence, a tentative conclusion seems to show that comorbid psychiatric disorders (anxiety, depression, psychoneurosis, somatic and psychosomatic complaints) predicted more intense pain and poorer quality of life outcomes. From a complementary medicine and holistic approach, this is not a surprising finding. The Cartesian method based on Rene Descartes argues there is a split between the human mind and corporeal body, whereas in healing practice this is far from the case. An excellent critique on how this has affected medicine can be found in Mehta 2011. Inherent in Traditional Chinese medicine underlying acupuncture practice is a spiritual and psychological component of the human being within the qi dynamic of the body organs. The term psychosomatic would have a widely different	Thank you for your comment and for this information.

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				interpretation in Chinese medicine compared to western. For example, spleen syndromes (e.g. spleen yang deficiency) may be a causation for chronic worry, ruminating or somatisation and hypochondriasis. Liver and gallbladder syndromes (e.g. liver qi stagnation and liver yang ascending) can cause anger, endogenous depression, and low self-esteem). Lung syndromes (e.g. lung qi deficiency) can cause despondency, chronic grief and sadness. Kidney syndromes (e.g. kidney qi or yin deficiency) can cause fear, chronic anxiety and panic disorders. Some of these syndrome diagnoses are particularly typical causes also of chronic pain, for example spleen yang deficiency underlying a phlegm-wind pattern of pain with deep dull aching muscle pain, or liver qi stagnation underlying a chronic cramping/spastic pain within viscera. Hence a competent acupuncture assessment and course of treatment may deal with both psychosocial comorbidity as well as the specific chronic pain symptoms – furthering the benefits of including this therapy into the guideline. Neeta Mehta. Mind-body Dualism: A critique from a Health Perspective. MSM Mens Sana Monographs 2011 Jan-Dec; 9(1): 202-209. doi: 10.4103/0973-1229.77436	
Faculty of Homeopathy	Evidence review B	018	033	I have witnessed such patient responses, where investigation test results have proved negative, and patients feel this implies their pain is being dismissed as psychosomatic, un-real or not requiring further management. Some patients seek a diagnosis as a means	Thank you for your comment. The committee agree this is an important aspect to include in the recommendations.

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				of understanding the root causes of their pain. Without a firm diagnosis, medical management is very difficult. But this is also where acupuncture can be of great benefit on two fronts. One is that functional and holistic models of diagnosis and pathogenesis of pain are part and parcel of Traditional Chinese medicine and can help a patient understand the causes and risk factors of their pain. Secondly, acupuncture does not need or require an organic physical pathology in order formulate clear treatment strategies for the underlying qi disturbances.	
Faculty of Homeopathy	Evidence review B	021	023	I advocate longer rather than shorter consultation times, including for follow-up appointments. A 30-minute duration is the minimum of time required, and even that is constrained. An effective service would include a re-appraisal of the patient's history to elicit any changes, identify new symptoms, probe deeper psychosocial factors and reveal further historical layers in their biography. Including an acupuncture treatment session requires a minimum of 20 minutes for patient preparation, acupoint localisation, needling and needle manipulation. And further time is usefully spent with explaining the diagnosis and investigation results, discussion of lifestyle changes, advising self-help methods and review of prescriptions or medication.	Thank you for your comment. The committee agree that longer appointments may be required to fully implement the recommendations for the assessment of chronic pain and note this in their discussion of the evidence.
Faculty of Homeopathy	Evidence review B	021	052	The problem of patients being seen by multiple service providers reinforces the argument for continuity of care through a gateway type medical doctor working in a chronic pain or Integrative medicine setting. This single	Thank you for your comment. The committee agree that continuity of care is important.

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				point of reference can instil enormous relief and trust in the process for chronic pain patients.	
Faculty of Homeopathy	Evidence review E (exercise)	155	010	Using an integrative model for understanding chronic pain in selected patients, the differing effects of exercise for managing chronic pain could be usefully analysed in accordance with Traditional Chinese medicine and acupuncture theory. For example, in my experience and in keeping with classical theory, two of the most prevalent syndrome patterns found when examining chronic pain patients are Blood Stasis and Qi Constraint. Blood Stasis is an extreme pathology deriving typically from qi stagnation, qi deficiency, blood deficiency and/or blood stagnation, and is broadly the equivalent to chronic pain after tissue injury and trauma, especially when complicated by significant haemorrhage or coagulation. Qi Constraint is often associated with liver qi stagnation and is typically found alongside psychological/emotional co-morbidity – although this is a very simplistic synopsis of a complicated network of disorders. At any rate, Chinese medicine strategy would advocate exercise (especially aerobic) as beneficial for promoting circulation and ameliorating blood stasis. Conversely, exercise (other than very gentle types of body-work such as chi kung or yoga therapy) could be counterproductive in some situations of qi and blood deficiency, where a better behaviour would be dealing with stress, sleep disorders, promoting rest and relaxation techniques. Hence, a heterogeneity in response to exercise may be	Thank you for your comment. The evidence review focussed on the evidence for exercise as a standalone exercise and did not include evidence for integration with Traditional Chinese Medicine Therapy. Research recommendations can only be made on areas that have been reviewed within the guideline so this research recommendation cannot be included.

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				evident in the studies when a holistic approach has not been applied to assessing individual patients' needs. A review of Traditional Chinese Medicine Exercise Therapy, which also encompasses Tai Chi, breathing techniques, self-massage and Chi Kung (Chinese Yoga) can be found in Jiang (2013). To fine-tune the approach to exercise in chronic pain patients, I would advocate a research initiative to integrate Sports Medicine and Exercise Therapy with Traditional Chinese Medicine Therapy. This highlights the committee's conclusion that "the most appropriate type of exercise may depend on the type of pain condition and it should be tailored to individual needs and preferences." (page 157, line 10). However, as implied by my reference to Chinese medicine treatment strategies, I would advocate a research area within an Integrative Medicine or Pain clinic setting would be to endorse specific types of exercise regimes in relation to holistic diagnoses – which of course patients may seek out and self-fund. This underlines the message from the American College of Sports Medicine in 2007 (Tipton 2014) when it launched a global initiative to mobilise physicians and healthcare providers to promote exercise to prevent, manage and treat disease. Indeed, exercise is historically rooted into health and disease prevention since antiquity. A pertinent comparison can be made between exercise regimens of the ancient Greek Athenian and Spartan city-states, and	

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				Athenian exercise would typically include promoting the health of body and mind (Demirel and Yildiran 2013). Duygu Demirel and Ibrahim Yildiran. The Philosophy of Physical Education and Sport from Ancient Times to the Enlightenment. European Journal of Educational Research. 2(4), 191-202. doi: 10.12973/eu-jer.2.4.191 Yan Jiang and Jun Zou. Analysis of the TCM theory of traditional Chinese health exercise. Journal of Sport and Health Science. 2 (4), Dec 2013, 204-208. doi: 10.1016/j.jshs.2013.03.008 Charles Tipton. The history of "Exercise is Medicine" in ancient civilizations. Advances in Physiology Education. 2014 Jun; 38(2); 109-117. doi: 10.1152/advan.00136.2013	
Faculty of Homeopathy	Evidence review G (acupuncture)	037	038	I would welcome acupuncture delivery in NHS Community Clinics, but also support their inclusion into outpatient clinics and during in-patient assessment. Any acupuncture treatment could be utilised as part of an Integrative Medicine service, so that a single doctor/practitioner is providing a one-stop shop for assessment, psychological therapies (e.g. cognitive behavioural therapy, hypnosis or mindfulness), acupuncture, review of medication etc. This could also include research areas such as homeopathic and herbal treatments, which currently involve private prescription anyway, so the only service cost is clinic time. But within a typical 30 minute initial or follow-up appointment, an	Thank you for your comment. In response to stakeholder comments, the recommendation has been amended slightly to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.

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				Integrative physician should be able to encompass at least one treatment modalities into the session. More time would allow two or more treatment modalities in the same session. Economic appraisal would make this a very cost-effective service when compared with funding multiple services in separate clinics.	We cannot comment on its combination with psychological therapies as that was not considered within the protocol for this review. Other complementary therapies were also not within the scope of this guideline and therefore cannot be recommended.
Faculty of Homeopathy	Evidence review G (acupuncture)	043	039	Acupuncture placebo research is fraught with methodological difficulty. There is really no such thing as placebo acupuncture. Inserting an acupuncture needle close to a recognised acupoint is itself potentially therapeutic. Activating an acupoint can be likened as 'hitting a target on a dartboard. Hitting the bullseye is the ideal for maximum therapeutic effect, especially when utilising other advanced techniques such as tonifying methods of inserting the needle in stages or reducing/detoxifying effects through gradually withdrawing the needle in stages. But inserting the needle anywhere on the dartboard may score points. Hence a body region approximately 1.5 cun (the equivalent of one and half thumb-widths, or about 3-4 cm) around the acupoint is still a therapeutic zone. Sham acupuncture may instead involve using a pressure device that does not actually penetrate the skin. However, this research method would therefore be comparing	Thank you for your comment. The committee discussed the methodological difficulties of research trials in acupuncture and took this into account in their interpretation of the evidence. They particularly noted that some of the sham procedures could have a therapeutic effect. If this were the case, it would underestimate the effect of acupuncture treatment in comparisons with sham and therefore the committee agreed that the benefit of acupuncture compared to sham was a promising finding. The details of the committee's deliberations are

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				acupuncture with acupressure. This latter is itself a therapy, for example one complete system of meridian acupressure would be shiatsu. Patients can also be taught acupuncture points for self-acupressure, to maintain their treatment between appointments. So really there is no inert placebo control and a therapeutic effect would be inherent in both verum and sham acupuncture arms of a typical acupuncture trial.	provided in the discussion of the evidence in Evidence report G.
Faculty of Homeopathy	Evidence review G (acupuncture)	046	034	My understanding is that acupuncture is now recognised as a viable treatment for many conditions by German health insurance companies (www.german-health-system.com/tk). This was a result of the German Acupuncture Trials (GERAC and ART), which showed a positive treatment effect of both true acupuncture and minimal acupuncture against conventional treatment and waiting list controls. The German trials also showed that acupuncture had an acceptable cost-utility calculation in terms of cost per QALY, but so long as the fee for the acupuncture session did not exceed 35 euros.	Thank you for your comment and for this information. The text has been edited to address your comment.
Faculty of Homeopathy	Evidence review G (acupuncture)	048	009	The cost of an acupuncture service is not necessarily related to the quality standard of the service provided. This may sound cynical, but I suspect that some private acupuncture providers subcontracted by the NHS (including providers of Traditional Chinese Medicine acupuncture) will over-charge for their service. For example, a modest fee invoiced for a patient may be about £40, but the clinic may run as a group synchrony clinic with several patients receiving needling in cubicles	Thank you for your comments. The committee agrees that it will be important to ensure payment levels are appropriate but this is beyond the remit of a NICE guideline. The committee also agrees that people delivering acupuncture should have the

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				or even in an open space. I argue that in some clinics there is insufficient time or attention focused on history taking, patient examination, assessment of possible holistic (and biopsychosocial) diagnoses, discussion of traditional Chinese medicine principles and lifestyle advice, or appraisal of any other treatment modalities such as herbalism. On the other hand, a lack of comprehensive management may also be evident in tertiary or NHS hospital clinics where for example a doctor may provide western medical acupuncture and predominantly local needling, but with very limited scope to incorporate traditional Chinese medicine acupoint protocols, distal needling, treating underlying energetic syndromes. Hence an ideal acupuncture service provision needs to be thought through. Possible solutions include a fixed price plan for NHS subcontracted acupuncture clinics, including differential fees paid for individual and group synchrony treatment settings. Also, there should be sufficient expertise and competency in hospital provided acupuncture services, including within an Integrative medicine clinic, where staff receive adequate acupuncture training. There is a great potential for in-hospital acupuncture services, including for outpatient and inpatient settings. An acupuncture department or speciality could be included within both a Pain Medicine department and	appropriate skills and training however this is not generally stated in NICE guidelines as this is the case for all health care professionals delivering recommended interventions. Service configuration will certainly be an important consideration when implementing this recommendation however this was not reviewed as part of the guideline update and so will be determined locally taking into account local circumstances. Your comments will also be considered by NICE where relevant support activity is being planned.

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				Integrative Medicine department. This latter may also be embedded into many other specialities, for example Integrative Medicine for Womens Health (Gynaecology). Chronic pain patients, even where treatment is undertaken by referrals to the private sector, should be seen during the early stage of their management by an appropriate medical doctor, ideally within a department of Integrative medicine or Chronic Pain, who also has competency in complementary medicine. This approach helps channel services appropriately, and provides a gateway for controlling and limiting excess, costly or mismanaged use of complementary therapies. It safeguards from any missed red flag symptoms of serious pathology, ensures key investigations are undertaken, and enables suitable monitoring of the patient's overall progress. Linking this into an Integrative Medicine department model may also reduce un-needed referrals to multiple tertiary departments particularly for complex chronic pain patients, e.g. with multi-morbidity. Assessment by several medical teams across specialities is sometimes wasteful, e.g. a chronic pelvic pain patient may ultimately be investigated and assessed by departments of gynaecology, urology, neurology, gastroenterology etc, but with poor networking or collaboration. Being seen by an Integrative medical doctor also allows adjustment of the patient's pharmacological conventional treatment, since this would be outside the competency of CAM practitioners and also	

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				may be impractical for the patient's General Practitioner, not being specialised in pain management. Diagnostic and investigation work-up would also be onerous on GP services. Indeed, similar points were raised during your scoping workshop on 04-10-2017 (see page 6, Assessment of Persistent Pain). Where non-medical practitioners are also involved, it is important that complementary therapies, including acupuncture, are delivered to a sufficiently high standard. Possible means of ensuring this include: (a) conducting audits regularly (e.g. annual) to monitor patients progress. There are various symptom assessment scores available, e.g. MYMOP. (b) Having an Integrative Medical doctor as a gateway for monitoring and regular appraisal of the patient. (c) Ensuring CAM practitioners are registered by industry specific regulatory bodies, and therefore adhere to a code of ethics, have suitable training/qualification, and undertake continual professional development. (d) Encouraging the industry to hold periodic Integrative Medicine workshops for local area resource planning, continual professional development of service providers, reviews of audit procedures, considerations of new developments and updates to guidelines. (e) Running short courses, for example acupuncture postgraduate training for chronic pain management.	
Faculty of Homeopathy	Evidence review G	048	030	One example where services have been affected by reduced Clinical Commissioning Group (CCG) funding is the Royal London Hospital for Integrated Medicine (part	The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery

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	(acupuncture)			of University College Hospital NHS Trust). This introduced acupuncture into NHS services from 1977 and had been the largest provider of acupuncture with several thousand patient sessions per year. Acupuncture can be delivered by conventionally qualified doctors, nurses and physiotherapists with additional training in acupuncture both Western and traditional Chinese techniques. The hospital has the infrastructure to deliver NHS acupuncture to the scale and frequency required to treat chronic painful conditions. However, the North Central CCG issued its updated Evidence Based Interventions and Clinical Standards Policy in April 2019 to restrict funding of acupuncture to conditions recommended by NICE (which were limited only to Tension-type and Migraine headache). This policy (previously called Procedures of Limited Clinical Effectiveness PoLCE), clearly should be reviewed. Any policy update at CCG level should not require continuing to make the onerous task of making individual patient funding requests for acupuncture. I also currently work at another hospital NHS Trust which has seen the local CCG withdraw funding for the acupuncture service last year within the Integrated medicine outpatient clinic for gynaecology, including chronic pain referrals. This was despite consistent audit results over several years showing positive outcomes. This service can be readily reinstated.	of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.

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Faculty of Homeopathy	Evidence review G (acupuncture)	048	035	In my experience, repeat courses of acupuncture are only of relevance if the patient's case is complex, with for example co-morbidity, polypharmacy medication, long-standing physical disability, or organic pathology. Hence further courses of acupuncture treatment should address deeper causations, systemic pathology, or co-morbidity. Approaching the patient with repeat courses of the same acupuncture strategy and point protocol as the first course may not be meaningful.	Thank you for your comment. The committee agree and have included a research recommendation which will hopefully inform future updates of this guideline.
Faculty of Homeopathy	Evidence review G (acupuncture)	048	047	Acupressure techniques and relevant points could easily be taught to patients for self-treatment between appointments, at minimal cost in terms of time taken for instructions.	Thank you for your comment. No evidence was identified for self acupuncture, therefore no recommendation could be made on this mode of delivery. Self-acupressure was not included in the review as an intervention.
Faculty of Homeopathy	Evidence review G (acupuncture)	049	001	There is a marked difference in the acupuncture diagnosis, treatment strategy and acupoint protocol used for treating back pain when comparing Traditional Chinese Medicine (TCM) and Western acupuncture. For example, TCM may place more focus on strengthening Kidney Qi with Kidney channel tonification points (Kidney-3 etc), improving the general flow along the Governor and Bladder channels, using distal opening points (e.g. Lung-7 and Bladder-62) or relieving certain pathologies such as blood stasis. By comparison, Western acupuncture may focus on myofascial trigger sensitive points that are local to the pain. It is beyond the scope of	Thank you for your comment. We agree it is beyond the scope of this guideline to differentiate between the different acupuncture approaches to chronic pain.

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				the Guideline to properly compare or differentiate between all the acupuncture approaches to chronic pain, but this could become part of a future industry Code of Practice.	
Faculty of Homeopathy	Evidence review G (acupuncture)	44	7	Several papers have discussed the problem of placebo acupuncture methodology (for example, Sizhe Deng et al 2015, and Frauke Musial 2019). Other than sham acupuncture, perhaps more valid controls to assess efficacy of acupuncture are waiting-list controls (no treatment control group) and/or standard care control group (e.g. on conventional medication). The terms 'sham acupuncture' and 'placebo acupuncture' or 'placebo needle' etc have not been clearly defined in trial methodology. For example, they may variously mean a non-penetrating needle, or needling at an alternative acupoint, or needling at a non-acupoint location, or superficial needling at the correct acupoint (minimal acupuncture) as opposed to deep needling. However, none of these control methods can be absolutely inert, and they will all likely induce some therapeutic effect. Several studies show that even non-penetrating placebo needles induce 'de qi' sensations that are indistinguishable from the effect of real needling (Chae 2017, 2018). For example, in Araha 2015, the sham acupuncture group had needles inserted 1cm distal to the correct acupoints. The acupoint protocol (for neck pain) was bilateral GB21, GB20, and unilateral LI-4 and LV-3. But most	Thank you for your comment. The review included both sham comparators and usual care/waiting list controls, analysed separately. The committee acknowledge the variety of shams that are used in their discussion of the evidence in the evidence review. It should be noted this is also true with usual care comparators, which also vary in their content, and in the detail given in the studies. The committee acknowledge that some sham procedures may themselves have a therapeutic effect. If this is the case, this would result in underestimating any benefit from acupuncture. The committee therefore noted that the fact that acupuncture demonstrated clinically important benefits compared to sham was a promising finding. The committee also note the variation

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				acupuncture meridians for much of their length run longitudinally along the body). Thus, 1cm distal to LI-4 (Large Intestine point 4) is still along the pathway of the large intestine meridian and will influence the flow of chi (energy) along the channel. And 1cm is not actually far from exactitude with the acupoint. In this study, I think there were also far too may exclusion criteria to make the findings externally valid or clinically representative of chronic neck pain. That significant improvement was found in both electrical acupoint and acupuncture compared to sham and when assuming sham is more than simply a placebo effect, my tentative conclusion is that the true efficacy of acupuncture is even greater. The therapeutic effect of placebo acupuncture is also hinted at by two 2005 trials which found little difference between verum acupuncture and placebo acupuncture, but a substantial difference between the placebo acupuncture and no acupuncture control groups (reviewed by Matias Vested Madsen et al 2009). But other trials only found a small to moderate effect of placebo to no acupuncture. The likelihood is that placebo acupuncture varies in its therapeutic effect. For example, it is dependent on how far away from the correct acupoint the sham needle is inserted. This study of a large meta-analysis showed a small statistically significant difference between acupuncture and placebo acupuncture, and a moderate difference between placebo acupuncture and no acupuncture groups. The placebo	among the interventions included within the review. There was no heterogeneity observed that could be explained by the type of acupuncture. The review can therefore not inform whether one type is more effective than another. The committee considered that this may depend on the type of pain and clinical judgement of the healthcare professional should be used to determine appropriate type for the person with chronic primary pain being treated.

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				methods were also scored by researchers into a scale of likely effect based on penetrative and non-penetrative needling, and whether electrically stimulated or not. Meta-analysis also showed placebo acupuncture was associated at times with large analgesic effects, but in other trials with none, or very small effects – thus finding heterogeneity in placebo controls. Also, where patients in the trial groups have had prior acupuncture experience (especially those with long history of treatments), then they may be able to discern which needling seems to be sham and which is authentic. For instance, the lack of needle manipulation or not pressing on trigger points could provide a clue of placebo. In effect, in my opinion, sham or placebo acupuncture controls amounts to a comparison between skilled acupuncture versus unskilled acupuncture (where placebo involves inaccurate needling), or a comparison between acupuncture and acupressure (where placebo involves non-penetrative needling). Hence, the results of acupuncture randomised control trials (RCTs) are more likely than not being underestimated in meta-analysis. Verum acupuncture nonetheless still tends to demonstrate greater effectiveness than placebo acupuncture, so the results when compared to a theoretical true placebo are likely to be even greater.	

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				But even more so, the true/verum acupuncture treatment cannot be compared as 'like for like' when comparing RCTs, including in meta-analyses. Some trials may not contain effective enough acupuncture treatment protocols. An analogy in pharmaceutical research is where an insufficient dose of a medication is compared with placebo and/or other conventional treatments. Hence, some acupuncture trial treatments may be relatively weak in terms of imprecise acupoints selection, low number of acupoints, lack of needle manipulations etc. Misleading data is thereby being generated. There are several ways by which the acupuncture treatment in the verum group could be more, or less, effective. For example, the frequency of clinic visits, needling for a long enough time duration, selection of acupoints that reflect the perceived disturbance of qi for traditional approaches, using needle manipulation techniques such as reinforcing or reducing methods to adjust the qi along the meridian etc. These last two techniques are not emphasised in western medical acupuncture. In conclusion, a comparative analysis of two or more acupuncture trials is not as straight-forward as it seems. There is a significant difference between experienced acupuncturist giving an individualised point formula, versus a less experienced acupuncturist needling only a fixed protocol of points for a chronic pain condition. Also, a significant up-lift occurs in the patient response when needling is exactly located at the true acupoint rather	

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				than a few millimetres away, and also when the acupuncturist performs correct needle manipulation to 'grasp the qi' and elicit a flow of energy along the acupuncture meridian. The problem of placebo and sham acupuncture as controls is thus highlighted by several studies or reviews: Sizhe Deng et al 2015, Is Acupuncture no more than placebo? Exp. and Ther. Medicine 10: 1247-1252. 2015. doi: 10.3892/etm.2015-2653 Matias Vested Madsen et al. Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. BMJ 2009;338:a3115. doi:10.1136/bmj.a3115 John Mcdonald, Why Randomised Placebo-controlled Trials are Inappropriate for Acupuncture Research, Journal of Chinese Medicine, Number 119, February 2019 Frauke Musial. Acupuncture for the Treatment of Pain – A Mega-Placebo? Frontiers in Neuroscience. 17 October 2019 doi: 10.3389/fnins.2019.01110 Claire Shuiqing Zhang et al, 'Placebo Devices as Effective Control Methods in Acupuncture Clinical Trials: A Systematic Review' PLOS ONE doi:10.1371/journal.pone.0140825 November 4, 2015	

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				Yan Xiang et al, 'Appropriateness of sham or placebo acupuncture for randomized controlled trials of acupuncture for nonspecific low back pain: a systematic review and meta-analysis'. Journal of Pain Research 2018:11 83–94	
Faculty of Homeopathy	Evidence review J (pharmacological)	068	022	From clinical experience it is predictable that many patients already on conventional analgesics, often polypharmacy at relatively high doses, would find it practically impossible to wean down and ultimately stop their medication – unless there is some overlapping support system in place. Although the aim with acupuncture is to treat the symptoms of chronic pain and ideally the root causes, an impasse is often evident when rebound pain is experienced on attempting to reduce existing analgesia. Although other treatments could assist, such as psychological, it would be reasonable to consider other forms of pharmacological support such as herbal medicine. Within many systems of herbal medicine, including western and Chinese, there are commonly used and empirically based formulae and single herbs for pain disorders of all types. Although my comments are focused on acupuncture, it should be acknowledged that in the real world, many acupuncturists also prescribe Chinese herbal medicines (often as patent formulae) as either adjunctive or main therapy alongside the acupuncture treatment. Some herbal medicines are even the original ethnobotanical sources of well-known analgesics such as	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations and research recommendations on this topic cannot

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				Filipendula ulmaria (meadowsweet) and Salix alba (willow bark) for aspirin. Some plants can be categorised along taxonomic families with certain therapeutic characteristics. For example, the Asteraceae (daisy family) contain prominent wound and trauma healers, including treatment of chronic pain as sequelae, e.g. Calendula and Arnica. The Lamiaceae (mint) family contains many analgesic herbs such as Rosmarinus (rosemary). Other examples of single herbs with well-known analgesic effects are Dioscorea villosa (wild yam, for pelvic spasm), Gingko biloba (maidenhair, for ischaemia), Curcuma longa (turmeric, for gastrointestinal pain) and Harpagophytum procumbens (devils claw, for arthralgia). Some herbs could also support the withdrawal of medications, such as Eschscholtzia californica (California poppy, to support opiate withdrawal). However, it is accepted that there is insufficient high quality or randomised control trial (RCT) evidence to support any NICE appraisal or recommendation for herbal medicines at this time. One Cochrane review (Gagnier et al) did show in particular Capsicum frutescens (cayenne) reduces low back pain more than placebo, and with low-moderate evidence for several other herbal medicines (Harpagophytum procumbens, Salix alba, Symphytum officinalis, Solidago chilensis and Lavandula essential oil). Additionally, methodological problems exist with RCTs in herbal medicine. This is also because real world data	be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development.

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				would involve individualised herbal prescriptions, often with unique formulae or combinations for each patient. It can also be difficult to adequately blind the herbal medication – since typical dispensing as tinctures or granulated powders will often have a strong taste. Perhaps a methodology is a 3-arm trial with a standard herbal formula, a customised individual herbal formula, and a placebo/conventional treatment. Or with the limitations in time, funding and resources, perhaps research is best suited to carefully designed case cohorts and also outcomes based research, even though these are lower in the NICE evidence hierarchy (however, even the report by Helen Bell et al 2016 found selection bias and use of non-RCT evidence is sometimes necessary and NICE increasingly use Real World Data). Dalziel et al found in their review of 47 NICE Health Technology Assessment (HTA) Reports that 14 (30%) had included information from case series studies. I therefore suggest that NICE issue an Individual Research Recommendation for two questions: (1) Whether herbal medicine (western or Chinese) are safe and effective as adjunctive or support treatment during the withdrawal of conventional analgesia for chronic pain. (2) Whether herbal medicine is safe and effective primary treatment for chronic pain. I note that NICE had issued a similar herbal medicine Research Recommendation (CG61/5) in Feb 2008 for	

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				irritable bowel syndrome, but perhaps a better response from the herbal industry will now be forthcoming. This is after all a growth field, with ethnobotanical research identifying many potentially active antinociceptive plant-derived active compounds (Joao Calixto et al 2005). It is also worth noting that referrals can be made to the western herbal clinic at the Royal London Hospital for Integrated Medicine (although the herbal medicines themselves no longer fall under NHS prescription reimbursement and are therefore privately funded). As well as the mentioned references, some relevant reviews on herbal research for national health systems can be listed: Helen Bell et al. The Use of Real World Data for the Estimation of Treatment Effects in NICE Decision Making. Report by the Decision Support Unit, ScHARR, University of Sheffield, 17th June 2016 (updated 12th Dec 2016). www.nicedsu.org.uk Joao B Calixto et al. Biological activity of plant extracts: novel analgesic drugs. Expert Opinion on Emerging Drugs. Vol 6 (2). doi: 10.1517/14728214.6.2.261 K. Dalziel et al. Do the findings of case series studies vary significantly according to methodological characteristics? Executive Summary. Health Technology Assessment 2005; Vol 9; No.2. doi: 10.3310/hta9020	

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				Joel Gagnier et al. Herbal Medicine for Low Back Pain: A Cochrane Review. Spine, Jan 2016 Vol 41 (2), p116-133. doi: 10.1097/BRS.0000000000001310 Jon Tilburt & Ted Kaptchuk. Herbal medicine research and global health: an ethical analysis. Bulletin of the World Health Organization. August 2008, 86 (8) doi:10.2471/BLT.07.042820	
Faculty of Homeopathy	Guideline	007	011 – 012	Delivery of acupuncture services should not be restricted to band 7 (or lower) healthcare professionals. There are hundreds (or more) of medical doctors trained, qualified and experienced in acupuncture, many of whom have provided this within Pain clinics, integrative clinic settings, on the NHS and in private practice. The British Medical Acupuncture Society is one registering body, and many members will be higher than band 7. A simple online search shows there are at least 74 medical doctors amongst the registered acupuncturists within the British Medical Acupuncture Society. Acupuncture treatment is not necessarily the only activity within a doctor's clinic appointment but may be part of a general assessment of the patient, e.g. after tertiary referral, and alongside further management and organising of investigations. The UK has a fragmented un-joined up acupuncture industry with voluntary registers, and since there is no statutory requirement for registration, there are a number of unregistered acupuncturists. I certainly advocate more acupuncture services through NHS Community Clinics,	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation. The committee agree that research is needed on repeat courses of acupuncture and have included a research recommendation which has been made high priority, and will hopefully inform future updates of this guideline.

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				and even in patients home visits. However, I think it would be very limiting for NHS referred acupuncture to be restricted largely to NHS Community Clinics, as regulated by the Health and Care Professions Council (HCPC), and/or delivery to be restricted largely to members of certain bodies the Acupuncture of Chartered Physiotherapists. For instance, acupuncturists registered by the British Acupuncture Council (BAcC) are also publicly recognised by the NHS as providers of acupuncture, and their membership of the Professional Standards Agency (PSA) legitimises the role of their members in health and social care. A useful review of the UK situation can be found in Cloatre and Ramas (2019). Emilie Cloatre and Francesco Salvini Ramas. The Regulation of acupuncture in France and the UK: Shifts and fragmentation in contrasting healthcare systems. Medical Law International 2019, 19(4), 235-257. doi: 10.1177/0968533220903373	
Faculty of Homeopathy	Guideline	012	008	I would invite the committee to also add homeopathy to the list of therapies that warrant further research for the management of chronic pain. I acknowledge that currently there is insufficient research evidence (good examples are Katja Boehm et al, and Marcus Zulian Teixeiraa et al) to provide a basis for a decision on its inclusion, but the following points may throw light on the possible benefits.	Thank you for your comment. Research recommendations can only be made for interventions where the evidence has been searched for within the guideline. Homeopathy was not highlighted as a priority area to include during guideline scoping nor when the protocols were being agreed and therefore recommendations or

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				Homeopathy has a very sophisticated set of case taking, case analysis and patient management tools. integral to the homeopathy is an exploration of the underlying biopsychosocial aspects of the individual, with detailed discussion of significant life events and biography. Causations and layers in the case are pointers to specific remedies. Many patients often already feel better from the homeopathic consultation itself (e.g. see Sarah Brien et al). Despite sceptical attitudes to the existence of an active principle within homeopathic medicines, advances have been made recently on plausible mechanisms in the fields of nanomolecules and electromagnetic properties of water. But in terms of available remedies, there are a very large repertory of possible homeopathic medicines for treatment of pain, whether acute or chronic. A professional homeopath would tailor the prescription in accordance with one or more methodological strategies, for example prescribing for a specific cause or aetiology to the pain, or treating the unique characteristics of the pain for that patient, or based on their constitutional or behavioural response to the chronic pain. A number of well-tried prescribing protocols and remedy sequences have had empirical success for treatment of pain over the past couple of hundred years, with the accumulation of a great deal of case reports, case series and expert opinion.	research recommendations cannot be made.

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				A useful review can be found in Burke Lennihan (2017) and Gabriel Tan (2007). Katja Boehm et al. Homeopathy in the treatment of fibromyalgia——A comprehensive literature-review and meta-analysis. Complementary Therapies in Medicine (2014) 22, 731-742. doi.org/10.1016/j.ctim.2014.06.005 Sarah Brien et al. Homeopathy enables rheumatoid arthritis patients to cope with their chronic ill health: A qualitative study of patient's perceptions of the homeopathic consultation. Patient Education and Counseling 89 (2012) 507–516. doi:10.1016/j.pec.2011.11.008 Burke Lennihan. Homeopathy for Pain Management. Alternative and complementary therapies. Oct 2017. Vol 23 (5). doi: 10.1089/act.2017.29129.ble Gabriel Tan et al. Efficacy of selected complementary and alternative medicine interventions for chronic pain. Journal of Rehabilitation Research & Development. Vol 44 (2), 2007, 195–222. doi: 10.1682/JRRD.2006.06.0063 Marcus Zulian Teixeiraa. Potentized estrogen in homeopathic treatment of endometriosis-associated pelvic pain: A 24-week, randomized, double-blind, placebo-controlled study. European Journal of Obstetrics & Gynecology and Reproductive Biology 211 (2017) 48–55. doi.org/10.1016/j.ejogrb.2017.01.052	

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Faculty of Pain Medicine	Guideline	General	General	Thank you for the opportunity to comment on the draft NICE guidelines on Chronic pain: assessment and management. We have submitted our comments below, however we would like to reinforce that we have significant concerns with the guidelines in their current form. These concerns are strongly shared by the Royal College of Anaesthetists, our multidisciplinary colleagues and lay groups. In particular, we would like to note that the FPM ANZCA have reached out to formally raise their concerns with us. Wetrust that the outlined concerns will be seriously considered as part of the review process and addressed in the final product. Should you wish to discuss our concerns further we would be happy to assist.	Thank you for your comments. Your individual comments have each been responded to below.
Faculty of Pain Medicine	Guideline	General	General	We are deeply concerned this recommendation uses confusing terminology. There is failure to succinctly distinguish between "chronic pain" and "chronic primary pain" in the document, made worse by the fact that the title is about chronic pain, and the content is predominantly about chronic primary pain.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and

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				While assessment guidance is for "all types of chronic pain", the only management guidance for "all types of chronic pain" given relates to Pain Management Programmes (more research needed) and Social Interventions (also more research needed). Everything else applies to "Chronic primary pain". This runs the risk of being highly confusing and damaging and essentially results in the guidelines not being fit for purpose. As a consequence, there is a serious risk that the recommendations will be taken to apply to all chronic pain. We have seen this in the way that the draft guidelines have been reported in the press.	added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Faculty of Pain Medicine				We are pleased to see ICD 11 recognised, but have serious concerns in the way in which ICD 11 classification has been used does not reflect clinical practice or the current research base. An important part of the ICD-11 definitions is that "chronic primary pain" can be changed to another ICD-11 diagnosis (e.g. neuropathic pain, cancer pain, musculoskeletal pain) when more evidence becomes available. In other words, "chronic primary pain" can be used as a terminology to acknowledge or validate the	Thank you for your comment. Recommendation has been included to highlight that initial diagnosis may change with time, particularly when presentation changes, and that diagnosis should be re-evaluated, and also to highlight that chronic primary

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				presence of chronic pain whilst awaiting further investigations or assessment that could then lead to diagnosing a specific pain condition. Whilst the advantage of ICD 11 is that it recognises pain as a condition in its own right, (allowing patients to be coded even if the underlying mechanism is yet to be fully elucidated), it does not infer a single defined entity, and as such forms a very heterogeneous group of patients. In fact, it is important to recognise that the diagnosis of chronic primary pain is a new entity, that has not yet found general applicability in clinical use in pain medicine, let alone been applied to a body of research about treatment. In fact, in several places in the document, the committee itself either explicitly acknowledges this and decides to include ALL chronic pain in the analysis, or in other places it seems to do this without acknowledgement. This confuses the reader and makes drawing rational conclusions tenuous. See the ICD-11 paper at https://pubmed.ncbi.nlm.nih.gov/30586067/ ICD-11 defines "chronic primary pain" as "pain in one or more anatomical regions that persists or recurs for longer than 3 months and is associated with significant emotional distress or functional disability (interference with activities of daily life and participation in social roles)	pain and chronic secondary pain can coexist. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with

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				and that cannot be better accounted for by another chronic pain condition". The flowchart in Fig 1 is, I think, where NICE have fallen down. Further, in the literature searches NICE have used, they have applied a different definition, so their evidence cannot directly apply: "People, aged 16 years and over, with chronic primary pain (whose pain management is not addressed by existing NICE guidance). This includes chronic widespread pain, complex regional pain syndrome, chronic visceral pain, chronic orofacial pain and chronic primary musculoskeletal pain other than orofacial pain." In particular, this does not include anything to do with distress or disability, and will exclude studies where patients from a related "secondary pain" group will have been included. Not surprisingly, few studies were found, of generally low quality, mostly comparing active treatment with placebo (which is always effective in itself), in each of the management categories, then concluded on the basis of these studies, that most treatments should not be offered on the NHS. There is a real risk that those classed as having "chronic primary pain" will include large numbers of people with a different, ultimately identifiable cause of pain, to whom this guidance should not apply. There is also the risk that	subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). The sentence you highlight is not the term that was used in the searches to cover chronic primary pain. The searches were broad and inclusive to include all conditions that were included under the ICD-11 umbrella term of chronic primary pain at the time of development of the guideline. Full details of the search strategies are

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				patients who are diagnosed with chronic primary pain, and who subsequently develop secondary pain are neither recognised nor treated appropriately. Nor does the guidance make any allowance for the frequent co-presentation of chronic primary pain and chronic secondary pain. The guidance is unhelpful to the general or primary care professional who may not have access to the resources required to confidently diagnose an underlying pain condition and who may erroneously perceive the problem to be Chronic primary pain This may deny appropriate management/onward referral to some. Whilst the use of ICD 11 classification is welcomed to signpost pain as a disease, it is important to recognize that in clinical practice, pain diagnoses are not discrete. A useful change would be to discuss pain diagnosis as overlapping, contextual, narrative, biopsychosocial diagnosis in detail and the implications. Crucially, the treatment rejection list is not evidence based as some of the treatments work in the areas of overlap of the various classifications used. The ICD 11 classification of Chronic Primary Pain does not represent physiologically or even phenotypically distinct groups of pain disorders. For example, CRPS is	available in appendix B of each evidence review chapter. The committee agreed that there was not evidence to support the use of the medicines that have been recommended against for chronic primary pain or in some cases the risk of harm outweighed the evidence of benefit. They agreed that where there was absence of evidence of effectiveness for a particular type of chronic primary pain, the knowledge of harm would not be condition specific and justified the recommendations not to use these medicines applying to all types of chronic primary pain. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions

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				widely regarded by experts as a distinct pain condition, with objectively verifiable phenomena- and either vaso-motor or neuropathic features often dominating. It is simply not reflective of our specialities attempts to help these patients that it is included in a "catch all" diagnosis of Chronic Primary Pain. It is not scientifically valid to assume evidence for one chronic primary pain condition can be generalised across all disorders included in the classification. NICE also does not consider the severity of the chronic primary pain condition in their treatment recommendations. A further personal member opinion was offered as follows: ICD-11 is confusing in my opinion: MJ60.1 – Primary chronic pain MJ60.11 – Chronic primary visceral pain i.e. reversal of "primary" and "chronic" Technically, "Chronic (unspecified) primary pain" does not exist. I think it would be helpful for NICE to substitute Primary Chronic Pain forChronic Primary Pain in their document. However, what is more important in my opinion is clarity that pharmacological recommendations only pertain to	may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised, but it is their view that it was appropriately categorised under chronic primary pain.

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				Primary Chronic Pain (Chronic primary pain as defined by NICE).	
Faculty of Pain Medicine	Guideline	General	General	We are concerned about the potential consequences of misinterpretation of these guidelines The conflation of chronic primary pain as defined by ICD 11 with chronic pain of other definitions and the subsequent rejection of efficacy of many established therapeutic options is likely to lead commissioning bodies gravely astray in their decisions regarding what treatments need to be provided by multidisciplinary pain units. The FPM harbour reservations about the possibility that the lack of clarity in the draft guidelines will lead directly to deskilling of pain services and adoption of ineffective modalities such as acupuncture instead of more appropriate and scientifically valid options. Specific concerns include: • Risk of decommissioning of Pain Management Programmes (PMP) because PMP is notrecommended by NICE	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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				• Risk of secondary pain services being decommissioned due to confusion caused by this guidance • Potential withdrawal of useful medications from patients by GPs	clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with

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					subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). The committee agreed that the evidence reviewed within this guideline did not enable a recommendation to be made for or against pain management programmes. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered

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					individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline. They also agreed that the evidence supported recommending against most medicines reviewed, but as stated above, have added clarity to the guideline to highlight the pharmacological recommendations are just for chronic primary pain. They

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					also have now added recommendations for a review of those who are already receiving these medicines. This includes considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms.
Faculty of Pain Medicine	Guideline	General	General	We have concerns about the approach to gathering and interpreting evidence used in these guidelines. The discussion of contentious areas such as gabapentinoids, acupuncture and opioids sees evidentiary standards inconsistently applied. The guidelines do not recommend pain management programs, for example, but do recommend acupuncture which has a highly suspect literature full of bias and extremely poor methodology, and is lacking in a rational scientific basis. The discussion of opioids is almost contradictory in places and seems to acknowledge that they may have short term efficacy but recommend against them on subjective grounds which are not made explicit. There are very significant difficulties with the application and the use of and approach to isolated areas of evidence in pain medicine in complex situations. The positivist or experimental method is methodologically unsound in this	Thank you for your comment. The methods followed to assess risk of bias in studies and quality of evidence are detailed in the methods chapter of this guideline. These methods are consistently applied across review topics. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. Methods for consideration of cost effectiveness were in line with NICE methodological guidance. The evidence for acupuncture demonstrates a consistent benefit in

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				context and sociological approaches should be considered in some areas. Lack of evidence from one methodological approach (e.g. randomised double blind trials) is not evidence of lack of effect. The FPM has concerns over removing treatments that are beneficial to individuals given the complexity of interpreting evidence whatever view is taken about future use of a treatment or procedure across the population of patients. Best pain practice requires a level of pragmatic support by experts in complex patients. Analysis of the cost-effectiveness of a specific treatment on an individual treatment basis could prove costly to the NHS if pathways are not considered as a whole. Management of these issues requires careful impact modelling on rebound costs from decision making around limiting treatments and new frameworks to determine the reliability of experiential, pragmatic evidence. (From FPM commissioning guidance 2020. In publication 2020). This NICE document risks showcasing these issues. It is expansive but confusing and therefore highly flawed to the potential serious detriment of patient care. Some specific points:-	pain and quality of life compared to usual care and sham as well as some benefits in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. Although the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee do not agree that the discussion on the evidence of opioids is contradictory. They highlight the lack of evidence of effectiveness and evidence of long term harm, and then comment that in their experience,

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				• PMPs when undertaken to defined National standards have a stronger evidence base than stated (See BPS document) notwithstanding the fact that many include CBT and ACT principles are used and reinforced which do have benefit. There is a large experiential type evidence much formally reported as well as trial data. • Strong opioids may be used for some (at a minimum intermittent, short term treatment of exacerbations of some chronic pain) from "opioids aware". This is a much wider consensus "experience" than that applied in this document. This consensus has been deliberated at length by multiple organisations. • Evidence for social and many other rehab interventions are pragmatic, small-scale, context specific but often make good and logical sense with visible benefit e.g. guidance on return to work. Competent social interventions will likely not ever gain traction under the medical evidence frameworks used. • The key benefit of providing advice on self-purchased) TENS in avoiding harmful or expensive treatments is underemphasised and	even short-term use of opioids could be harmful for a chronic condition. The committee were aware of the BPS Guidelines for pain management programmes for adults. Where programmes with CBT/ACT elements as well as a physical component were identified, they were included within the guideline review. The levels of evidence applied in the BPS document cannot be directly compared to the quality of evidence ratings applied in this review as the methodologies differ. The methods followed by the BPS guideline are only described very briefly but state that they follow the approach used by SIGN. The protocol used for selection of included studies is not provided. This guideline review uses the GRADE approach for assessing quality of evidence as detailed in the NICE guidelines manual

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				will not be resolved by the unhelpful trial data. The experience is that in contrast to acupuncture, this helpfully promotes self-efficacy and is much cheaper and saves money beyond its low cost even if the measure of efficacy is ultimately "n of 1" patient reports.	and the methods chapter for this review. The evidence for pain management programmes was much poorer than that for acupuncture. The quality of evidence was similar ranging from very low to moderate at best. Benefits were only consistently observed for quality of life for mixed types of chronic pain, when the chronic primary pain population was separated in subgroup analysis no consistent benefit was observed in any other outcome, and the majority of evidence for chronic primary pain showed no difference compared to usual care. The review considered published RCT evidence for TENS in people with chronic primary pain, which is agreed as the best type of evidence for an intervention review. Only 2 studies were identified relevant to the review

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					protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
Faculty of Pain Medicine	Committee membership			We have concerns the NICE committee is not representative of the majority of expert pain opinion. In many areas, there are references to subjective interpretations and "in the committee's experience" but this is a somewhat weak, evidential approach for qualitative evidence. There are wider bodies of expertise available and better qualitative evidential approaches. In	Thank you for your comment. The committee were recruited according to processes set out in the Developing NICE guidelines: The Manual, and represent the range of expertise agreed appropriate to cover the scope of the guideline discussed at the

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				particular, we are concerned there is minimal pain medicine representation on the committee. Some members also have concern over conflicts of interest where the committees "experience" is used - Two of the members of the committee are involved with a company called Connect Health which offers community exercise programs and MSK education - two areas the guidelines recommend. They are likely to benefit from this personally.	stakeholder workshop. The discussion of the evidence sections of the evidence reviews reflect the committee's distillation of the evidence into recommendations. The Committee must use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others. They are recruited for their experience and expertise which contributes to their judgement of the evidence and when consensus recommendations are made this is explicitly stated in the discussion of the evidence. The committee adhered to the NICE conflicts of interest policy and all members with any potential conflicts declared them and appropriate actions were taken and noted on the

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					declarations register that is publicly available. Where the conflict required them to withdraw from discussions, the committee member withdrew from all discussions and decision making on recommendations for that topic. The minutes of each meeting state where committee members withdrew from discussions.
Faculty of Pain Medicine	Method	General	General	We have concerns about the interpretation of evidence relating to acupuncture and the subsequent recommendations. The benefits of acupuncture are over-emphasised against the clinical experience of practitioners who have a range of other options, reflecting lack of weight given to technical flaws in the interpretation of trials. The potential harm of frequent practitioner dependency treatments in patients is not carefully considered. There is the assumption in assessment of studies relating to acupuncture and exercise, that 'other care' for both intervention and non-intervention groups was equal. This is - pragmatically - improbable. The evidence chosen for acupuncture is heavily biased towards those with a likely muscular component to their	Thank you for your comment. The same methodological criteria and quality assessment is applied to all reviews in the guideline as detailed in the methods chapter. Each study is assessed for risk of bias including an assessment of the comparability of care in each arm of the study. Where this is not considered to be equal, this would be considered as a risk of bias. The quality of each outcome is assessed following GRADE processes taking into account risk of bias of the individual studies, the inconsistency, imprecision and indirectness.

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				pain presentation. There are no included studies on patients with CRPS, yet this treatment is now recommended for them because they fall under the umbrella classification of 'chronic primary pain'.	The evidence informing the acupuncture review does consist of a large number of trials of fibromyalgia and head/neck/shoulder pain. There are also studies included in people with myofascial pain and pelvic pain. There was no evidence in the review to indicate a difference in effect according to subtype of chronic pain. Where there was heterogeneity in pooled analysis, subgroup analysis was undertaken by type of chronic primary pain, but this did not explain the heterogeneity. The committee therefore agreed there was no reason that the recommendation should not apply for all types of chronic primary pain.
Faculty of Pain Medicine	Guideline	Page 005	015 1.1.8	Good to see patient's concerns with negative or normal results are addressed and empathised with.	Thank you for your comment.
Faculty of Pain Medicine	Guideline	Page 009	010 1.3.11	Not offering prescription medication could lead to patients not disclosing over the counter/non-prescribed medications they are taking for fear of criticism. Painkillers are available everywhere so they will be a person in pain's "go to" medication as a first choice and it	Thank you for your comment. We are aware that some of these medicines are available to buy over the counter. The evidence reviewed in this guideline did not support recommending the use of these

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				is better for them to be prescribed and supervised rather than the patient self-medicate inappropriately.	medicines however. These guidelines are intended for people with chronic pain and chronic primary pain, as well as healthcare professionals and we hope will highlight the lack of evidence that these medicines will help chronic primary pain.
Faculty of Pain Medicine	Guideline	Page 009	0028	Patients may be reluctant to disclose this information if they know they will be unlikely to receive any prescribed medications as above.	Thank you for your comment. This statement relates to an MHRA safety update and is required to be considered for anyone who may be prescribed pregabalin or gabapentin.
Faculty of Pain Medicine	Guideline	Page 011	017	Limitations in availability of these services and it varies dramatically throughout England.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where

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					resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Faculty of Pain Medicine	Guideline	Page 028	022	Patients with a long term chronic condition may feel lost if the referral to a specialist will become less likely and the GP would not have the clinical experience to manage these long term cases. This could cause strain on the GP/patient relationship as there is no onward referral pathway if the GP has to manage the patient themselves and is not expected to prescribe long term pain relief medications.	Thank you for your comment. The committee agree that specialist assessment for diagnosis and management of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. Clinical judgement should be used when specialist advice is required.

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Faculty of Pain Medicine	Evidence			Several large, high quality, randomised, double-blind trials that were used to judge evidence by, amongst others, the FDA, EMEA and Cochrane reviews have been excluded, thereby informed judgement in writing these guidelines will have been affected.	Thank you for your comment. At each stage in the review process, inclusion and exclusion decisions were checked and verified with the committee. Further to this we have cross-checked with the relevant high quality systematic reviews (such as the Cochrane reviews) for any included studies that meet the review protocols for this guideline. The references provided by stakeholders following consultation have also been checked, however, with the exception of 4 studies on exercise in people with shoulder pain (the overall impact of these slightly strengthened the clinical evidence base for exercise), all other studies were agreed to have been excluded appropriately. All relevant Cochrane reviews were considered and references lists checked for any relevant studies, where these couldn't be included.

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Faculty of Pain Medicine	Guideline	017	013	RCoA Lay Committee comment: This comment may imply there are no circumstances or individuals for which supporting the costs of ongoing physical activity costs are financially effective.	Thank you for your comment. This has been reworded to clarify that there may not be a cost incurred by remaining physically active.
Faculty of Pain Medicine	Guideline	010	003	RCoA Lay Committee comment: The guidelines should include that patients can receive medical help and other help for withdrawal problems Withdrawal management is mentioned though it looks like only in passing.	Thank you for your comment. We have not reviewed the evidence or withdrawal management strategies within this guideline, however this guideline will cross refer to the NICE guideline on safe prescribing and withdrawal management where guidance on this topic will be addressed.
Faculty of Pain Medicine	Guideline	General	General	RCoA Lay Committee comment: The guidance recommends discounting some treatments currently used quite widely, e.g. some pharmacological therapies and electrical physical modalities. This will be challenging and may discourage patients if the alternative treatments which are recommended are not available in a timely manner, e.g. CBT therapy. The risk of this may be greater if the original and new treatments are provided by different organisations. Where physical exercise is advised as a treatment there may be a challenge if local facilities, e.g. swimming pools, gyms etc. are less available or have ceased to be available because of COVID precautions.	The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where

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				The guidelines are overly full of do's and don'ts to the extent that it seems thin on what practitioners can usefully do. They should recommend a face to face consultation to examine what the issue is and what currently helps the patient. As there wasn't enough evidence for anything except research recommendations, this makes the guidelines sound negative. The parts about exercise, patient involvement and recognition of patients' needs were good. Despite what they, the public may still look to Tens, ultrasound and over the counter meds when they have chronic pain.	resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The committee agree that a holistic assessment and fostering a collaborative supportive relationship with the person is critical to good pain management. The assessment recommendations have been reworded and strengthen the importance of this, including discussing what currently helps as well as discussing the risks and benefits of all treatment options when developing the shared care and support plan and at all stages of care.
Fair Treatment for the Women of Wales	Guidance	007	001	Access to psychological therapies is likely to be a key determining factor in how beneficial they will be; currently, at least in Wales, those with confirmed mental health conditions are already waiting years for CBT or similar. As we emerge from Covid-19, there will be an inevitable increase in demand, so adding chronic pain patients to the list is likely to see totally unreasonable	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment,

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				waiting times, even for those who have heightened clinical need. It is well-known that the earlier one accesses psychological therapy, the more likely it is to be successful, therefore, any potential benefit associated with therapy will be vastly reduced for all recipients on a waiting list longer than 6 months. Given a UK-wide unavailability of services, it seems even more pressing that chronic pain patients are only offered psychological therapy where it is most appropriate and where the patient is likely to be fully compliant. This should take into account the patient's preparedness and ability to continue with therapeutic exercises in their own time, something that may not be possible for all patients and is very much dependent on their home circumstances, lifestyles, and capacity. Our chief concern is that patients with – as yet – undiagnosed conditions causing their pain will be referred for 'acceptance and commitment therapy' inappropriately, something that is particularly worrisome when we consider that this guideline is aimed at those aged 16 and over. We would ask NICE to make clear its protocols for ensuring that all potential pathologies are ruled-out first.	such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. The committee agreed that some guidance was required in identifying people with chronic primary pain and the need to consider other causes of the pain. Additional recommendations have been included in the assessment section (1.1) to address this. The assessment recommendations highlight the importance of fostering a collaborative supportive relationship, and include highlighting the need to

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				Where young women and other marginalised communities are concerned, the fear is that such patients will be hastened onto the 'Chronic Primary Pain' pathway, including its recommendations for ACT and CBT, resulting in an even more firmly entrenched tendency to dismiss those conditions which, without routine access to specialists, cannot be reliably visualised, diagnosed or ruled-out. Equally, it is of vital importance that people with chronic pain are not made to feel as though they're being offered 'therapy' because their pain is imagined. Historically, women have been subjected to labelling of this sort, with symptoms dismissed as being evidence of 'hysteria'. To a degree, these attitudes persist, with pelvic and / or menstrual pain often linked to stress or a tendency to 'over-dramatise'. Given that it is only relatively recently that gynaecological conditions are getting the recognition they deserve, it is essential that any referrals of this nature are handled sensitively and explained carefully as additional tools to help the patient manage their very real experience of pain. Trauma psychotherapists in our network suggest that whilst CBT may have its place, integration of the skills of ACT, MCBT (Mindful-based CBT), CFT (Compassion-focused Therapy) and Somatic Therapy were most successful with their cohort of fibromyalgia patients, as it	be sensitive to the risk of invalidating the person's experience of pain. The evidence for pain management programmes is reviewed in evidence report C. In consideration of stakeholder comments, the evidence in that review has been reanalysed to separate the chronic primary pain population, to be consistent with other reviews within the guideline. The committee agree that for this population most of the evidence did not show an improvement in quality of life and there was no evidence of benefit for pain, physical function or psychological distress. They therefore did not include a recommendation on the topic.

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				was possible to tailor aspects of this integrative approach to suit patients' individual needs. Our colleagues report that the most empowering and powerful means to psychological improvement and wellbeing was the sharing of experiences with others by way of facilitated group interaction. Patient autonomy and co-production of the programme's development proved hugely empowering and beneficial, demonstrating the importance of collaboration for mental health. Ultimately, there is a tentative acceptance that psychological therapy can be useful in helping patients find a way to live with their chronic pain, something that can be completely life-altering and life-limiting. For the most part, patients understand that being in a better place mentally can help with the management of their pain. However, they also point out that psychological therapy does not treat the chronic pain itself and that there needs to be a specific pain management programme in place so that symptoms are sufficiently under control for them to get the most out of any psychological therapies offered. In Wales, we often hear of patients being seen by a community mental health team (the first step to accessing therapy) only to be turned away, as their issue is 'physical pain' not a mental health condition. We would imagine that this applies equally to the rest of the UK. Clearly,	

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				there is much work to be done on ensuring there is both adequate service provision to cope with additional demand, as well as an appreciation on the part of mental health personnel that their services are appropriate for such patients. Unfortunately, as we write, not enough mental health professionals understand the psychological implications of chronic pain or how to help manage it. We would strongly recommend that chronic pain management features far more strongly in the training of community mental health teams and NHS psychotherapists / psychologists, alongside the development of multi-disciplinary team-working to ensure psychological interventions are a fully integrated part of pain / disease management.	
Fair Treatment for the Women of Wales	Guideline	001	General	Despite assurances on page 1 of the guideline, we are concerned that assumptions are being made that the conditions listed will be suspected / diagnosed in a timely fashion to ensure the most appropriate guidance is used. Where endometriosis is concerned for example, research shows that this is likely not the case. Diagnostic delay for the condition can be several years (even longer if initially presenting at a young age). As such, the problem with this guideline is that patients may find themselves consigned to a non-specific 'chronic primary pain' classification, with the inherent risk that no further investigations are	Thank you for your comment. This guideline provides general principles for assessment of all types of chronic pain, but does not cover the diagnosis of these. For chronic secondary pain, that is covered in the condition specific NICE guidelines. Recommendations have been added to this guideline to highlight when to consider a diagnosis of chronic

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				initiated. The same can be said for any condition where diagnosis takes a long time and where investigations may be convoluted, often requiring repetition / further analysis by different specialists.	primary pain (including if there is no clear underlying cause) and that initial diagnosis may change with time and should be re-evaluated.
Fair Treatment for the Women of Wales	Guideline	004	006	The guideline refers to knowing the patient as an individual; however, in general practice this is something which is increasingly less likely. Changes to models of care mean that there will often be multiple healthcare professionals involved in delivering services. Further, fewer GPs, alongside increased demand, often results in patients seeing locums rather than one consistent 'family doctor'. This can have very real implications for patients with complex, chronic pain and co-morbidities.	Thank you for your comment. The guideline reflects best practice and therefore the committee agreed this is an important factor to include in the recommendations and is what should be aimed for.
Fair Treatment for the Women of Wales	Guideline	004	010	The guideline refers to shared decision-making as the most effective way to improve patient experience. However, there remains a real lack of consensus between patients and healthcare providers on what this entails. Patients with complex health issues, multifarious (and, at least initially) unexplained symptoms regularly report feeling disempowered and unable to exert voice and control over their care. This is particularly pronounced in those instances where the patient has to navigate complicated referral pathways and where systems and processes appear unwieldy and not patient-centred. Often, the patient will be reliant upon the GP to make numerous, repeated referrals to various specialisms in the	Thank you for your comment. The committee are aware of the NICE guideline on shared decision making which is currently in development. This has been added to the list of guidelines currently in development in the methods chapter that accompanies the guideline. There are also recommendations in the NICE guideline on patient experience in adult NHS services (CG138) which this guideline cross refers to.

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				quest for a diagnosis and most appropriate treatment plan. For those with 'rarer', multi-factorial health conditions, this can be a lengthy, even tortuous journey, requiring persistence and strength on the part of the patient and particular dedication on the part of the GP. It is at these junctures that the patient most requires the open-mindedness, support, and advocacy of their healthcare providers; however, pressures of time and lack of capacity can often result in the opposite. Clearly, much needs to be done to make shared decision-making a real possibility, not only in terms of re-examining the form of care provided to chronic pain / complex patients but also how medical training can focus on the development of shared decision-making as an approach. We would ask that the Committee uses this guideline as an opportunity to recommend the inclusion of training on shared decision-making as a core component of the medical curriculum and as part of on-going professional development. Further, we would ask for a recommendation to be made for this to kind of training to be co-produced and co-delivered by patients to make it as authentic and effective as possible. We would ask that the guideline makes a recommendation for universal access to electronic	

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				patient records, so that patients are enabled to participate fully in the management of their own healthcare.	
Fair Treatment for the Women of Wales	Guideline	004	011	There is concern that medical appointments focused on the discussion of pain tend to appear to be of lower importance to healthcare professionals unless that professional is a pain specialist. There needs to be a recommendation in the guideline making explicit that the doctor-patient relationship in these instances must be completely collaborative, where the patient is an active participant in the creation and implementation of any treatment plan, that it is personalised to their individual needs, and flexible enough to accommodate changes.	Thank you for your comment. The recommendations include one to highlight the need to foster a collaborative and supportive relationship. The committee agree this should be a shared process based on a person-centred assessment and that a shared care and support plan should be based on the person's priorities, abilities and goals. The recommendations are worded accordingly and intend to highlight these elements.
Fair Treatment for the Women of Wales	Guideline	004	018	The guideline recommends asking the person about their 'understanding' of their condition. It is important to be aware that in this technological age, access to clinical research, information, and medical specialists (many of whom give their time freely in online support groups, for example) is far easier. As such, many patients will have spent considerable time and energy investigating underlying pathologies; the level of personal expertise, garnered both through this process and personal experience, should not be under-estimated. Despite this and the recommendation for shared decision-making,	Thank you for your comment. The committee agree that people with chronic pain may be very well informed and agree this should form part of the discussion and shared decision making. Recommendations of training requirements are beyond the remit of the guideline.

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				there still tends to persist a paternalistic culture where patients' own knowledge and understanding is diminished. We would ask that the guideline makes a recommendation for training on shared decision-making be a key part of all initial and continuing professional development, and that this training be co-produced and co-delivered by patients / patient groups.	
Fair Treatment for the Women of Wales	Guideline	004	018	The guideline recommends asking the person about their 'acceptance' of their condition. We have significant concerns over the use / mis-use of this word and its connotations, particularly when the guideline is aimed at young people of 16 and those people who may well have complex and / or rare health conditions. Our respondents encompass those for whom an underlying cause for pain has eventually been found after several years and numerous investigative procedures. There is a very real fear that patients will be asked to 'accept' a life of 'chronic primary pain', legitimising healthcare providers' reluctance to investigate possible (if rarer) pathologies or emerging research. We would ask that the guideline considers alternative descriptions for the process of working through a patient's pain and that the word 'acceptance' is used cautiously and with certain provisos attached.	Thank you for your comment. On consideration of stakeholder comments the committee agree that the word 'acceptance' should not be included in the recommendation and have now removed it.

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Fair Treatment for the Women of Wales	Guideline	004	018	It is worth noting that small-scale research by trauma psychotherapists would tend to suggest that around 50% of cases of 'chronic primary pain' appear to show a correlation between the experience of historical trauma and persistent pain. It is therefore very important that the doctor-patient relationship is sufficiently robust and long-term to enable time to be spent on exploring any links between physical / emotional trauma and how it may connect to current physiology. It is also crucial that healthcare professionals possess a comprehensive understanding of what constitutes 'trauma', as it is wide-ranging and unique to the individual. For example, someone with a history of invasive abdominal operations may be said to have experienced a form of physical trauma; likewise, a person who has experienced a sudden or unexpected bereavement may be experiencing emotional trauma. Conversely, these indications also demonstrate that around 50% of chronic pain patients will not have experienced any form of historical trauma, so conversations of this nature need to be carefully managed to avoid erroneous and damaging assumptions about the patient experience.	Thank you for your comment. The committee agree this is important. Consideration of previous physical or emotional trauma has been added to the assessment recommendations.
Fair Treatment for the	Guideline	005	001	The guideline refers to discussions with patients about what causes their pain. The guideline does not make clear	Thank you for your comment. The guideline applies to all settings in

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Women of Wales				who will be leading this discussion, but our understanding is that that conversations of this nature tend to be held in primary care settings. We would wish to know how far this section of the guideline allows for cases where pain may be linked to a rare / difficult to diagnose condition or where the clinician hasn't yet had the exposure to, or specialist training in, a particular condition to be able to discuss causes, expectations, or outcomes. We would like to emphasise that it should only be decided that a person's pain has no apparent cause when there have been comprehensive investigations and all potential pathologies have been categorically ruled-out. It is important that clinicians bear in mind that less common conditions may have been overlooked, or that there may be causal factors not fully appreciated or understood at that point in time. We are particularly concerned that the guideline may see patients fall into the 'chronic primary pain' category by default when they actually have a secondary pain condition that has not (yet) been diagnosed or where the pain implications of a diagnosis are not universally accepted (particularly where the clinician responsible for ongoing management of the patient may not be a specialist in the condition). This problem can be compounded if there is no NICE guideline for that specific condition. A considerable number of our	which NHS care or local authority funded care is provided. The recommendations apply to any healthcare professional who is undertaking an assessment of someone with chronic pain, but the committee agree it is likely that this will be in primary care. The guideline includes recommendations for general principles of assessment of chronic pain, but not diagnosis of specific conditions. For chronic secondary pain this is covered in the condition specific NICE guidance. The committee acknowledge that not all conditions are covered by NICE guidelines. Clinical judgement must be used in these situations. Recommendations have been added to this guideline to highlight that chronic primary pain should be

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				respondents have either suspected or confirmed Ehlers Danlos Syndrome, a notoriously complicated condition to diagnose as it has many variations and classifications. Often, the pain implications of the condition go unrecognised, but patients report repeated episodes of acute pain from repeated tissue trauma or musculoskeletal injuries which ultimately overlap, resulting in chronic if intermittent pain. It is most important that this guideline is not used erroneously to manoeuvre patients onto a pathway which doesn't adequately represent their situation. We would also ask that there be acknowledgement of how this guideline may have pronounced implications for marginalised communities, including women, people of colour, disabled and learning disabled people, autistic people, and those with neuro-developmental conditions. These communities are more likely to experience their symptoms being under-estimated or misunderstood and incurring increased diagnostic delay. It is vitally important for the future wellbeing of these people that pain is not classified as 'chronic' and 'primary' without explicit awareness of the role unconscious biases may play and full, proper, timely investigation of possible causation. We would ask that the guideline incorporate wording to demonstrate that doctor-patient discussions will be on-going, that there will be an openness to emerging	considered only if there are no underlying causes. An equalities impact assessment form is published to accompany the guideline where the committee's consideration of equalities issues in relation to the recommendations are considered. The committee do agree that there are particular considerations for assessments of some groups of people and cross refer to the NICE guideline on Patient experience in adult NHS services, CG138. The guideline did not include reviews on specific training for healthcare professionals and therefore recommendations on this topic cannot be included.

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				research and innovations, and that there is a willingness to engage in continuing dialogue with other specialties. We would ask that the Committee consider including a recommendation around unconscious bias awareness and training, both as part of the medical curriculum and on-going professional development. We would also ask that this training involve real-life patient experience(s) to make it as authentic and effective as possible,	
Fair Treatment for the Women of Wales	Guideline	005	012	The guideline is correct in recommending that all care plans should be developed collaboratively, with the person with chronic pain. We know that each disease, condition, or symptom will affect individuals differently, and that people's lives are vastly different in terms of work / relationships / demands. No two people will experience the same things exactly or respond to every intervention in the same way. This does not mean that the patient is unwilling or non-compliant but that the healthcare provider needs to be open to hearing and taking on-board those unique perspectives and be prepared to tailor any care / treatment plan to the individual's needs. The guideline should make explicit recommendations around relationship-building, continuity of care, and extended appointments being required.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there are areas that may need support and investment, to implement some recommendations in the guideline and also highlight that to fully implement these recommendations for people with chronic pain, longer consultations or additional follow-up may be needed to discuss self-management and treatment options. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas.
Fair Treatment for the Women of Wales	Guideline	005	015	The guideline refers to 'communicating negative or normal test results': the focus on not invalidating the person's experience is an important one. It is equally important however for the healthcare professional not to view such results as necessarily final or conclusive. The guideline should make clear the need for both parties to appreciate that one set of test results are just one part of an on-going conversation. The patient may require reassurance to this effect.	Thank you for your comment. The committee agree that it is important to note that initial diagnosis may change with time and have included a recommendation stating this, and that it should be re-evaluated if the presentation changes.
Fair Treatment for the Women of Wales	Guideline	005	017	We would ask how NICE proposes to ensure that the appropriate condition-specific guideline is utilised, given the diagnostic delay for endometriosis, for example. Whilst we appreciate its being listed as a condition causing pain and for which a guideline exists that should be consulted, the very real concern is that it is often many years before the condition is suspected or formally diagnosed. As such, how can patients be assured that symptoms are properly managed, and a diagnosis expedited, so as to ensure they are not erroneously placed on the 'chronic primary pain' pathway? These same concerns apply to any number of conditions which incur diagnostic delay, rarer conditions, and conditions for which unconscious biases may play a part. We would suggest that a recommendation be made regarding unconscious bias awareness and its	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate so that the correct guidance is followed. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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				incorporation into initial medical training and continuing professional development, given the significant role it can play in classifying patients and designating pathways.	included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Fair Treatment for the Women of Wales	Guideline	006	011	The guideline recommends 'a supervised group exercise programme' whilst conversely also asking healthcare professionals to consider 'people's specific needs and preferences'. It is worth pointing out that, for some individuals or communities, group exercise may not be either desirable or appropriate. It is also important that any recommendation around exercise takes heed from the increasingly criticised recommendations regarding 'graded exercise' programmes for those with ME / CFS. Patients should not feel forced into undertaking an exercise programme which is unsuitable or even exacerbates symptoms, nor should they be made to feel that any justifiable	Thank you for your comment. The evidence reviewed in the guideline demonstrated effectiveness of supervised group exercise programmes. The committee agreed that the type of exercise may depend on the type of pain, but also that people are more likely to continue with exercise if the programme offered suits their lifestyle and physical ability and addresses their individual health needs. They agreed that the choice of programme as well

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				reluctance on their part will see them labelled as non-compliant. Whilst many of our respondents appreciate that exercise can have benefits, they also ask that prescribers be aware that such sessions require significant rest and recovery periods afterwards – not always possible for those with families or work commitments. Trauma psychotherapists working with fibromyalgia patients point out that many of their clients had very active lives prior to onset of symptoms but that exercise now leaves them exhausted and in more pain, something that can be counter-productive to both self-management of the condition and psychologically, as an association between exercise and pain exacerbation develops. Logistically-speaking, we wonder how far it's possible for a group exercise programme to accommodate very different and specific needs, abilities, and health conditions. Even within symptom groups, patients will be impacted to different degrees, so a one-size-fits all approach would be unsuitable and likely difficult to facilitate. From the patient perspective, exercise isn't always a viable option, depending on the nature of the health condition(s) with which they are living. We know that for	as the content should take into account people's abilities and preferences. This might include providing individual exercise advice for different members of a group. This was highlighted in the recommendation and in more detail in the rationale underpinning the recommendation.

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				some with gynaecological disease, the amount of inflammation can cause extensive bloating when undertaking exercise; for those with EDS, exercise can cause subluxation or dislocation of joints. These points suggest that if group exercise is to be considered as a key part of any chronic primary pain treatment plan, there needs to be a very careful, person-centred approach which has far more cost implications than a far more generalised group approach. Furthermore, whilst exercise may well help some patients manage their condition to a certain degree, it is our opinion that such programmes should really only be seen as supplementary to an approach that treats or controls any underlying pathology, enabling participation in exercise programmes in the first instance. Conditions for which there are no cure or specific treatment can often deteriorate over time, making exercise programmes more difficult or damaging; ensuring that the approach is sufficiently flexible and agile enough to adapt to the patient's changing needs may make access more complicated and costly.	
Fair Treatment for the Women of Wales	Guideline	007	007	Access to services will again be a determining factor in how far acupuncture can be utilised as a standard approach to chronic primary pain management.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services

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				We would agree with the committee that acupuncture as a modality needs further research in terms of frequency of sessions, ie whether short courses can be repeated throughout a patient's life. Existing evidence does not necessarily account for various skill levels of practitioners, varying the types of acupuncture and placing of needles, for example. However, if subsequent evidence shows that additional courses or follow-on courses of different types could be effective, there will need to be a re-examination of costs. It is most important that NICE recommendations do not further exacerbate socio-economic inequalities in terms of access to services and resultant health outcomes.	across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This highlights areas where resources should be focussed and those that should not be recommended, saving resource in other areas.
Fair Treatment for the Women of Wales	Guideline	007	011	The recommendation that acupuncture be delivered in a community setting may pose problems for those in rural areas with limited access to services and / or appropriate settings for a clinical intervention of this nature.	The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation. We acknowledge that access to some of these services is likely to vary geographically.

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					However the committee considered it important to recommend those with evidence of effectiveness to encourage the development of pathways and access.
Fair Treatment for the Women of Wales	Guideline	007	013	The duration of the acupuncture course offered demonstrates that this is seen as only a short-term intervention when chronic pain by definition is long-term.	The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This

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					research recommendation has been made high priority in response to stakeholder comments.
Fair Treatment for the Women of Wales	Guideline	008	004	The recommendation to not offer TENS machines to people aged 16 or over with chronic primary pain may have particularly negative repercussions for women with pelvic pain / cyclical pain for whom, as we have established, diagnostic delay is a very real problem. Patients in this category can often find themselves erroneously classified as having pain with no discernible cause and are forced to find ways to self-manage symptoms; TENS machines are devices they tend to source for themselves which may be one reason why research on their efficacy is limited. It is important that NICE recommendations do not exclude approaches which are easily and readily available to patients and which are generally free of risk / side-effects. The decision to not recommend TENS (and similar devices / self-applied modalities such as ultrasound) contravenes the overarching theme of the guideline to facilitate individualised care, bespoke pain management programmes, and patient autonomy. We would urge the Committee to reconsider its wording on approaches like TENS which, whilst not effective for all, can be appropriate for some patients especially as	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any

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				they give those patients some capacity to self-manage symptoms as and when they occur. Given that there are likely to be extended waiting times for services and interventions, it is important that patients have options available to them in the interim and ones over which they have control as opposed to being passive recipients.	evidence of benefit this should not be recommended. This guideline includes recommendations to aid assessment and diagnosis of chronic primary pain and recommends other interventions for which there is demonstrable evidence of benefit. There are areas that may need support and investment to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Fair Treatment for the Women of Wales	Guideline	008	008	We would ask that a list of what the Committee considers to be manual therapy is clearly delineated within the main guideline.	Thank you for your comment. The list of types of manual therapy considered within the review is detailed in Evidence review I in the PICO table

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					(table 1) and in the full protocol in appendix A.
Fair Treatment for the Women of Wales	Guideline	008	010	We would agree with the Committee that more research is needed on the efficacy of manual therapies. However, we would argue that, for women with chronic pelvic pain for whom no diagnosis has been posited or which persists after repeated operations, focused pelvic physiotherapy for pain, including myofascial release and visceral manipulation, are amongst a range of a well-established and effective modalities. In Wales, the Welsh Government is investing in the provision of pelvic physiotherapy for pain as part of its pelvic wellbeing pathway implementation programme. Assuming that research is conducted, and efficacy established, the next step is to ensure that services are universally accessible for patients in need. Like psychological therapy, acupuncture, bespoke exercise programmes and the like, interventions of this nature are frequently only available at cost to the patient, rendering them inaccessible for those on low incomes. NICE must be careful not to further entrench health inequalities according to socio-economic status. NICE must also be mindful of how people in rural areas may not be able to access certain services due to lack of appropriate providers or settings.	Thank you for your comment. The committee agreed that the evidence reviewed in the guideline was not sufficient to recommend manual therapy for chronic primary pain at present. It is hoped that research will be able to inform future updates of the guidelines. Where recommendations are made for interventions, this is for interventions to be provided on the NHS not at the cost of the individual. We acknowledge that access to these services is likely to vary geographically. However the committee considered recommending these services can help encourage the development of services and improve access. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS

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				As part of its research, NICE should examine how manual therapies can be better integrated into a multi-disciplinary approach to care. This should include investigating how the NHS can ensure appropriate training for healthcare professionals, both for those providing the service, and for colleagues working alongside and as part of a MDT. Also, with Covid-19 still affecting service provision, NICE needs to consider how physical, 'hands-on' interventions of this nature can take place and what can be offered in their stead whilst there are restrictions in place.	services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
Fair Treatment for the Women of Wales	Guideline	008	General	The guideline recommends considering antidepressants in the treatment of chronic primary pain, a recommendation based mainly on a small number of studies done on women with fibromyalgia. We are concerned at the assumption that data drawn from such studies can be extrapolated to all chronic primary pain patients. This seems to be a poor example of evidence-based practice, not least because fibromyalgia itself suffers a dearth of large-scale research into causation and treatment. We would ask the Committee's recommendation on offering antidepressants in place of traditional analgesia be carefully worded, both in the context of the guideline itself and in any clinical setting. This is to reflect the fact that, whilst there is some evidence to show the	Thank you for your comment. Whilst it is true that a number of studies included in the review were in women with fibromyalgia, the evidence for antidepressants included other chronic primary pain populations such a chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Heterogeneity was not observed between types of chronic primary pain, so the committee agreed it provided no evidence against

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				usefulness of certain psychiatric drugs in the management of chronic primary pain, it is important for prescribers to acknowledge to patients that they are being used off-label and that, as such, pain management is not their primary purpose. Further, this would tend to point to a continuing lack of compelling evidence for their efficacy in these situations / for all patients. We would ask that the guideline makes clear to both practitioners and patients that the taking of psychiatric medication, even in low doses, is not to be taken lightly or be perceived as a panacea. Evidence continues to emerge around the mis-prescribing of these medicines and the under-reporting of serious side-effects, including suicidal ideation and action. Certainly, where SSRIs like paroxetine / Seroxat are concerned, we would like more clarity over how the chronic primary pain guidance corresponds with contraindications for the use of such medicines in young people. It is vital that the guideline makes clear that anti-depressants should be used with caution. There is a significant difference between offering patients a very low dose of a tricyclic medication like amitriptyline and a full dose of an SNRI like duloxetine. The guideline doesn't make this distinction clear enough and, if prescribing is taking place in typically shorter appointments utilised in primary care, it is perhaps not realistic to assume that all	making this recommendation to be for all people with chronic primary pain. We have highlighted in the rationale for this recommendation that this is off license use, but also the evidence underpinning the recommendation, demonstrating benefit in this population for outcomes including pain. Thank you for your comment. Detail on the suggested doses for off license use of the antidepressants recommended has been added to the rationale for this recommendation. The recommendations in the assessment section highlight that development of a shared care and support plan should include a discussion of the benefits and harms of all treatment options. The committee agree this should include information about what outcomes treatments have been shown to

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				associated / linked guidance documents will be to hand. In the first instance, the healthcare provider should clearly explain to the patient how the drug works in the context of pain rather than depression. It is also important for healthcare professionals to appreciate that chronic primary pain may cause depression and anxiety rather than the reverse. As such, developing a supportive, collaborative relationship with the patient is vital, particularly when conversations are likely to include long-term management of both physical and associated mental health. Open, honest dialogue is required, so that doctor and patient can discuss benefits and limitations of antidepressants. It may be that for some patients, antidepressants improve mood which, in turn, make coping with pain easier. However, discussions of this nature should always be tailored to the individual's perspective, condition, and needs. Potential side-effects and issues around withdrawal should be explained clearly, so as to allow the patient to make an informed choice and facilitate shared decision-making. We would ask that the Committee suggests that psychiatric medication be prescribed with the oversight of a clinician with a special interest in mental health / psychiatry, particularly as, in some patients, these	benefit, these have been detailed in the rationale sections to aid the discussion. The committee agree that developing a supportive and collaborative relationship with the person with pain is critical to good management as is tailoring the discussion according to the person's perspective and needs. These points were included within the assessment recommendations in section 1.1 of the guideline. The committee also agree that side effects and risk of withdrawal symptoms should be discussed. The recommendation specifically states that there should be a full discussion of the benefits and risks. A separate recommendation is also included to highlight the need to discuss the problems associated with withdrawal.

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				medicines can trigger psychiatric or mental health issues which require specialist intervention. As the guideline acknowledges, withdrawal from these medications can be difficult, so prompt access to mental health professionals needs to be factored into any pathway initiating a potentially widespread use of drugs of this nature. We would also ask that the Committee make a recommendation to healthcare providers around the terminology used in suggesting psychiatric medication to chronic primary pain patients. It is vital that clinicians are cognisant of residual stigma associated with the use of psychiatric medication and the inference that pain is 'not real' but an imagined or psychiatric disorder. These issues may well affect compliance with any drug regimen imposed. For female patients, the offer of antidepressants to manage pain, irrespective of their physiological benefits, should be handled sensitively and reasoning clearly explained. It is essential that prescribers take into account historical (and sometimes continuing) prejudices encountered in medicine, which can see women's and other marginalised communities' physical symptoms denied or misattributed to a psychological cause.	It is the committee's opinion that these medicines can be prescribed and reviewed in primary care, not only in specialist settings. The committee agree that there should be a move away from the stigma associated with the use of antidepressants. They also agree with the view that discussions should be handled sensitively, and reasoning clearly explained, taking into account the person's previous experiences and context. The committee believe this should apply to the assessment of all people with chronic pain. The assessment recommendations have been reworded, but includes these points. A recommendation has also been added to highlight that these are not recommended for depression but because they may help with quality of life, pain, sleep and psychological distress.

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Fair Treatment for the Women of Wales	Guideline	009	General	The guideline recommends not offering conventional analgesia to chronic primary pain patients, a recommendation which fails to account for the varying nature of chronic pain. Some patients may experience intermittent episodes of acute pain on a long-term basis, a situation which patients may well find best managed with periodic, short-term use of analgesia. In particular, this situation may apply to women with cyclical pain associated with adenomyosis or endometriosis, for example, where the condition hasn't (yet) been suspected or diagnosed, a not uncommon scenario. Given that the guideline defines 'chronic pain' is anything in excess of 3 months, this in no way provides the means for most patients to be properly investigated or formally diagnosed with any underlying pathology. We are also concerned that a blanket rejection of those pain medications with which patients are familiar and which may have served them well and been carefully managed over the years may lead them to obtain them from less reputable sources. Whilst unpalatable to contemplate, it is an issue deserving of consideration and amelioration. Another issue of great significance when reducing pain medication prescriptions is the availability of alternatives. Aside from antidepressants which, as already discussed, will be prescribed off-label, all other interventions	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline (including endometriosis) was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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				recommended by the guideline are in-person interventions which will be short-term in duration (largely due to cost and capacity) and not necessarily available to all. For those in a lower socio-economic bracket, disabled people with reduced access to transport or support, or people living in a rural area, it is probable that access to such services will be limited. It is most important that the guideline considers how chronic primary pain patients can be expected to manage pain on a day to day basis when almost all the recommendations are subject to further research, long waiting times and / or personal financial cost to the patient. The guideline as it stands runs the very real risk of further disempowering patients who already feel very isolated and misunderstood. In turn, this may well exacerbate the symptoms the guideline is trying to address. Our respondents appreciate that there will always be scenarios where pain-killing medication is not appropriate, for example where side-effects and risk factors are too severe for it to be a safe option, or where their usage would hinder daily functioning more than the chronic pain itself. However, this should not preclude their usage in some patients and in certain instances. The key is to fully and properly assess the patient, their case, and most appropriate medication on a case-by-case basis,	For chronic primary pain, the committee do not agree that there is evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up (for example, stressful life events). The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS and geographically.

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				as part of a bespoke treatment plan that enables the patient to best manage both their symptoms and daily functionality. It requires a much more long-term, collaborative relationship between doctor and patient, with regular appointments and reviews – anything else would not be considered optimum care.	There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The committee considered recommending these services can help encourage the development of services and improve access. The committee agree people should be able to make informed decisions on which treatment to use, but that this should be based on those treatments demonstrated to be effective for chronic primary pain. The assessment recommendations in section 1.1 of the guideline have been reworded to strengthen the emphasis of fostering a

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					collaborative and supportive relationship between the healthcare professional and person with pain to facilitate good management and effective shared decision making. The recommendations also state that a shared care and support plan should be developed, including having an informed discussion about the benefits and harms of all treatment options, and all stages of care. The means of delivery of the interventions can be determined locally to facilitate access for those who are less able to travel.
Fair Treatment for the Women of Wales	Guideline	010	003	The guideline refers to a very specific example of 'shared decision making'. We would ask that a reference to the imminent NICE guideline on this topic be made here. It is most important that both doctor and patient have clarity and mutual understanding of what shared decision-making entails and what to expect from dialogue of this nature. We would also recommend that guidance around shared decision making is made available in an easy read format for the benefit of patients who need additional support to effectively advocate for themselves.	Thank you for your comment. The committee agree that shared decision making and building a good relationship between the person with chronic pain and the healthcare professional is critical to good management of chronic pain. A separate section has been added underneath section 1.1 for

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				We would ask that references to shared decision making be made throughout the guideline, not just in reference to withdrawal, as it is an essential component in the management of patients who are likely to require care for extended periods and whose active participation in the process is vital in ensuring compliance with any treatment plan. Patients need to know what recourse they have if they feel that shared decision making protocols are not being followed, as far too often in reality, patients report feeling disempowered and unheard. Shared decision making in the context of withdrawal from any form of pain management regimen needs to be part of a collaborative plan which is likely to involve more than just an awareness of the physiological problems associated with it. Withdrawal from a medication being used to manage pain is not going to solve the original problem or symptoms with which the patient presented, so options to manage those symptoms need to be agreed and in place alongside. Further, by creating and implementing a withdrawal and ongoing management plan together, withdrawal can take place at the right time and pace for the patient and additional, practical and emotional support organised. Withdrawal from psychiatric medication in particular can be associated with suicidal ideation, so it is important that	assessment, on developing a shared care and support plan. The assessment recommendations also state the importance of a collaborative approach. The committee also agree that side effects and risk of withdrawal symptoms should be discussed. The recommendation for antidepressants specifically states that there should be a full discussion of the benefits and risks. A separate recommendation is also included to highlight the need to discuss the problems associated with withdrawal.

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				the patient understands the risks, how to identify signs, and what to do should they experience them.	
Fair Treatment for the Women of Wales	Guideline	010	008	We note that the use of cannabis-based medicinal products is subject to a recommendation for further research. We agree that this is important. However, we would ask that the various ways in which CBD-based products can be utilised be given more prominence within the guideline, especially as a potential alternative to opioids and gabapentinoids and particularly in the context of their routine usage for medicinal purposes in many other regions. There may need to be some recognition of CBD not being just 'one' treatment but several different strains which can be used independently or in conjunction with one another, depending on the presenting symptoms. Like all other approaches to chronic pain management, working with individual patients to formulate a bespoke treatment plan for each is vital. It is important that NICE be aware of the prejudices which exist towards cannabis-based products as a treatment option and how these can be a factor in preventing participation in research, both on the part of clinicians and patients. As an organisation designed to promote clinical excellence, we would ask that NICE makes some form of commitment to measures designed	Thank you for your comment. Cannabis based medicinal products were included within the protocol for the review of pharmacological interventions for chronic primary pain, and the committee agreed there was insufficient evidence for a recommendation, but that further research was important. During the development of this guideline the NICE guideline for cannabis based medicinal products was commissioned and published. This guideline covers the use of these for a range of conditions and therefore it was agreed appropriate to cross refer to this for all guidance and considerations for cannabis based medicinal products. Other natural remedies were not highlighted as priority interventions to include during scoping or when agreeing the review protocols for the

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				to overcome attitudes and practices which may stifle innovation in this regard. Alongside this, the guideline may wish to make mention of other 'natural' remedies, such as turmeric, piperine, topical application of magnesium, capsaicin, castor oil, etc, many of which are already being utilised by patients but with little to no formal supervision or guidance on where to source or utilise them. A NICE recommendation that such remedies be researched would provide patients with more ways to take control of their health and self-manage pain in the absence of many pharmacological alternatives.	guideline and therefore recommendations on these topics cannot be made.
Fair Treatment for the Women of Wales	Guideline	010	013	The guideline makes the assertion that a patient can be classified as having 'chronic primary pain' after 3 months' duration. This seems incredibly short, given that waiting times for an initial consultation with a specialist can be 6 months or more, and that diagnostic mechanisms such as scans may not be available within 3 months. For patients with more complex symptomatology, rarer diseases, conditions which aren't immediately apparent, or people from communities who typically experience biases which delay diagnosis, the reclassification of them as being patients for whom a cause cannot be discerned runs the risk of further delaying or derailing investigations.	Thank you for your comment. The committee agreed that the most widely accepted definition of when pain becomes chronic is at a minimum of 3 months duration. The guideline definition for chronic primary pain follows that stated in the ICD-11.
Fair Treatment for the	Guideline	010	016	The description of chronic primary pain as being characterised by significant emotional distress strikes us as tautological; any pain / symptomatology for which	Thank you for your comment. The committee agree that emotional distress can be a feature with any

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Women of Wales				there is as yet no identifiable cause is likely to cause emotional distress. This does not mean it is primary pain, ie that the pain has no underlying pathology.	pain, but they note that this is particularly prominent in presentations of chronic primary pain. This is reflected in the rewording of the context section.
Fair Treatment for the Women of Wales	Guideline	010	020	The guideline asserts that the diagnosis of chronic primary pain is appropriate if no cause / more appropriate diagnosis can be attributed. Given that this guideline applies to anyone over the age of 16, how can patients be certain that all possible diagnoses have been adequately explored? This is particularly concerning for those people for whom underlying pathology is / was present but for whom diagnosis was hugely delayed.	Thank you for your comment. The committee agree this should form part of the assessment of chronic pain.
Fair Treatment for the Women of Wales	Guideline	013	012	It is concerning that the part of the guideline which seems most clear is that which refers to the removal of conventional analgesia and pain management programmes for chronic primary pain patients whilst also admitting that there is not enough evidence to indicate any factors that may predict successful pain management. The guideline provides very few long-term, or universally acceptable, alternatives for the chronic pain patient and, for our respondents, has led merely to increased anxiety about how they will manage their symptoms sufficiently to continue daily functioning, work lives, or relationships. Understandably, this will do little to improve their mental well-being which, in turn, may well exacerbate pain	Thank you for your comment. For pain management programmes the committee agreed that the evidence did not enable a recommendation to be made for or against their use. The committee recommend those treatments that have been demonstrated to be effective for people with chronic primary pain; exercise, CBT or ACT, acupuncture or antidepressants for their effects on symptoms of chronic primary pain. The guideline reflects best practice

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				symptoms as has been mentioned already in the guideline itself. Similarly, the lack of certainty expressed around what form care plans may take, the content of them, or future prospects for the patient may well have pronounced and negative implications for autistic patients, patients with neurodevelopmental conditions, or learning disabilities, many of whom cite clarity and certainty as being necessary for self-management and wellbeing.	and where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The committee agree that assessment and clarity in communication are vital aspects for all people, and that this should be tailored to individual needs. This is reflected in the recommendations. The guideline also cross refers to the NICE patient experience guideline where these factors are also highlighted.
Fair Treatment for the Women of Wales	Guideline	014	004	Alongside an understanding of how a patient's social circle views their pain and its effects, it is just as important for the healthcare professional to appreciate that the pain management interventions offered to that patient can also influence the way others perceive them. For example, any indication that the clinician has deemed the patient's pain as being psychological in origin, not 'real', not 'worthy' or requiring of further investigations will likely influence other people's perceptions of the patient's experiences or reporting of them. This has the potential to damage relationships and make it more difficult to access reasonable adjustments in the workplace.	Thank you for your comment. It is beyond the remit of this NICE guideline to advise how medical notes should be kept.

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				We would suggest that advice be issued to healthcare professionals on the writing up of medical notes or letters for chronic primary pain patients, as they may subsequently be required as evidence for social security / benefits, reasonable adjustments in the workplace, compliance with sickness policies, or employment tribunals. It is very important that outside observers / those with little expertise in chronic pain are not able to use the classification as an excuse to dismiss the legitimacy of the person's experience or needs.	
Fair Treatment for the Women of Wales	Guideline	015	023	We note the reference to social prescribing link workers and the 'NHS long term plan'. We would ask that this be clarified as to whether the reference applies equally to the NHS in devolved nations or, if not, what similar initiatives are in place (if any). The terminology used may need to reflect differences in approach.	Thank you for your comment. The reference to the NHS long term plan is to document available here: https://www.longtermplan.nhs.uk/
Fair Treatment for the Women of Wales	Guideline	015	027	We would suggest that some of the arguments made within the guideline for the benefits of supervised group exercise for chronic pain patients would apply to any form of supervised group activity. In fact, if we acknowledge that some forms of exercise may actually be detrimental for people with particular health conditions or not appropriate for certain populations, it may be that it is the peer support and socialising elements of the activity that are most beneficial, especially when we consider the prevailing sense of isolation many chronic pain patients report experiencing.	Thank you for your comment. This evidence was specific to supervised group exercise where consistent benefits were demonstrated for people with chronic primary pain. The evidence for social interventions was looked for in the guideline, as reported in evidence review D, but no evidence was identified specific to chronic pain. The committee therefore

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				As a patient-led women's health organisation already facilitating various forms of peer support and engagement activity for its membership, we feel confident in making the assertion that social interventions can be beneficial for the chronic pain population. We believe that key to the success of social interventions is that they be led by those with lived experience of the issues experienced and content co-produced with participants. This provides more assurance that they will be bespoke, fit for purpose, and effective, as opposed to offering activities based on supposition and / or other groups. The latter approach can be demoralising and counter-productive, often exacerbating the participant's symptoms and stress. Finding something that has meaning, importance, and attachment for the patient or participant is key to the success of social interventions, ensuring continuing compliance and improved well-being. We would also add a word of caution: with technological advances, whilst peer support can take forms which potentially enable it to be available to participants 24 hours a day, the same cannot be said for all other types of social intervention, such as art classes or meditation sessions, for example. These may provide temporary respite from pain through distraction, but they are short in duration whilst chronic pain can be anticipated to	included a research recommendation on this topic.

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				persist throughout the day. As such, even the best, most collaboratively produced social intervention can only be supplementary to a proper, all-encompassing treatment plan.	
Fair Treatment for the Women of Wales	Guideline	015	029	We would add that any analysis of cost-effectiveness will need to consider who it is that generally provides social interventions for patient populations currently. Our experience would suggest that this is the voluntary / third sector, for whom funding is a major obstacle to ensuring sustainability of services. Increasingly, as the NHS and local authorities utilise social prescribing as a means to support patients / clients, the third sector is expected to meet that demand. However, with the funding landscape unpredictable and usually short-term, the danger is that social interventions on which populations come to rely cease to exist, exacerbating participants' stress and symptoms. It is important that the offer of social interventions does not exacerbate existing health inequalities by only being available to those who can pay. It's also important to consider how accessible they will be to those in areas where they're not available or, if provided digitally, for those without access to technology. We would ask that, alongside the recommendation for further research, the Committee includes a	Thank you for your comment. No evidence was identified for the area of social prescribing and cost effectiveness analysis was not undertaken in this area. Due to this no recommendation was made and research was recommended. The guideline scope specified that the settings covered would be all those in which NHS and local authority commissioned care is provided and so funding is assumed to come via these routes for interventions recommended in the guideline.

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				recommendation around sustainable funding and support for third sector services across the UK, particularly those interventions which may well form part of a NICE guideline and treatment plan for such a significant number of people.	
Fair Treatment for the Women of Wales	Guideline	016	013	We note the serious limitations on evidence for exercise as a form of pain management and would question the decision to extrapolate data mainly pertaining to women with fibromyalgia to an entire chronic primary pain community. Similarly, the recommendation that the offer be 'supervised group exercise' is based on very limited studies and may just as easily be applied to any supervised group activity where peer support, compassion, and reduced isolation can be said to improve wellbeing.	Thank you for your comment. The committee acknowledge that the evidence informing the exercise review was largely from populations with fibromyalgia or chronic neck pain. The committee considered that response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions. However it was also considered that the most appropriate type of exercise may depend on the type of pain condition and it should therefore be tailored to individual needs and preferences. This is detailed in the discussion of evidence in the evidence review and has been added to the rationale in the guideline for clarity.

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					The committee do not agree the recommendation is based on a limited number of studies. There were 92 studies included in the review, the majority of which were for supervised group exercise programmes.
Fair Treatment for the Women of Wales	Guideline	016	023	Given that pain presents in so many ways and is unique to the individual, even amongst those with shared pain sites or symptoms, we would like more information regarding the committee's agreement that such limited data was generalisable to the chronic primary pain population. On what grounds were these conclusions reached?	Thank you for your comment. The details on the evidence informing the recommendations and rationales where this has come from predominantly only a few types of chronic primary pain, is detailed in the relevant rationales in the guideline and further discussed in the discussion of the evidence in the evidence reviews. Furthermore the committee noted that many of the interventions recommended would be tailored according to the type of chronic primary pain.

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Fair Treatment for the Women of Wales	Guideline	016	026	We would argue that people discontinuing their exercise programmes, if indeed this is the only form of pain management being offered to them, as an extremely negative effect. We would also ask how much research was done into the reasons given for discontinuing such a programme. Amongst those chronic pain patients with whom we and / or our colleagues have spoken, commonly given reasons for discontinuing exercise include ensuing fatigue, the need for recovery time to compensate for exercise activity and the implications of this on other parts of the patient's life, that repeated physical activity exacerbated degeneration, and how worsening of the patient's condition made continuing the agreed exercise programme impossible. It is worth noting that it is more difficult to make individual adjustments for patients in a group exercise programme and that such programmes can be more difficult to access for certain communities, including those in rural areas.	Thank you for your comment. The committee do not recommend people should discontinue their exercise programmes. A recommendation is included to state that people should be encouraged to carry on with their physical activity for longer-term general health benefits. The committee agreed that people running exercise programmes are able to tailor programmes to individuals and frequently do this in current practice. We acknowledge that access to these services is likely to vary geographically. However the committee considered recommending these services can help encourage the development of services and improve access.
Fair Treatment for the Women of Wales	Guideline	017	006	We note the guideline's reference to the need for exercise to be sustainable for the person and would wish to make clear that this includes it being physically and financially sustainable for that individual.	Thank you for your comment. The committee agreed that people should be encouraged to remain physically active after a group programme ends.

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					They note that this does not necessarily have to incur a cost.
Fair Treatment for the Women of Wales	Guideline	017	013	The reference to exercise programmes being a 'personal cost for people with chronic primary pain' and not the NHS makes this option untenable for many patients. It is worth pointing out that those living with chronic pain are already at increased risk of unemployment, especially where a lack of diagnosis can make accessing reasonable adjustments in the workplace more difficult. Irrespective of this, where managing a health condition is concerned, NICE should be very cautious about making recommendations which exacerbate health inequalities and outcomes on the basis of socio-economic status, as this one most certainly does. Financial cost is likely to be a key determining factor in whether a person continues with a formal, supervised exercise programme; if the committee perceives health benefits in such a programme for chronic primary pain patients and the recommendation is made in the absence of any other pain management alternatives, then the cost should be covered by the NHS otherwise we can no longer legitimately say that the service is free at the point of delivery.	Thank you for your comment. This statement relates to the recommendation to encourage people to maintain their physical activity. The recommendation for supervised group exercise programmes is recommended to be offered by the NHS. We acknowledge that continuing a formal supervised exercise programmes may come at a cost that some people cannot afford. This was not the intention of the recommendation and this has been reworded to encourage ongoing physical activity. This is known to have longer term health benefits, but does not have to be activity that requires a gym membership or financial outgoings. We have clarified this where the statement is made.
Fair Treatment for the	Guideline	018	007 - 008	The recommendation for CBT (for pain) is likely to be of more benefit to those with a higher disposable income, as they may choose to access psychological therapies	Thank you for your comment. These guideline recommendations are for all

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Women of Wales				privately, enabling prompt intervention, compared to those who are reliant on NHS provision and for whom excessive waiting times are likely to render the therapy less effective. The Committee acknowledges that studies looking at the use of CBT for pain had varied results due to the way the therapy was delivered, so it is important for this to incorporate an understanding that speed of access and duration of the course may well impact on the efficacy of therapy. As such, NICE should be mindful of recommending a treatment in the absence of many alternatives which will exacerbate existing health inequalities and outcomes on the basis of socio-economic status and geographical location (CBT services are likely to be more widespread and accessible in urban areas). For those able to afford private therapy sessions, there will still need to be guidance on how and where to access NHS / NICE-approved services.	settings where NHS or local authority funded care is provided. It is not expected that people should have to access recommended services privately. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Fair Treatment for the	Guideline	018	016	The decision not to recommend biofeedback for chronic primary pain overlooks the possibility of overlapping	Thank you for your comment. These recommendations are for the

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Women of Wales				bowel and bladder dysfunction, particularly in women with complex pelvic pain.	management of chronic primary pain. For management of other overlapping conditions healthcare professionals should use their clinical judgement to determine management according to the relevant NICE guideline where available.
Fair Treatment for the Women of Wales	Guideline	019	007	The guideline looks at financial cost of psychological interventions; this is important, both to the NHS and to individuals who may have to pay privately for care. However, in the context of the NHS it is important to recognise that, in the interest of cost effectiveness and capacity, psychological therapies are likely to be short in duration, requiring patients to continue therapeutic exercises at home. This fails to take into account the varying home circumstances of individuals, issues which may well affect compliance and longer-term efficacy of the therapy provided.	Thank you for your comment. The committee agree that individual circumstances should be taken into account when managing patients. The guideline refers to this in section 1.1 for the assessment of people with chronic pain. This should also be taken into account when developing the shared care and support plan and in any tailoring of the intervention for the person.
Fair Treatment for the Women of Wales	Guideline	021	007	The Committee acknowledges that acupuncture provision has recently reduced and that existing services are likely to be stretched beyond capacity. Therefore, the recommendation to offer acupuncture in the current climate will exacerbate health inequalities and outcomes on the basis of socio-economic status, as accessing services privately is not an option for those on low incomes.	The guideline reflects the evidence for best practice and makes recommendations for interventions to be provided by the NHS. The committee agree that there is variation in the delivery of some of the recommended services across the

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				Not only is the recommendation currently unfeasible for those reliant on the NHS, due to lack of provision and excessive waiting times, it is also unreasonable to expect patients with more financial resources to have to pay for almost all the interventions recommended. Our concern is that the guideline strongly asserts the need for a wholesale reduction in conventional pain management modalities whilst the alternatives are not in place.	NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Fair Treatment for the Women of Wales	Guideline	023	015	We would like to reiterate our concern that the one widely available chronic pain treatment modality recommended within the guideline – antidepressants – is based on small studies focused on the experience of one sex with one condition, ie women with fibromyalgia. Given that fibromyalgia is most often offered up as a diagnosis to women who have experienced historical trauma (including previous operations for other conditions) and struggled for extended periods with symptoms and prejudicial attitudes, it is little wonder that this condition has a clear association with psychological distress. Offering antidepressants to such patients would	Thank you for your comment. Whilst it is true that a number of studies included in the review were in women with fibromyalgia, the evidence for antidepressants included other chronic primary pain populations such a chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Heterogeneity was not observed between types of chronic primary pain, so the committee

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				make sense and likely see evidence of benefit. However, the very specific nature of this cohort's experiences also seems to make it unwise to use them as the basis for the entire chronic primary pain population's treatment options. Such an approach would appear to contradict the committee's stated desire to see care plans highly individualised.	agreed it provided no evidence against making this recommendation to be for all people with chronic primary pain.
Fair Treatment for the Women of Wales	Guideline	024	005	Whilst the guideline makes clear that antidepressants are already used in practice for chronic primary pain, albeit off-label, it fails to also make clear that they are just as often rejected by patients, whether because of connotations around pain being 'imagined' or psychological, intolerable side-effects, or simply that they don't work in reducing physical manifestations of pain.	Thank you for your comment. The decision to take any of the options recommended in the guideline should be made jointly between the healthcare professional and the patient based on a balanced discussion of the benefits and harms. This is included in section 1.1 of the guideline and applies throughout.
Fair Treatment for the Women of Wales	Guideline	024	022	We note the Committee's agreement that even short-term use of opioids 'could be' harmful for chronic conditions; however, as a patient community, we would disagree with the decision to use what seems a rather tentative judgment call as the basis for removing them entirely from the limited range of options available. To do so denies doctor and patient the ability to make decisions together based on the unique needs of the individual. The recommendation to not offer opioids under any circumstances for all patients classed as having chronic	Thank you for your comment. The committee do not agree that short term treatment with opioids is any more beneficial for people with chronic primary pain. They agree it is important for other causes for the pain to be considered and for those to be managed accordingly. This has been added to the recommendations in section 1.1. Furthermore a

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				primary pain seems to deny the possibility that an underlying pathology will be found and resolved during the course of investigations. It also takes away the option of a time-limited and closely monitored course of opioids to make the intervening period manageable for the patient and enable them to continue functioning normally in their everyday lives.	recommendation has been added to highlight that the original diagnosis may change and should be re-evaluated if presentation changes. The guideline recommends that other NICE guidelines should be followed for management of chronic secondary pain.
Fair Treatment for the Women of Wales	Guideline	025	General	The recommendation to not offer patients classed as having chronic primary pain any forms of medication other than antidepressants actively reduces the opportunity for doctors and patients to tailor a bespoke pain management programme / care plan for the individual's needs. We wonder how far patients will be able to control their own pain levels in the absence of any immediate, practical offer. This may well have significant and negative implications for the functionality and wellbeing of a considerable number of patients, many of whom are responsible users of pain medication, carefully monitored and supported in their treatment regimen by their doctor(s).	Thank you for your comment. The committee agree people should be able to make informed decisions on which treatment to use, but that this should be based on those treatments demonstrated to be effective for chronic primary pain. The guideline recommends non-pharmacological options including exercise, acupuncture, CBT or ACT.
Fair Treatment for the Women of Wales	Guideline	026	020	The Committee rightly refers to the resource implications of opioid and gabapentinoid cessation, citing cost(s) of various antidepressants. However, we would also ask that there be a cost / resource analysis of any increased attendance at accident & emergency units, as patients withdrawing from pain medications or experiencing acute	Thank you for your comment. The committee agree there may be increased resource use from helping people to stop treatment and have noted this. The cost of implementing the recommendations is considered

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				pain episodes may well resort to visiting out of hours services in desperation.	within the resource impact assessment produced by NICE alongside the guideline.
Fair Treatment for the Women of Wales	Guideline	026	029	We find the suggestion that removing pain medication from the chronic primary pain patient's armoury as likely to yield benefits such as a return to the workforce rather implausible. In the absence of any reliable alternatives, particularly interventions which are easily and routinely accessible to all and which provide long-term solutions, there seems little prospect that any patient for whom no underlying pathology has been found and resolved will no longer experience the pain that saw them seeking help in the first instance. In our experience as a women's health organisation, it is the initial symptomatology which sees patients unable to work rather than a properly managed treatment regimen comprising various forms of analgesia. In fact, on reading this guideline, many of our members, who are in employment but periodically or regularly rely on pain medication to manage symptoms, are afraid that their productivity will be reduced or that they will be completely unable to work.	Thank you for your comment. This sentence has been removed from the guideline.
Fair Treatment for the Women of Wales	Guideline	027	015	The guideline mentions a lack of data pertaining to the proportion of people with chronic pain who need or seek treatment. We would add to that a question over the proportion that subsequently has an underlying cause for their chronic pain identified.	Thank you for your comment. The committee agree that is true. The context section highlights the uncertainty in the prevalence of both chronic pain and chronic primary pain.

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Fair Treatment for the Women of Wales	Guideline	028	013 - 014	We would argue that women are particularly likely to experience negative perceptions of their pain, both on the part of clinician and the public at large. Pelvic pain is frequently normalised, diminished, and misdiagnosed but there are a host of pain-causing conditions which predominantly or only affect females, and which are not taken seriously, are under-researched, or misunderstood. These may include EDS, Auto-Immune conditions, fibromyalgia, vulvodynia, vaginismus, etc. The resulting diagnostic delay incurs the strong possibility that symptoms will be reclassified as chronic primary pain, thereby perpetuating the negative perceptions.	Thank you for your comment. Additional recommendations have been included in the assessment section to clarify when a diagnosis of chronic primary pain should be considered.
Fibromyalgia Action UK	Guideline	007	003	CBT is a treatment that several people have benefited from within our community, but we do not have any figures to measure its benefit. However, we are often told by people that there is no service running or close to them. Rheumatologists have spoken of difficulties in provisioning it as part of their options. One consultant spoke of falling back to a telephone led option that had benefit when there was no ability to offer in person therapy. Recommendations are welcome but for it to be beneficial their needs to be the resource available, of the correct type, modality and frequency.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Fibromyalgia Action UK	Guideline	009	015	Clinical trials of gabapentin and pregabalin have shown positive results in fibromyalgia. These are class C drugs, in patients with severe symptoms, we believe secondary care specialists should be able to prescribe these medications. Patient comment "What assurances can you give to patients, like me, who have found gabapentinoids a successful treatment pathway, that they will not be denied treatment that works?"	Thank you for your comment. The evidence reviewed in this guideline did not demonstrate good effectiveness of gabapentinoids for people with chronic primary pain (including fibromyalgia). The committee do not agree there is any reason the efficacy would be different if prescribed in specialist settings. Indeed, many of the included studies were conducted by secondary care specialists. Recommendations have now been included in the guideline to consider people who are already receiving these medicines and getting benefit from them to agree a shared decision to continue safely if appropriate.
Fibromyalgia Action UK	Guideline	General	General	Definition of chronic primary pain as opposed to chronic pain There could be more clarity on what conditions and situations that this guidance will cover. The definition of	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled;

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				chronic primary pain is not clear enough. Chronic Primary Pain is an ICD-11 classification. Most healthcare professionals and patients will not be recognised as having this as a diagnosis, yet it includes fibromyalgia which affects up to 5% of the population. Without defining chronic primary pain adequately this will affect any implementation and auditing of care.	definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Fibromyalgia Action UK	Guideline	General	General	Longer time with GPs is not available at present and cannot see there being more time available as the guidance recommends. Even prior to covid there was little scope for longer appointment times and people with fibromyalgia / chronic pain already present as complex patients requiring extra time that is not normally available to them. The document does not specify whether care will be	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, to implement some recommendations in

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				provided by GP or secondary care. Given biopsychosocial assessment and explanation of investigation results and treatment are important. The committee should include this a recommendation which can be audited in the future.	the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. The guideline applies to all settings in which NHS or local authority funded care is provided. The majority of recommendations are not setting specific. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised

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					that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered.
Fibromyalgia Action UK	Guideline	006	011	We recognised the guidance recommends increasing activity to improve quality of life. We fully support this, and social prescription is an area where this could help people with fibromyalgia. However, we are often starting from a point where movement is difficult and the option of going swimming or the gym may be beyond us. Medications are an important step to allow people increasing activity levels and progressing to a place where they can reduce overall medications and eventually leaving them behind in certain cases. Similar to activity levels, medications can and do enable people to continue or take up employment. Maintaining quality of life and being able to maintain positive contribution to society is important in not allowing chronic primary pain conditions to bring on anxiety and depression.	Thank you for your comment. The committee agree that there is no evidence that the medicines recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. They do recommend that exercise is tailored to the person's abilities and agree that the programmes should be adapted to enable people to participate.
Fibromyalgia Action UK	Guideline	007	008	People that have spoken of Acupuncture helping them with fibromyalgia have commented that 5 sessions would not be enough in their experience. It is also not a treatment that is mentioned often within our community.	Thank you for your comment. The evidence reviewed demonstrated that 5 hours of acupuncture (which may be delivered in more short sessions, not

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					necessarily 5 hour long sessions) was both clinically and cost effective for chronic primary pain. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Fibromyalgia Action UK	Guideline	008	010	Overall, the document suggests many medications currently used should be stopped or considered for stopping because of lack of evidence. Many patients are currently taking these medications, if they are stopped suddenly it can lead to a severe flare. Also saying that there is not enough high-quality	Thank you for your comment. Recommendations have now been added to address considerations for people who are already receiving these medicines. We agree it is

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				evidence for medications is different to saying that medications do not work.	important that treatment is not stopped suddenly. Whilst we do agree that absence of evidence is not the same as evidence of absence, in some cases there was evidence that there was no difference between the medicine and placebo, and for many of these medicines there are known harms associated with their use.
Fibromyalgia Action UK	Guideline	008	010	Drugs available for fibromyalgia are limited and it often will take several drugs beingworked through until the patient finds one that benefits them. Studies on FDA approved drugs for fibromyalgia showed a 30 – 40% range of effective treatment was experienced on drugs including gabapentin. It is therefore reasonable to assume that medicines are useful for subsections offibromyalgia groups and we do not understand why it can take a number of attempts at medications before people with fibro find something that makes a difference. i.e. 1 in 3 drugs may be effective.	Thank you for your comment. The evidence reviewed in this guideline did not demonstrate effectiveness for the medicines considered or the harms outweighed the benefits, with the exception of antidepressants. The committee were aware of research suggesting that there may be a subgroup of people with chronic primary pain who may respond to some pharmacological interventions, however there is no evidence to suggest how to identify any subgroup. The committee therefore agreed it was inappropriate to recommend

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					trying medicines for which there is no good evidence that most people will benefit from or to risk exposing all of the fibromyalgia population to medicines with a potential for harm, without evidence on how to determine the small subgroup that may benefit.
Fibromyalgia Action UK	Guideline	010	003	Change of meds are already being enforced on patients with fibromyalgia and we are continually hearing of examples of doctors conducting medicine reviews prior to this guidance and telling the patient to immediately stop their gabapentin or tramadol without tapering or providing alternatives While the guidance does not definitively say that these meds should be removed there are already doctors making these decisions for patients whether it be opioids or other treatments that can help. We cannot have people with fibromyalgia despairing at being left with no support from their medical profession and heading into withdrawal symptoms from their medications.	Thank you for your comment. We have added a recommendation for considerations for people already receiving these medicines. We agree that people should be supported to reduce their use if a shared decision is made to do so, and medicines should not be stopped abruptly. The guideline also cross refers to the NICE guideline for safe prescribing and withdrawal management which is currently in development.
Fibromyalgia Action UK	Guideline	General	General	We would like to mention that when this draft was published that our followers have reacted in the most part with concern through to serious worry that this could mean that when they are already in a desperate position with their treatment regime or with difficulty on	Thank you for your comment. Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important

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				obtaining medications that they will be left in a much worse position and with less hope as a result.	consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The guideline highlights the importance of shared decision making and discussing the benefits and harms of all treatment options at all stages of care.
Fibromyalgia Action UK	Guideline	General	General	The guidance can be perceived that quality of life is not taken into due consideration with many of the interventions, seeing short term benefits as irrelevant when quite often those short bursts of being pain free, or reduced levels of pain are very important to someone with chronic pain. The only short-term treatment is	Thank you for your comment. Health related quality of life was an outcome

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				acupuncture which features heavily in the guideline despite evidence for 3 months or less benefit? How can this be explained where many other interventions (TENS machines, hydrotherapy, mindfulness, manual therapy) have been completely disregarded?	considered critical for decision making for all reviews within the guideline. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent

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					benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost effectiveness evidence supporting the recommendation.

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Fibromyalgia Action UK	Guideline	006	009	Hydrotherapy should be considered as an treatment option especially for those that have difficulty exercising in cold water or find water based/ supported activity more beneficial.	Thank you for your comment. Hydrotherapy was included in the review of exercise interventions where evidence was available relevant to the review protocol. No studies were identified that met the review protocol criteria. The recommendation for exercise does not specify the type of exercise that should be undertaken as the review did not identify one type to be more effective than another and the committee considered that this may need to be determined by the type of pain and individual preferences and abilities.
Fibromyalgia Action UK	Guideline	Gene ral	General	No reference to pain clinics or their role in helping people accesses the mentioned treatments. Also, no mention of programmes constructed to help people with fibromyalgia by drawing on multiple treatments referenced within this document. Often physiotherapist led programmes that vary around the country most notably defined by the availability of scare resource. E.g. lack of an in person CBT resource led one clinic to source phone based CBT resource. The decision on which resource is offered is based on	Thank you for your comment. The guideline applies to all settings in which NHS or local authority funded care is provided. The majority of recommendations are not setting specific. The guideline does include a review of pain management programmes. The

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				availability rather than need. More research is needed to validate the effectiveness of these MDT approaches so the good practice can be more easily adopted elsewhere.	committee agreed the evidence was insufficient to inform recommendations for or against pain management programmes.
Fibromyalgia Action UK	Guideline	010	008	Several non-approved treatments are used by people with chronic pain including but not limited to cannabis or CBD oil. We recognise the lack of evidence in these non-approved options, but people still seek them out and report to us of their benefit albeit anecdotally. If people are no longer able to obtain previously working approved medications, they will seek out those on the street corner and try to self-medicate. NICE refers to the other cannabis guidance but as there is an already recognised lack of research in this area within the UK it should be part of the recommendations on chronic primary pain that more research in this area is carried out.	Thank you for your comment. The rationale included in the guideline explains that the committee agree further research is required for cannabis based medicinal products for chronic primary pain. The research recommendation for this is already covered in the NICE guideline on cannabis-based medicinal products and therefore is not duplicated here. The NICE pathway will directly link to this guideline so ensure recommendations are joined up.
Fibromyalgia Action UK	Guideline	General	General	Chronic pain relief is not a binary thing. A patient existing with a pain score of 7 taking a medication and having their pain score reduced to a 4 is not a complete success but for the patient this is very significant and allows a much better quality of life. It may not be there end goal of total pain relief but may allow return to work and with other measures could allow the patient to have a drastic improvement in their life.	Thank you for your comment. The committee agree that improvement in pain cannot be taken in isolation to demonstrate benefits of an intervention. All reviews consider a range of patient reported outcomes (for example, quality of life, pain, function, psychological distress, sleep,

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					discontinuation due to adverse events). The committee consider the whole body of evidence and the trade of between benefits and harms when making recommendations.
Fibromyalgia Action UK	Evidence review J	068	031	Service User Contribution: ""[coming off gabapentinoids] could have wider benefits both to an individual and to other sectors outside healthcare, for example through people returning to the workforce." Where is the evidence that people who have chronic pain and take on gabapentinoids or opioids are unable to work (including part-time work?). These medications can help increase mobility and day-to-day pain management and improve chances of returning to the workforce. The only reason I can work part-time is because my pain has been 'turned down' to a more manageable level. Pregabalin helps me work part-time, reduces the frequency and intensity of flare ups, enables me to participate in events like family get-togethers and cope daily. The thought of going back to the way things were before gabapentinoids is deeply disturbing. This is because being on them has given me more independence and mobility. With my pain 'turned down', I still have pain symptoms, but they are manageable. My work is very important to me, as is participating in family events – having that taken away from me and my pain ramped up to levels worse than my current 'flare ups' is frankly	Thank you for your comment. This statement has now been removed from the discussion of the evidence.

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				terrifying. These new guidelines will condemn thousands of people to a severe increase in their suffering."	
Fibromyalgia Action UK	Evidence review J	062	038	"Where evidence were available, it was further discussed that the majority was at short term follow up only, and so the effectiveness of these medications in the long term was uncertain." Chronic pain is a long-term condition which can require a significant adjustment period. We would encourage more long-term follow-up studies to be conducted and review benefits over time.	Thank you for your comment. The committee agree that chronic primary pain requires long term management and that further research on long term follow up would be beneficial for all interventions for chronic primary pain. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care.
GP reference panel	Guideline	General	General	Brave and bold! This very important guideline was well received by the GP forum. We welcome the overall message to halt the ever increasing and unnecessary use of interventions, and escalating drug therapy regimes. We also applaud your honesty about what does and does not work.	Thank you for your comment.

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GP reference panel	Guideline	General	General	The guideline is clear and easy to follow, and lends itself for use as a quick-access resource.	Thank you for your comment.
GP reference panel	Guideline	General	General	Whilst the forum welcomes the emphasis on drug avoidance most respondents expressed concerns about implementation. Both primary and secondary care clinicians find it difficult to access exercise, psychological, and social interventions. We have highlighted specific issues in later sections.	Thank you for your comment. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
GP reference panel	Guideline	General	General	Please acknowledge in the guideline that the majorityof the management of people with primary persistent pain falls on primary care. The access to pain clinics across the country is woeful, and the focus is often on pharmacological interventions. The change in emphasis to alternative treatment modalities and medication withdrawal will further increase the burden on primary care workload and resources (and mental health teams).	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement

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					some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
GP reference panel	Guideline	General	General	Even experts have difficulty in deciding when pain can be properly identified as neuropathic, chronic primary, or chronic secondary in a clinical environment, especially where co-morbidities of painful conditions are present. It will be tempting for doctors and patients to have pain relabelled or attributed to co-morbidities so as to justify using drugs especially as other resources may not be available. This would, therefore, merely shift the problem.	Thank you for your comment. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered

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GP reference panel	Guideline	General	General	Please replace 'chronic pain' with 'persistent' pain. Most patients consider chronic to mean 'awful'. This can drive a negative spiral of helplessness and dysfunctional core beliefs, which is difficult to reverse.	Thank you for your comment. During the scope consultation for this guideline a specific question was asked of stakeholders regarding whether the term persistent or chronic should be used. The majority of stakeholders said that chronic pain should be used for consistency with ICD-11 terminology.
GP reference panel	Guideline	001	General	In the opening box please provide greater clarity on the focus of the guideline: primary persistent pain (even though it is explained at the end of the document). Then please state what this term means: the brief mention that primary pain is in ICD-11 is not helpful, especially as the code itself is complex and disputed.	Thank you for your comment. The text on the overview page has been edited following stakeholder comments. The context section has also been reworded to include more detail on the population and definitions used and this has been placed before the recommendations to aid clarity.
GP reference panel	Guideline	001	General	Please clarify whether fibromyalgia is included (this is not referenced in the introduction or in section 1.3.2). Some later forum comments assume that fibromyalgic pain is covered by this guideline.	Thank you for your comment. Fibromyalgia has been included as an example of chronic primary pain in the context of the guideline to clarify that it is included.
GP reference panel	Guideline	001	General	The neuropathic pain guideline is referenced in 1.3.2 but not in the Introduction.	Thank you for your comment. Neuropathic pain CG173, has been added to the introduction.

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GP reference panel	Guideline	005 - 010	017 - 010	Please consider the resources produced by NHS Sheffield on persistent pain.	Thank you for your comment. The committee are aware of the resources highlighted.
GP reference panel	Guideline	006	010-017	We welcome the greater emphasis on exercise. Overuse of drugs has detracted from the things that do work, namely exercise.	Thank you for your comment.
GP reference panel	Guideline	006	011-014	We welcome this statement but the guideline should recognise the problems arising from current poor access and under-resource. Until provision catches up, please identify resources for home-based exercise programmes.	Thank you for your comment. We hope that by recommending that group exercise should be offered to people with chronic primary pain that provision will be increased and allow better signposting to existing provision. Evidence reviewed demonstrated the most benefits for supervised exercise programmes and therefore the recommendation has been made specific for that rather than home-based as recommendations should encourage best care.
GP reference panel	Guideline	007	012	Are recommendations possible for clinicians over Band7?	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering

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					acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.
GP reference panel	Guideline	008-010	013-005	Currently, in order to reduce polypharmacy, some recommendations advise a step and reduce approach to prescribing in chronic pain i.e. double dose x 3 rounds and if no response wean off before starting an alternative.	Thank you for your comment. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline.
GP reference panel	Guideline	008 - 009	014-002	Please comment on: 1) whether anti-depressants have an optimum duration of treatment.	Thank you for your comment. The committee agreed that there was not

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				2) whether anti-depressants are equally effective (unlike in the management of neuropathic pain).	enough evidence to determine whether one antidepressant was more effective than another. The recommend that the choice of which one should be based on a fully informed discussion with the person with chronic primary pain, taking into account the risks and benefits. This is stated in the rationale for the recommendation and further detail is given in the committee's discussion of the evidence in evidence report J. The evidence did not inform the optimum duration of treatment. The committee considered this should be informed by regular review of medicines as recommended in the NICE guidelines for Medicines optimisation and Medicines adherence.
GP reference panel	Guideline	009	010-204	Whilst we welcome the non-tablet features of this guideline how can we manage those patients (perhaps a minority?) who truly and clearly benefit? This section leaves very little, if any, choice of analgesics for primary care clinicians. As the provision of alternative management strategies is unsatisfactory, will patients	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation

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				seek treatments (including opioids and gabapentinoids) fromsources such as the internet?	has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas.
GP reference panel	Guideline	009	015 - 017	Assuming this guideline includes fibromyalgia) There is strong evidence (albeit short term only) for the use of pregabalin in moderate/severe fibromyalgia (the results are similar to duloxetine) Ref: Derry S et al Pregabalin for pain in fibromyalgia in adults, Cochrane systematic review 2016	Thank you for your comment. When setting the protocol, the committee agreed that studies with an enriched enrolment design would be excluded from the review, due to the potential to over-estimate of an interventions effect and lack of generalisability to a wider population. We believe this is appropriate and a robust methodological decision for a guideline evidence review that is intended to inform population based recommendations for the NHS. The conclusion of our review of gabapentinoids therefore differs from that of this Cochrane review which included such studies.
GP reference panel	Guideline	010	001-002	Please advise on current drug combinations e.g. many patients are on both tramadol and amitryptylline, which is associated with increased side-effects?	Thank you for your comment. The review protocol did not include combinations of the medicines. However the committee agree that the only group of medicines that can be recommended for chronic primary

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					pain is antidepressants and that the others should not be offered, even in combination with antidepressants.
GP reference panel	Guideline	010	003-007	Please make recommendations on effective interventions to achieve the aims in this section and/or co-ordinate publication with that of guidance on safe prescribing and withdrawal of medicines.	Thank you for your comment. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible.
GP reference panel	Guideline	011	005	We need more research on antidepressants in chronic pain- low dose? best antidepressant? duration?	Thank you for your comment. Although the evidence wasn't able to inform the details on best antidepressant, the committee did not agree this was a priority area for further research. They considered this should be based on the person's additional symptoms and the side effect profiles of these drugs. The suggested doses have been given in the rationale accompanying the

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					recommendation. The committee considered that the duration should be informed by review of the efficacy of the medicine.
GP reference panel	Guideline	011	005	One respondent's patients are predominantly of Pakistani heritage. They report that older women in particular have a very high incidence of chronic pain without a clinical explanation. Their beliefs and expectations can be different from those of other groups. Cultural and language factors mean that IAPT and some of the other psychological services are inaccessible and may not be appropriate. There is a knowledge gap here.	Thank you for your comment. The committee agree that these are important factors to consider and have added a recommendation in the assessment section to acknowledge that socioeconomic, cultural and ethnic background, and faith group might influence people's symptoms, understanding and choice of management.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	The feedback to this consultation given below is a consensus opinion from the speciality leads of paediatric pain services across the UK. Overall there is much that is relevant to the delivery of care of chronic pain according to the experience of this group, and practioners within their services, and with the evidence for chronic pain management in children and young people. There are concerns, however, both with the general scope and relevance of the guideline and its appropriateness to young people. It does not acknowledge that young people (from 16 up to 25yrs) are a different group to older adults. Plus that for this group	Thank you for your comment. The committee agree that this should be clarified within the guideline. A recommendation has been added for considerations when assessing chronic pain in young people. A cross reference to the NICE guidelines for Transition to adult services, NG43, is also included.

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				there are differences in presentation and management (assessment and treatment) and that they may be seen in paediatric settings. It also does not address transition. **We would recommend that the guideline contains an appendix specifically addressing young people (16 - 25yrs) that recognises the age specific differences in presentation and management, adheres to relevant NICE guidance for this age group, gives guidance on the transition process and recognises that they may have access to both paediatric or adult services and allows for management pathways from either that are relevant to the individual patient.**	
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	**We would also recommend more input from professionals experienced in treating children and young people with chronic pain is needed in the development of this guideline.**	Thank you for your comment. The committee composition was agreed during the scoping phase as appropriate for the expertise for the guideline scope. Members of the committee do have experience of treating young people with chronic pain.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	The significant majority of adult pain services will not treat patients less than 18years of age. Where some may initially assess younger patients this can be further complicated by the multi-disciplinary treatment pathways/interventions then not being available or	Thank you for your comment. The committee agree that there are areas that may need support and investment, such as training costs, to implement some recommendations in

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				appropriate to patients under 18yrs. Thus most patients up to the age of 18yrs (or until no longer in full time (pre-adult) education i.e. up to 19ys) will be treated by paediatric chronic pain services. There are some adolescent pain services but the numbers are very small and thus there is little impact on the overall pattern of where these patients are seen. Current thinking would reflect the need to identify this age group and plan healthcare relevant to their specific needs - "*Arguably, the transition period from childhood to adulthood now occupies a greater portion of the life course than ever before at a time when unprecedented social forces, including marketing and digital media, are affecting health and wellbeing across these years. An expanded and more inclusive definition of adolescence is essential for developmentally appropriate framing of laws, social policies, and service systems. Rather than age 10–19 years, a definition of 10–24 years corresponds more closely to adolescent growth and popular understandings of this life phase and would facilitate extended investments across a broader range of settings*". (Sawyer 2018) The guideline in its current format does not acknowledge these points, highlight different assessment and management approaches or pathways that may be seen in paediatric chronic pain clinics, discuss age related differences that may be appropriate to chronic pain	the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. They agree that on consideration of comments an additional recommendation on considerations for assessment of young people with chronic pain was needed. Separate recommendations have also been made for pharmacological management. The committee's consideration of how the recommendation would apply for young people is detailed in the committee's discussion of the evidence, where relevant.

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				management or acknowledge the significant gap in evidence for this group of patients. Thus: - We feel there are significant omissions and differences in practice that question the guideline's overall validity for the population 16-19yrs and perhaps to 25ys. - This advice does not accord with other NICE guidelines that cover populations up to 19yrs and in some cases up to 25 years. - Some of the assessment and management recommendations are out of line with normal practices within a paediatric chronic pain setting. This can potentially lead to either patients in this age group being treated differently from normal practices in our clinics or from the recommendations in the guideline. Without addressing these factors, the guidance on Chronic Pain potentially places an already vulnerable population at greater risk and sets the wrong precedent for adult based services who do not liaise with paediatric services or organise care specifically for adolescents and young adults.	

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Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	NICE guidance is often used by commissioners to guide and reassess budgets and resources for services. There is the potential for the recommendations in this guideline to either be extrapolated in to paediatric settings or have patients 16-19yrs (or up to 25yrs) being denied aspects of care. A further concern is that commissioners will use the proposed guidelines to reduce spending on secondary and tertiary care pain clinics. Primary care pain clinics do not have provision or expertise in undertaking rehabilitation for this vulnerable population. A significant increase in primary care manpower and expertise in treating complex physical and psychological illness within the correct diagnosis and treatment for pain conditions in young people would be required. **We recommend the guideline needs to emphasise that these young people may be seen in secondary and tertiary paediatric settings and that patients are not denied trials of reasonable treatment pathways that are standard practice in paediatric chronic pain clinics to see if they respond.** (FPM Core standards for pain management services in the UK, Scottish Government guideline for the management of chronic pain in children and young people)	Thank you for your comment. The committee agreed that where there was not sufficient evidence to support a recommendation for adults with chronic primary pain, there was no reason to believe these treatments would be more effective, or have fewer risks, for people aged 16 and 17, and therefore agreed recommendations should apply for the whole age spectrum of the guideline. The committee agree that there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in

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					other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	**What makes this age group vulnerable?** It is recognised that during this adolescence period there are ongoing neurodevelopmental changes and major transitions in life (psychological, behavioural , spiritual, cultural, educational and familial) that are having a huge influence on all healthcare presentations and place this population at greater risk for a poor outcome (Rosenbloom 2017, Twiddy 2017, Arnett 2000, De Rizze 2016, Casey 2000). These risks are reflected in other NICE guidance (see comment 20) and need to be addressed in the guideline. There is a high prevalence of chronic pain in this age group associated with mental health difficulties including anxiety and autistic spectrum disorder. There are also higher levels of associated safeguarding concerns. These issues have also been addressed in other NICE guidance (see comment 20) and need to be included in the guideline.	Thank you for your comment, the committee agree this should be taken into account in the assessment of pain in young people and also cross refer to the NICE guidelines Transition to adult services, NG43.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	**Other factors not addressed in the guideline:** - Up to a quarter of all young people are still in long term education by the age of 25y and requires services to engage with educational	Thank you for your comment. An additional recommendation has been included for the assessment of chronic

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				needs (including learning difficulties) and with education services. - A large proportion of this population are still living at home, or spend a significant amount of time at home. They may also still be dependent (emotionally, financially and spiritually) on their parents and families and not able to totally exist independently. In this situation there still needs to be specific regard for parents and not just as a family member or carer. There is a specific dynamic to the relationship between parent and their offspring that is different to other relationships and research in chronic pain has demonstrated this needs to be addressed (Rosenbloom 2017, Twiddy 2017). - Physical activity is especially important in the care of young people. However, the experience and capacity to access physical activity is different to adults and specific NICE guidance is available. The advice set out in the guideline is also not easily transferable to the paediatric chronic pain clinic setting as services are set up differently and there is a different level and availability of resource.	pain in young people, defined as age 16-25. The committee agreed that as the exercise recommendation states that it should be tailored to the individual needs of the person, that it could equally apply to 16 and 17 year olds.

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Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	NICE guidance and quality standards for transition should be addressed. This includes both the transfer from paediatric to adult services as well as more specifically the needs of young people who are managing multiple transitions in their life. The authors may wish to reconsider the following taken from other NICE guidance 1. Help the young person to continue their education. Contact the school or college, subject to consent, to ask for additional educational support if their performance has been affected by their condition. 2. Consider young people with chronic pain for assessment according to local safeguarding procedures if there are concerns regarding exploitation or self care, 3. Health and social care providers should ensure young people with chronic pain o can routinely receive care and treatment from a single multidisciplinary community team o are not passed from one team to another unnecessarily o do not undergo multiple assessments unnecessarily 4. Work in partnership with young people with chronic pain of an appropriate developmental level,	Thank you for your comment. A cross reference is included to the NICE guideline for Transition to adult services, NG43. A recommendation has also been added for considerations in the assessment of young people with chronic pain, including some of these issues as appropriate.

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				emotional maturity and cognitive capacity and parents or carers. 5. When working with young people aim to foster autonomy, promote active participation in treatment decisions, and support self management and access to peer support in young people of an appropriate developmental level, emotional maturity and cognitive capacity 6. Make sure that discussions take place in settings in which confidentiality, privacy and dignity are understood and respected and be clear with the young person and their parents or carers about limits of confidentiality 7. Discuss with young people with chronic pain of an appropriate developmental level, emotional maturity and cognitive capacity how they want their parents or carers to be involved in their care. 8. Health and social care professionals working with young people with chronic pain should be trained and skilled in: o negotiating and working with parents and carers, and o managing issues relating to information sharing and confidentiality as these apply to young people. 9. Provide young people with chronic pain and their parents or carers, comprehensive written and other information that takes into account the young	

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				person's developmental level, emotional maturity and cognitive capacity including any learning disabilities, sight or hearing problems or delays in language development. 10. There should also be links with support groups, such as third sector, including voluntary, organisations who are skilled in supporting this age group.	
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	**Potential Treatment Differences** The suggested assessment and management recommendations in the guideline are generated from the evidence that covers data from the complete adult age range. Very little of this is specific to, or contains stratification for, the adolescent age range. In addition treatment approaches can differ between adult and paediatric settings (Liossi 2016, Rajapakse 2014) and adherence to this guideline may lead to paediatric clinics having to change pathways, treatments or approaches for some of their patients without clear evidence that this is appropriate.	Thank you for your comment. The committee acknowledge that evidence for people aged under 18 was lacking. They considered in most cases it was acceptable for the recommendations to apply to 16 and 17 year olds as well, however they detailed where specific considerations may be required in their consideration of the evidence in the review chapter. For pharmacological management the committee agreed a separate recommendation was required. A specific recommendation was also added for the assessment of young people with chronic pain.

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Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	Patient Reported Outcome Measures – these are not specifically mentioned in the guideline but are used as part of initial and ongoing assessment of patients. They need to be age specific and verified and again for young people include the family/parents.	Thank you for your comment. The review protocols in the evidence review chapters detail the outcome measures considered in the reviews, the majority of which were patient reported outcome measures. No evidence was identified in people aged under 18 however.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	Pain Education – This often forms an integral part of management in paediatric pain clinics and is delivered in a number of formats. The delivery is again aimed at both patients and their families. It also allows for a consistence of message from all the practioners within a service which can promote better outcomes (Liossi 2019, Rajapakse 2014).	Thank you for your comment. The age range covered by this guideline is from 16 years upwards. If studies included mixed populations with younger people, these would be included if the majority (80%) were within the guideline population age range, or if the mean age included indicated that they were. We have reviewed the references provided and all of the included studies have a mean age under 16 so were not relevant to include in this guideline.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	**Comments on Guideline as a whole but also relevant to young people** Whilst it is recognised that it is difficult to present chronic pain management in a single guideline due to the	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are

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				broad scope of the speciality in terms of diagnosis, presentation, complexity and age range, in its current format the guideline is inconsistent and potentially confusing for the reader. This may lead to variable interpretation of recommendations, unintended alterations or restrictions to management and potentially poorer outcomes. Areas of concern are: - The guideline has sections relevant to assessment and management of all chronic pain but then other sections relevant to the one diagnosis of chronic primary pain. It is often not clear in the guideline which sections are relevant to which diagnosis(es). Clear clarification within the document is needed. - Often patients with pain presentations have more than one pain diagnosis and/or complex presentations. The guideline needs to be clear in this aspect and highlight the need for individual assessment by appropriately trained practioners. Management strategies and pathways also need to reflect this and allow for all treatments considered relevant to be available rather than a one size fits all approach which is based only on treating the chronic primary pain.	relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. Recommendations have also been added for when to consider a diagnosis of chronic primary pain and to highlight that chronic primary pain and chronic secondary pain can coexist. The guideline cross refers to other relevant NICE guidelines for management of chronic secondary

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				- Chronic pain as a whole, and chronic primary pain in particular, are diagnoses that encapsulate of very heterogeneous group of biological mechanisms. This again leads to individual presentations which are not easily generalisable in to a single guideline and will impact on the quality of the research data.	pain. Where they coexist clinical judgement should be used to determine management for the type of pain being treated, according to the relevant guideline. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The view of the committee is that there are likely to be shared

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					mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to for all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS).
Great Ormond Street Hospital for	Guideline	General	General	**Research** There is a lack of available high quality research in many areas of chronic pain management and the reasons for	Thank you for your comment. The committee agree that there was a lack of evidence for people aged under 18.

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Children NHS Trust				this are addressed in the scope of the guideline. This is especially seen for young people where the evidence base is even more sparse. As a consequence the guideline needs to reflect and acknowledge: - Lack of high quality data does not equal an absence of therapeutic value. - Many of the recommendations are extrapolated from studies that do not stratify for age and thus are potentially erroneous when considering specific age groups. - In young people the neuroplasticity of the developing brain, within the context of overwhelming pain, adds further to this model and can be directly affected (positively and negatively) by aspects of treatment. Further research continues to inform pain practice in this vulnerable group. - As chronic pain is a complex model looking at management options in isolation may not reflect real practice and the synergistic effect of multiple multi-disciplinary interventions. - Research studies do not wholly reflect clinical practice, exclude some patients (often those with	The population of interest for the guideline was aged 16 and over. In the majority of cases the committee considered that although some considerations may differ on the needs of the individual, this equally applied to the adult population, and therefore specific recommendations were not required. The exception to this was the recommendation for antidepressants. The committee agree that this recommendation should be amended and now state that for those aged 16 and 17, specialist advice should be sought if considering pharmacological management. Although the committee agree that more research in younger age groups would be beneficial, this has not been specifically stated in the research templates as the specific details of these will be further determined by those undertaking the research.

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				complex or mixed presentations) and are not designed around the individual presentations of patients. - There is a danger that treatments which are not recommended for pain will be decommissioned. PMP therapy is not recommended and may be decommissioned even though there is a recommendation for research. PMP decommissioning would prevent PMP research. - Thus the opinions of experienced practioners and the consistency of approach to clinical management must be taken in to consideration. **We would agree with the guideline that there are many areas involved in the management of chronic pain that need further research and that the proposed areas and topics are important. We would recommend that more is included in terms of suggesting research has age stratification as part of the design and there is specific research in to many of the areas we have discussed above that are more specific to young people e.g. transition, treatment effects, PMP etc.**	
Great Ormond Street Hospital for	Guideline	General	General	As stated above we are concerned that if this guideline is used as a tool, or has the effect, to decrease services or treatment options available to young people there will be	Thank you for your comment. The committee agreed that where there was not sufficient evidence to support

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Children NHS Trust				potentially associated poorer outcomes in this group. This may also have an economic impact. Not promoting management pathways specific and appropriate to young people will Increase rather than decrease conservative and non-conservative costs due to impact of pain on acute health services (increased ED attendance, attendance to primary and secondary care services, loss of education, loss of work, longterm and expensive use of ineffective medical and pharmacological therapies).	a recommendation for adults with chronic primary pain, there was no reason to believe these treatments would be more effective, or have fewer risks, for people aged 16 and 17, and therefore agreed recommendations should apply for the whole age spectrum of the guideline.
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	**References** Sawyer SM, Azzopardi PS, Wickremarathne D, Patton GC. The age of adolescence. Lancet Child Adolesc Health. 2018;2(3):223-228. doi:10.1016/S2352-4642(18)30022-1 Faculty of Pain Medicine. Core Standards for Pain Services in the UK. https://fpm.ac.uk/standards-publications-workforce/core-standards Scottish Government. Management of Chronic Pain in Children and Young People. https://www.gov.scot/publications/management-chronic-pain-children-young-people Rosenbloom BN, Rabbitts JA, Palermo TM. A developmental perspective on the impact of chronic pain	Thank you for your comment and for these references. We have responded in your comments above.

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				in late adolescence and early adulthood: implications for assessment and intervention. Pain. 2017;158(9):1629-1632. Twiddy H, Hanna J, Haynes L. Growing pains: understanding the needs of emerging adults with chronic pain. Br J Pain. 2017;11(3):108-118. Arnett JJEmerging adulthood. A theory of development from the late teens through the twenties. Am Psychol. 2000 May; 55(5):469-80 Di Rezze B, Nguyen T, Mulvale G, Barr NG, Longo CJ, Randall GEA scoping review of evaluated interventions addressing developmental transitions for youth with mental health disorders. Child Care Health Dev. 2016 Mar; 42(2):176-87. Casey BJ, Giedd JN, Thomas KMStructural and functional brain development and its relation to cognitive development. Biol Psychol. 2000 Oct; 54(1-3):241-57. Liossi C, Howard RF.Pediatric Chronic Pain: Biopsychosocial Assessment and Formulation. Pediatrics. 2016 Nov;138(5):e20160331. doi: 10.1542/peds.2016-0331. Epub 2016 Oct 14.	

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				Rajapakse D,Liossi C, Howard RFPresentation and management of chronic pain. Arch Dis Child. 2014 May;99(5):474-80. doi: 10.1136/archdischild-2013-304207. Epub 2014 Feb 19. Liossi C, Johnstone L, Lilley S, Caes L, Williams G, Schoth DEEffectiveness of interdisciplinary interventions in paediatric chronic pain management: a systematic review and subset meta-analysis. Br J Anaesth. 2019 Aug;123(2):e359-e371. doi: 10.1016/j.bja.2019.01.024. Epub 2019 Mar 1	
Great Ormond Street Hospital for Children NHS Trust	Guideline	General	General	NICE guidance and quality standards relevant to young people and Chronic Pain: **Safeguarding** for young people • NICE guidance NG 26, 55, 76, CG89, PH50 • Standards QS 116, 133, 154 179 • Child maltreatment: when to suspect maltreatment in under 18s Clinical guideline [CG89] **Transition** • Transition from children's to adults' services for young people using health or social care services (NG43) **Mental Health**	Thank you for your comment. The NICE pathway will link to relevant NICE guidelines. A cross reference for the NICE guideline for transition from children's to adults' services for young people using health or social care services, NG43, has been added to the guideline as well.

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				• Autism spectrum disorder in under 19s: recognition, referral and diagnosis Clinical guideline [CG128] • Autism spectrum disorder in under 19s: support and management (CG170) • Antisocial behaviour and conduct disorders in children and young people: recognition and management Clinical guideline [CG158] • Depression in young people NG134 • Learning disabilities and behaviour that challenges: service design and delivery. NICE guideline [NG93] **Other key guidance:** **Physical activity**for children and young people (PH17) **Looked-after children and young people**. Public health guideline [PH28] up to age 25y	
Great Ormond Street Hospital for Children NHS Trust	Guideline	Page 4	1.1	Assessment –Assessment of pain and its impact on a young person needs to include the family/parents and its interactions/dynamics.	Thank you for your comment. A recommendation has been added for assessment of young people, including interaction with their family.
Great Ormond Street Hospital for	Guideline	Page 7	1.3.3	In paediatric practice, psychological therapy is an integral part of multidisciplinary interventions and would be considered fundamental to treatment pathways. We	Thank you for your comment. There was no evidence identified for the use of psychological therapy in young people. The committee agreed it was

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Children NHS Trust				would therefore recommend it is given a strong recommendations i.e. "Offer" instead of "Consider".	appropriate to extrapolate evidence from the adult population and this recommendation could apply for those aged 16 and 17, but this recommendation was no sufficient to support a recommendation to offer psychological therapies for chronic primary pain.
Great Ormond Street Hospital for Children NHS Trust	Guideline	Page 7	1.3.5	Accupuncture and other non-pharmacological strategies – the access to these for patients under 18yrs across the country is variable and the training/experience of practioners not completely regulated. The evidence of efficacy and economic benefit is also not available. Though for some patients again there may be benefit. For our patients we would often assess the safety and appropriateness of a particular therapy on an individual patient basis and then refer for treatment if appropriate and regulated and qualified practioners were available.	The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also

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					be considered by NICE where relevant support activity is being planned. The committee agree that decisions on which treatment are appropriate should be based on a holistic assessment and considering the risks and benefits of all treatment options and the person's goals and priorities, amongst other factors. This should be a shared decision with the person. This is reflected in the recommendations in section 1.1 of the guideline on developing a care and support plan.
Great Ormond Street Hospital for Children NHS Trust	Guideline	Page 8	1.3.6	TENS – there is almost no evidence in its use specific to children and young people and as the guideline states there may not now be further trials as it is an established therapy. It is however low cost, non-invasive and for a significant proportion of patients can have benefit. Thus it is widely used in paediatric pain clinics and may be appropriate for many young people.	Thank you for your comment. The committee agreed that there was no evidence of benefit of TENS from the evidence reviewed for chronic primary pain. They do not believe there is any reason to believe this would differ for 16-17 year olds and agree the recommendation not to use TENS for chronic primary pain should apply to

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					the whole guideline age range from those aged 16 and over.
Great Ormond Street Hospital for Children NHS Trust	Guideline	Page 8	1.3.8-11	Medications – There is very limited evidence for the use of medications in pain presentations in young people. The use of certain medications is widespread however and although the evidence for this is often extrapolated from adult data it does need to be done with care. We would agree with many of the principles set out in the guideline - detailed discussion with patients/families, medications are started only as a trial with appropriate monitoring and regular review, cessation of treatment if not effective or significant side-effects. Families expect analgesic medication discussion when they visit a doctor with pain. This guideline will result in conversations between doctors and patients which most patients will find frustrating and unhelpful. This will be challenging for primary care physicians as well as in secondary and tertiary care services for young people where there are no other alternatives. The list of not recommended medications is long, very limiting and includes therapies that patients may already be taking. They may also be appropriate and recommended in other, and potentially co-existing, pain diagnoses. For some patients efficacy is seen promoting pain reduction and an improved quality of life. The blanket denial of these medications may deny some	Thank you for your comment. The committee agree that the evidence for young people was particularly limited. No evidence was identified covering people aged under 18. The guideline population starts at age 16. The committee have added an additional recommendation to state that specialist advice should be sought if pharmacological management is being considered for people aged 16-17. The committee agreed that the evidence reviewed did not support recommending the majority of medicines considered. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who

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				patients effective treatment, be distressing, limit engagement with other therapies and promote further costs in terms of other therapies needed in their place. The use of SNRI`s in young people promotes concern due to the increased suicidal ideation risk. These would not be felt to be first line choices.	are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
Grunenthal Ltd	Guideline	001 / 010 / General	004-005 / General	The draft guideline is titled 'Chronic pain in over 16s: assessment and management'. Page 1 states that the guideline 'includes recommendations on managing chronic primary pain (as defined in ICD-11)'. The term 'Chronic Pain' is then used again in points 1.1 and 1.2 before introducing the term 'Chronic Primary Pain' on point 1.3. ICD-11 makes a clear definition between chronic primary pain and chronic secondary pain. Whilst the draft guideline (on page 10) defines the terms 'Chronic Pain' and 'Chronic Primary Pain' it makes no mention of Chronic Secondary Pain. The lack of clear definition may potentially create confusion for HCPs and patients around what is covered by the guideline and what is not.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in

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					the context section which both also include discussion of chronic secondary pain. This now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Grunenthal Ltd	Guideline	005	007	The Guideline refers to individualising patient care and developing a care plan informed by a person's individual priorities, strengths, preferences, interests and abilities. As it is recognised that the pain management of older patients is often complicated by an individual's comorbidities and risks from polypharmacy, we suggest that this should be given a greater emphasis within the draft guidance.	Thank you for your comment. The committee agree that comorbidities and polypharmacy are important factors to consider. Recommendations in the assessment section have been edits, including highlighting the need for a holistic assessment and also to discuss the risks and benefits of all treatments and their preferred approach to treatment and balance of treatments for multiple conditions.
Grunenthal Ltd	Guideline	006	002-004	NICE NG59 (Low back pain and sciatica in over 16s: assessment and management), states that pain management programmes can be considered (physical & psychological) whereas this draft guidance makes a recommendation for research. We believe this may cause confusion. Within clinical practice there are specific tailored programmes which allow patients to better manage their pain and by not giving clear guidance this	Thank you for your comment. The committee were aware of the recommendation in NG59. Evidence in low back pain was included in this review where relevant to the review protocol, however the committee agreed the evidence couldn't inform a

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				may prevent appropriate patients gaining better pain control. A tailored and holistic approach may be needed.	recommendation for chronic pain as a whole. They were also aware the recommendation in NG59 was partly based on the ability to stratify people based on risk, which wasn't possible across the whole chronic pain population. This guideline will include a cross reference to the low back pain guideline and other related NICE guidelines.
Grunenthal Ltd	Guideline	007	007	NG59 states "1.2.8 Do not offer acupuncture for managing low back pain with or without sciatica." However the proposed text on this guidance suggests that Acupuncture should be considered for chronic primary pain. This suggests an inconsistency of recommendations which may cause confusion in clinical practice regarding which guideline to follow, without a clear rational as to why acupuncture is advised in managing chronic primary pain but not in managing all other types of chronic pain.	Thank you for your comment. The committee were aware of the recommendation and evidence review underpinning the recommendation in the current NICE low back pain guideline (NG59). However, the review for this guideline excluded evidence in people with low back pain and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica and was supported by a large evidence base. Consistent benefits

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					were observed for quality of life, and pain compared to sham as well as usual care as well as some benefits in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. We acknowledge that there will be overlap in painful conditions in many cases. Clinical judgement should be used to determine the appropriate treatment option relevant to the type of pain they are treating.
Grunenthal Ltd	Guideline	008	008	NG59 1.2.13 states "consider therapies with or without manual therapy". The guideline proposed states that there was not enough evidence on manual therapy in chronic primary pain and therefore this contradiction to the previous guidance could cause confusion within clinical practice. Manual therapy may be beneficial in some patients and therefore should be considered as an option, with caution, if necessary. As this guidance is for chronic pain in the over 16s, it makes no comment on whether manual therapy should be offered in chronic pain which is not chronic primary pain, and is therefore likely to cause confusion for health care professionals.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification

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					has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. This review for manual therapies therefore excluded evidence in people with low back pain and sciatica and therefore these two reviews and guideline recommendations are based on different populations. The committee agreed that there is insufficient evidence to recommend manual therapies for chronic primary pain.
Grunenthal Ltd	Guideline	008, 009	014-015 and 001,002	We are concerned with the inclusion of agents that are not licenced for the management of pain within this guideline. Evidence supporting the use of antidepressants	Thank you for your comment. There are no medicines that have a specific

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				in this setting is moderate/ weak. In addition, the Committee are suggesting that these agents should be considered as first line pharmacological options for the management of chronic pain, when there are licenced agents available; we do not believe this promotes responsible prescribing. Inclusion of these agents should support safe use of these medicines in individuals where they could offer an improvement in quality of life. We would like to raise the following points for consideration: - A need for appropriate and responsible prescribing of antidepressants drugs. Consider additional reference out to the latest NICE pathway update on Antidepressant treatment in adults updated 19th August 2020. This is more up to date than the NICE guideline on depression in adults. This Pathway update also includes appropriate information on interactions of SSRIs with other medications. Advice needs to be included within this guideline on monitoring requirements for individuals prescribed an antidepressant. Individual patients should be reassessed at each review and prescribers should stop any medicines that are not effective.	marketing authorisation for chronic primary pain or types of chronic primary pain in the UK. The reviews in this guideline intended to review all those that are most commonly used and for which there is uncertainty about their efficacy. The evidence did not support a positive recommendation for any of the other medicines reviewed, but the committee did agree that there was sufficient evidence of benefit from antidepressants to consider their use. When this guideline is published the NICE pathway will link to other relevant NICE pathways and guidance within them, including Depression in adults with a chronic physical health problem: CG91 which is where the information on SSRI interactions is from. This guideline includes a section on assessment and developing a care and support plan. This includes stating that benefits and harms of all treatment

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					options should be considered at every assessment throughout management. The committee also note that initial efficacy of the antidepressant medicine should be at 4-6 weeks. A recommendation is also included to cross refer to the Depression in adults guideline for advice on stopping or reducing antidepressants.
Grunenthal Ltd	Guideline	009	004	We would like to point out the incongruency of recommending the use of an off label treatment, whilst at the same time recommending that, licenced, on label treatments are not used. This does not seem congruent with NICE's role being "to improve outcomes for people using the NHS and other public health and social care services, we do this by producing evidence based guidance…..". By recommending the use of off label medicines over and above those which have gained a licence, can give the impression of undermining NICE's respect for the UK regulatory process.	Thank you for your comment. The recommendations are based on reviews of the evidence for each intervention specific to the review population of chronic primary pain. The committee note that antidepressants are used off-license for chronic primary pain, however no medications are specifically licensed for chronic primary pain in the UK (although some are for other types of pain) and therefore off-license use is current practice.
Grunenthal Ltd	Guideline	009	010	NICE NG59 recommendation 1.2.20 states to consider weak opioids (with or without paracetamol) for managing acute low back pain only if an NSAID is contraindicated,	Thank you for your comment. The reviews for specific interventions

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				not tolerated or has been ineffective. However this proposed guidance rules out the options listed which may be of benefit to patients who develop chronicity in clinical practice. If this guidance is unaltered, then it may cause a shift towards withdrawal of certain medications which are tailored to individual patients providing effective pain relief. The proposed text would be contradicting the previous NG59 guidance alongside the guidance from Faculty of Pain Medicine regarding Opioids Aware. Additionally, in contrast to NG59, this draft guidance does not take into account or recognise the challenge of treating chronic pain which may have both a nociceptive and a neuropathic component.	included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline (including low back pain) was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Grunenthal Ltd	Guideline	009	010	Referring to the RCGP document on "Pain Management Services: Planning for the Future", page 13 states: "Opioids can be effective in some, but not in all patients and they have the potential to cause harm". The document does not state that opioids should not be	Thank you for your comment. The RCGP document is for all types of chronic pain. The review and recommendations for pharmacological

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				offered. Therefore the proposed text in this draft guidance is inconsistent with other commissioning documentation by respected bodies.	management in this guideline is only for chronic primary pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. The guideline recommends that recommendations in these guidelines should be followed in acknowledgement of the fact that chronic secondary pain will require different management in many cases.
Grunenthal Ltd	Guideline	009	010	According to Faculty of Pain medicine website, the Opioids Aware section clearly states "Opioids are very good analgesics for acute pain and for pain at the end of life but there is little evidence that they are helpful for long term pain. 2. *A small proportion of people may obtain good pain relief with opioids in the long-term if the dose can be kept low and especially if their use is intermittent*". Thus reflecting that opioids should not be ruled out altogether. Comparing to the proposed text of this guidance, this would cause confusion and divide between healthcare professionals involved in management of pain patients.	Thank you for your comment. The evidence reviewed within this guideline, and the expert consensus opinion of the committee did not support recommending opioids for chronic primary pain however. There is no evidence we are aware of to define the small proportion of people who may benefit, and therefore these potentially harmful medicines, for which there's no evidence that they help the majority of people, cannot be recommended for prescribing within the NHS.

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Grunenthal Ltd	Guideline	048	013,014 ,015	With reference to: Chronic pain: assessment and management evidence review for pharmacological management, NICE guideline Intervention evidence review underpinning recommendations 1.3.7 to 1.3.12 and the research recommendations in the NICE guideline August 2020: We would like to draw the NICE committees attention to the following key messages from Opioids Aware Resource: *A small proportion of people may obtain good pain relief with opioids in the long-term if the dose can be kept low and especially if their use is intermittent (however it is difficult to identify these people at the point of opioid initiation). If a patient has pain that remains severe despite opioid treatment it means they are not working and should be stopped even if no treatment is available.*1 We support the NICE committee's view on taking an individualized care approach for people living with chronic pain. An emphasis should be placed on general principles of good prescribing practice underpinned by an understanding of the condition being treated, appropriate pain assessment and monitoring of prescribing to ensure that medicines that are ineffective are stopped1. Whilst we respect that the Briefing paper by the British Medical Association on Chronic Pain: supporting safer prescribing of analgesics2, Opioids Aware Resource1 and this NICE draft Guideline all reference evidence that demonstrates a lack of data for efficacy of opioids in	Thank you for your comment. The Opioids Aware resource covers use of opioids for conditions much broader than chronic primary pain, which was the focus of this guideline review. This includes chronic secondary pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. For chronic primary pain the committee do not agree that there is evidence to support short term use for the same type of pain. The guideline recommends that recommendations in these guidelines should be followed in acknowledgement of the fact that chronic secondary pain will require different management in many cases. Clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating

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				treating long-term pain, we ask the NICE Committee to consider opioids that have a licence for the management of long term pain, supported by high quality data. We would urge the NICE Committee to reconsider their position on excluding opioids entirely from use in the management of chronic pain patients, in favour of strong recommendations for appropriate prescribing of specific opioid treatments that have demonstrated efficacy and safety in patients with severe chronic pain manageable only with opioid analgesics. 1: https://fpm.ac.uk/opioids-aware 2: https://www.bma.org.uk/media/2100/analgesics-chronic-pain.pdf	what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Grunenthal Ltd	Guideline	9	10	Referring to CG140 on palliative care where guidance is given based on a holistic approach of prescribing of opioids, the text in this proposed guidance is contradictory. Even with regards to NG180 (peri-operative setting), there is not a clear rule out of opioids and therefore this proposed guidance would not be in-line with previous recommendations around pain.	Thank you for your comment. The review and recommendations on pharmacological management in this guideline is only for chronic primary pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with

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					a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Grunenthal Ltd	Guideline	General	General	According to "Appendix 3 Suggested Treatment Pathways" of the Public Health England document on Managing Persistent Pain in Secure Settings, it is recommended that a holistic approach to the management of pain should be implemented by discussing the risk versus benefit and by using an individualised approach. Although mentioned, the emphasis on an individualised approach seems to be lacking from this proposed guidance, contrary to the Public Health England guidance.	Thank you for your comment. The committee agree that an individualised approach and a holistic assessment is key to good management of chronic pain. The assessment recommendations have been amended to strengthen the importance of these aspects.
Grunenthal Ltd	Guideline	General	General	We would like to question the validity of issuing this guidance at this stage. Due a lack of evidence, section 1.2 offers no further guidance outside of existing guidelines, only making recommendations for further research. With regards to managing all types of chronic pain, the draft document is, for the most part, not evidence based. The draft guidance supports the	Thank you for your comment. The primary focus on this guideline is assessment of all types of chronic pain and the management of chronic primary pain. In consideration of the stakeholder comments received we

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				adoption of an individualised care plan, but then goes on to provide advice which is very limited in its evidence based recommendations. With regards to the management of chronic primary pain, there are recommendations for interventions which Clinical Commissioning Groups (CCGs) do not have in their current work plans, there not being sufficient capacity or capability currently within the present healthcare system. As a consequence, this draft guidance is not offering any meaningful support to clinicians. The pharmacological recommendations, seemingly ignore the existing evidence base for where certain patients do get meaningful pain relief from receiving appropriate licenced in label medications, in favour of off label antidepressants. It is incongruent with the role and workplan of NICE that, in summary, the recommendations advocate the use off label treatments in favour of licenced on label treatments and the use of interventions, which have not been fully researched and which are not readily available throughout CCGs in the NHS. Furthermore, there is an inconsistency where NICE have advised to use interventions within this guidance which is not advised in other parallel guidance (e.g. acupuncture in NG59). The overall impact of this draft guidance is that, although it provides advice on the management of primary chronic pain, it does not give adequate, evidence based advice regarding the treatment of chronic pain in the over 16s, which is its intended purpose. This draft guideline	have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. There was evidence underpinning the recommendations. Where this is supplemented with committee expert consensus views, that is also detailed in the rationale and the discussion of the evidence. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain

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				provides no new evidence or advice on the management of all types of chronic pain, outside of those specific conditions listed (which already have NICE guidelines in place). As this draft guideline only actually contains guidance on both assessing and managing chronic primary pain in over 16s, we believe this should be made clear in a re-worded title of the guideline to "Chronic Primary Pain in over 16s:assessment and management".	will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. The committee note that there are suggestions that small subgroups of people with chronic primary pain may benefit from some treatment. These guidelines provide recommendations for the population with chronic primary pain. Unfortunately research to date does not enable this group of responders for different interventions to be identified and therefore recommendations for more targeted prescribing are not possible. The committee agreed it was inappropriate to recommend trying medicines for which there is no good evidence that most people will benefit

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					from or to risk exposing all of the chronic primary pain population to medicines with a potential for harm, without evidence on how to determine the small subgroup that may benefit. The committee do agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.

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Grunenthal Ltd	Guideline	General	General	We feel that this draft guideline is incongruent with NICE guidelines and recommendations such as NG59; The guidance within these recommendations, and of other professional agencies including Public Health England and bodies such as the Faculty of Pain Medicine of the Royal College of Anaesthetists Opioids Aware resource, along with British Pain Society, all recommend that an individualised, patient-centred approach for diagnosis and treatment of pain is essential to establish a therapeutic alliance between patient and clinician. It is also recommended by the Faculty of Pain Medicine of the Royal College of Anaesthetists Opioids Aware resource that all patients should be carefully selected, abuse risk factors evaluated and regular monitoring and follow-up implemented, to ensure that opioids are used appropriately and in alignment with treatment goals (pain intensity and functionality) as agreed with the patient. This draft guideline does not reflect alignment with these other, consistent, recommendations and does not provide a rationale or acknowledgement of why it differs so significantly to other guidance.	Thank you for your comment. The committee agree that an individualised patient centred approach is central to the holistic assessment of chronic pain and this is reflected in the recommendations in the sections on assessment and development of a care and support plan included in the beginning of the guideline for all types of chronic pain. The reviews and recommendations for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each

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					recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The evidence base considered therefore differs from other related NICE guidelines particularly in terms of the population, as does the population considered here and in the other documents from other bodies. There are also different methodologies applied by different organisations which can explain differences in conclusions even when the populations considered are the same. Recommendations in this guideline are based on systematic reviews of the clinical and economic evidence interpreted by the committees.
Grunenthal Ltd	Guideline	General	General	According to the British Pain Society, along with the CENT 2015 statement published in J Clin Epidemiology 2016 Aug, "the society prefers a holistic approach whereby patients with complex pain are assessed using multidisciplinary skills, as are found in specialist pain clinics, and appropriate therapies are offered, sometimes	Thank you for your comment. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in

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				on an individual trial basis, according to the best available evidence". Within the proposed guidance there seems to be a lack of holistic or patient centred approach, with respect to treatment options at the discretion of the prescriber who will have the best knowledge of the patient (both physically and mentally). This could translate to limiting patients of treatments which are currently working/could work for individuals in the future. We support the more holistic approach to pain management which is now occurring in the NHS in England CCG MSK services, where we estimate about 30% of these services have a multi-disciplinary team approach. We do not feel this approach is adopted within this draft guidance.	primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The committee agrees the assessment should take a patient centred approach and have stated this in the recommendation. The recommendations also state that the risks, benefits and evidence for all treatment options should be discussed with the patient at all stages of the assessment.
GSK Consumer Healthcare	Guideline	001	007	The guideline draft states, "this guideline is for people with chronic pain, their families and carers". The language is directed to healthcare professionals/ providers. If targeted to patients, ensure in the final document that there is a clear definition of chronic pain	The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other

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				that would be understood by the patient/ carers? It is important that the guidance is correctly understood by patients, their carers or consumers in general. Would be good to understand if the Guideline Summary in plain language will be available for public review whilst in draft?	guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The guideline webpage will also include information for the public.
GSK Consumer Healthcare	Guideline	001	007	These guidelines state they were developed prior to COVID-19, when the position of using antipyretics (paracetamol or ibuprofen) was still unclear, and a general perception of preferential use of Paracetamol existed. In context of chronic pain, clear guidance would be helpful for patients with COVID-19. Use of analgesic / antipyretics is mentioned COVID 19 GUIDANCE (COVID-19 rapid guideline: managing	Thank you for your comment. This guideline recommends against the use of both NSAIDs and paracetamol for chronic primary pain and therefore no further statement is included here in relation to their use in this population for people who also have COVID-19.

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				symptoms (including at the end of life) in the community) states 'Advise patients to take paracetamol or ibuprofen if they have fever and other symptoms that antipyretics would help treat' Reference:- https://www.nice.org.uk/guidance/ng163/resources/covid19-rapid-guideline-managing-symptoms-including-at-the-end-of-life-in-the-community-pdf-66141899069893 There might be need to further consider relevant information to be included in this Guidance relating to COVID 19. e.g. based on recently published data from UK (Prior Routine Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Important Outcomes in Hospitalised Patients with COVID-19. Bruce et al, 2020) Reference:- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7465199/, Denmark (Adverse outcomes and mortality in users of non-steroidal anti-inflammatory drugs who tested positive for SARS-CoV-2: A Danish nationwide cohort study. Lund et al, 2020) Reference:- https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003308	
GSK Consumer Healthcare	Guideline	008	013	Since these guidelines will also be read by patients, it would be useful to state that pharmacological interventions are to be considered under HCP recommendation, however there are some medicines available without prescription which patients may use on	Thank you for your comment. This guideline recommends against the use of the medicines that can be purchased over the counter for the management chronic primary pain

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				their own, so clear advice on duration of use for these medicines maybe be of benefit to encourage appropriate use.	and therefore we have not included guidance on dose and duration for these for this indication.
GSK Consumer Healthcare	Guideline	026	007	Does the statement "the committee agreed that these medicines have possible harms" apply only to single ingredients as well or only to combinations? Please clarify.	Thank you for your comment. These recommendations recommend against the use of all of these medicines for chronic primary pain (with the exception of antidepressants). The committee have no evidence to suggest the harms would be less if used in combination.
GUTS UK Charity	Evidence review B	018	042 - 044	Despite the judgement of low confidence in the applicability of negative test results reporting over the spectrum of chronic pain, Guts UK charity welcome the consideration for this guideline of the findings around discussion of negative test results as "good news" and the discord that is evident between this description and possibly what the patient feels. Guts UK's own survey results from in 2017 (as Core) An online survey with 787 people who have or have had a digestive condition and their caregivers and 10 qualitative interviews, with eight people who have or have had a digestive condition and two caregivers. Over half of the respondents (56%) said they were satisfied or very satisfied with the ongoing management of their digestive condition. Those who were dissatisfied felt this way due to not receiving adequate guidance or	Thank you for your comment. The committee hope that these recommendations will help address these issues.

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				advice on how to control symptoms, a lack of effective treatments, and a perceived unsupportive/negative attitude from HCPs.	
GUTS UK Charity	Guideline	001	007	Box, should the pancreatitis guidelines NG104 be added to this list?	Thank you for your comment. The overview page links to the most directly relevant NICE guidelines but is not an exhaustive list.
GUTS UK Charity	Guideline	005	020	Should guidelines on pancreatitis NG104 be added here to the list of other conditions to refer to these guidelines for chronic pancreatitis pain.	Thank you for your comment. This lists the most directly relevant NICE guidelines but is not an exhaustive list.
GUTS UK Charity	Guideline	007	007	Please note, acupuncture treatment discussed here contradicts the guidelines for IBS (CG61) 1.2.4.1 The use of acupuncture should not be encouraged for the treatment of IBS. [2008] Whilst IBS is not chronic primary pain, some people with fibromyalgia also have IBS (Monden R, Rosmalen JGM, Wardenaar KJ, Creed F. Predictors of new onsets of irritable bowel syndrome, chronic fatigue syndrome and fibromyalgia: the lifelines study *Psychol Med*. 2020;1-9. doi:10.1017/S0033291720001774) would it be helpful to state that it is unknown if it helps abdominal pain in IBS, to add note of clarification here?	Thank you for your comment. The review of acupuncture for this guideline excluded evidence in people with IBS as this is covered by CG61 as you correctly highlight. Therefore a different evidence base was included within this review for chronic primary pain. The NICE pathway will directly link to the relevant guidelines to aid with clarification for readers.
GUTS UK Charity	Guideline	007	012	Is it appropriate for a band 3 or 4 HCP to be giving acupuncture treatment? Does a lower banding limit need to be added?	Thank you for your comment. The committee do not agree there is a need to state a minimum band limit. All guideline recommendations for NHS care assume the healthcare

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					professional delivering the intervention or service are appropriately trained to do so. This has been added to the recommendation for clarity.
GUTS UK Charity	Guideline	General	General	The definition of chronic primary pain used from ICD-11 is not at all clear for patients or carers. We asked our community via social media if they would like to comment on these guidelines and we had two replies giving a personal history of chronic abdominal pain but when they were then asked for direct comment on the guidelines they did not respond. It would be useful to have chronic pain and chronic primary pain explained in a clearer way, perhaps in the lay summary, if not in the main guideline document. If fibromyalgia is a primary chronic pain condition it would be useful to have this stated in the guidelines.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.

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GUTS UK Charity	Methods	008	028	Does the NICE guidelines for IBS and pancreatitis need to be added to this list?	Thank you for your comment. IBS has now been added. This list is not intended to be all inclusive however, pancreatitis was not considered a key guideline to add.
Healthwatch UK	DOC Committee membership list/Register of Interests	003		We are concerned that one member of the committee, Dr Jens Foell, is described in the committee membership list as "General Practitioner, Llanfairfechan, and Senior Clinical Teaching Fellow, Imperial College London". No mention is made of the fact that he is a medical acupuncturist. It is surely possible that, even though Dr Foell is described as having "declared [his potential COI} and withdraw[n] from drafting recommendations on acupuncture" his presence on the committee could still have influenced the other members in their views of this form of treatment. In our view it would have been much more appropriate for him to have been called in as an outside expert to give evidence to the committee (and be questioned by them) rather than being an actual committee member.	Thank you for your comment. The NICE conflict of interests policy was followed throughout development of this guideline. The declaration of interests register is publicly available with the guideline documents and the minutes of each meeting state where committee members withdrew from discussions. Dr Foell declared his potential declarations relating to acupuncture at appointment. These are detailed in the register and the appropriate action was taken for him to withdraw from all decision making relating to acupuncture. He was available to the committee to answer matters of fact or clarification relating to this topic only and did not unduly influence the committee in forming the review protocol nor their

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					interpretation of the evidence or drafting of the recommendations.
Healthwatch UK	Evidence report	043	036-043	The evidence report admits that the evidence for acupuncture was *"of low to very low quality, with only a small amount of moderate quality evidence."*It goes onto say that the evidence was mainly downgraded due to risk of bias and imprecision. Risk of bias, we are told, *"was often high due to attrition and selection bias. In the usual care comparisons there was a lack of blinding in the studies due to the nature of the intervention; this combined with the mostly subjective outcomes resulted in a high risk of performance bias"*.These comments are in line with the 54 Cochrane reviews of acupuncture published to date. Only two reached positive conclusions based on more than one high-quality study; these two were concerned, respectively, with the prevention of migraine and the prevention of tension-type headache. If the committee had considered the issue of consistency when discussing LETR, there are Cochrane reviews of the use of acupuncture in conditions that are more relevant to the management of chronic pain. The committee should have noted, for example, the review into low back pain by Furlan et al (https://doi.org/10.1002/14651858.CD001351.pub2). The authors' conclusion in this study was that *"[f]or chronic low-back pain, acupuncture is more effective for pain relief and functional improvement than no treatment or sham treatment****immediately after treatment and in the***	Thank you for your comment. The committee were aware of the differing conclusions in other types of chronic pain, including recommendations in NICE guidelines for low back pain and osteoarthritis. These differences are a result of the different evidence bases informing each recommendation. The committee took the quality of evidence and risk of bias into account in their interpretation of the evidence. This is reflected in the committee's discussion of the evidence in the evidence review. The committee agreed that overall the body of evidence was demonstrating a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for

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				short-term only*[our emphasis]. Acupuncture is not more effective than other conventional and "alternative" treatments.*"Another example the committee should have noted is the review by Zi et al https://doi.org/10.1002/14651858.CD012057.pub2) concerning neuropathic pain. Their conclusion is that *"there is insufficient evidence to support or refute the use of acupuncture for neuropathic pain in general, or for any specific neuropathic pain condition when compared with sham acupuncture or other active therapies."* We believe the committee did not consider the inconsistency with other evidence adequately when reaching their 'consider' conclusion (albeit that was relatively limited).	quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. Comparison with the systematic reviews you highlight are not of equal populations. As you state, Furlan et al. was in chronic pow back pain, and Zi et al. was in people with neuropathic pain. Both of these types of chronic pain were excluded from this review which focussed on chronic primary pain. This is detailed in the protocol and scope, further clarification has

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					been provided in a visual summary to accompany the guideline detailing what population each review and relevant recommendations are covering.
Healthwatch UK	Evidence report	045 175	038 - 042 Fig. 8	The report says that *"[t]he committee noted that the majority of evidence was based on women with chronic neck pain or fibromyalgia. However, the committee agreed that for interventions such as acupuncture, response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions, even when evidence was available for only one condition."*This statement is remarkable for several reasons. Firstly, the technique used to treat fibromyalgia is dry needling, which is different in both theory and practice from actual acupuncture. Secondly, the report offers no evidence at all to support the assertion that what works for fibromyalgia is likely to work for other forms of chronic pain; this assertion (or rather, this leap of faith), is fundamental to the whole argument in favour of recommending acupuncture for chronic pain. It surely needs to be supported by data. The report itself provides evidence that fibromyalgia is not the same as other chronic pain syndromes: for example, figure 8 on p175 shows that the effect of acupuncture on health-related quality of life is significantly different for fibromyalgia as compared to myofascial pain syndrome. Therefore NICE	Thank you for your comment. This review included both acupuncture and dry needling, including a number of studies of acupuncture in people with fibromyalgia. The committee considered that there was considerable variation in the type of acupuncture or dry needing included in the studies and conclusions could not be drawn on whether either were more effective. They therefore agreed the type should be determined based on the individual needs of the person with pain. Although it is stated in the discussion of the evidence that the majority of evidence is for people with neck pain or fibromyalgia, studies were also included in people with myofascial

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				has an internal inconsistency, as it has demonstrable evidence that the leap from one to the other is not justifiable. In summary, the committee's bald statement is tantamount to saying that 'because steroid inhalers work for chronic bronchitis they should also work for congestive heart failure, since both diseases cause shortness of breath and exercise limitation'. Due to this breakdown of logic, and inapplicability of the data, we believe the current 'consider' recommendation is unsustainable and should be withdrawn.	pain, vulvodynia, chronic pelvic pain and shoulder pain and therefore there was some evidence underpinning this. There was no evidence in the review to indicate a difference in effect according to subtype of chronic pain. Where there was heterogeneity in pooled analysis, subgroup analysis was undertaken by type of chronic primary pain, but this did not explain the heterogeneity. The committee therefore agreed there was no reason that the recommendation should not apply for all types of chronic primary pain.
Healthwatch UK	Evidence report	048	040	This page says that *"[t]he committee considered the potential harms related to the use of acupuncture. One of the most serious possible harms of acupuncture is organ puncture, although there were no reports of this within the evidence."*Since the evidence consisted of trials which sought to test the efficacy of acupuncture and not its safety, it is hardly surprising that no such information was forthcoming. It is also worth noting that the PICO table on p7 makes no mention of harms from treatment other than obliquely, by referring to discontinuation.	Thank you for your comment. As you state, efficacy trials rarely inform on all the harms of the treatment. We do therefore note and consider the committee's views and experience regarding this. Discontinuation due to adverse events was considered in the review and the committee agreed this would capture serious adverse events.

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Healthwatch UK	General	General	General	We are intrigued by the finding, and can see that for patients and practitioners, the idea that there is an effective remedy for pain is very attractive. However, given the problems and short term nature of the benefit, we believe that the committee has stepped too far from the evidence base. If, by whatever mechanism, acupuncture did 'work' and was both clinically and cost effective then it might be a great boon. However, what the review shows is that this is a potentially promising modality. It should be offered 'in research only'. And that research should be prioritised. It would be much more important to have just one single research recommendation to generate high quality evidence about these matters, than to provide a few sessions of a not very effective treatment on the NHS, but give enormous credence and an 'imprimatur' to the private complementary medicine sector. We believe that if it does 'work', then it would be very important to offer it. This 'consider' recommendation does not move evidence and equitable patient care forward. We would urge NICE to urge NIHR to fund a definitive high quality RCT which is powered on better outcomes, at a year (and beyond) with pre-specified subgroup analyses. This would then at least lead to a firm Offer or Do Not Offer recommendation that will be more meaningful and helpful in years to come to patients with chronic pain of unknown origin. Patients are simply not well served by this feeble recommendation.	Thank you for your comment. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.

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Healthwatch UK	Guideline	011	General	In view of the admitted uncertainties surrounding the use of acupuncture for the treatment of chronic pain and the fact that the evidence available to the committee is of low or very low quality, we are surprised that there is no comment about the need for further (and better) research into the use of this treatment modality.	Thank you for your comment. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee agreed that the area

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					of uncertainty in use of acupuncture for chronic primary pain that did require further research was the use of repeat courses. This research recommendation has now been made high priority.
Healthwatch UK	Guideline Evidence report	019 044	023 – 024 003	The draft guideline states that *"[m]any studies … showed that acupuncture reduced pain and improved quality of life in the short term (3 months) compared with usual care or sham acupuncture."*However, as the evidence report admits, *"[a] large range of sham procedures were included within this review, which were pooled in the analysis. These included procedures such as not fully inserting needles, needles contacting the skin only or needles inserted in the wrong acupoints."*This statement undermines the whole basis of the comparison between acupuncture and other treatments. It also contains the extraordinary notion that there are such things as *"right"*and *"wrong"*acupuncture points. We believe that extraordinary claims require extraordinary evidence. Qi does not exist. Since there is no rational, reliable basis that has been found for the so-called *"right"* acupuncture points, the distinction between "right and "wrong" points becomes meaningless. If the statement about sham acupuncture is to have any value at all, it needs to be rewritten to explain what the effect might have been of comparing "real" acupuncture with one or more of the different forms of sham treatment.	Thank you for your comment. The discussion of the evidence details the committee's deliberations of possible factors that could impact the interpretation and the observed effects. However, the committee agreed when setting the review protocol that all types of acupuncture and dry needling (with the exception of electroacupuncture) would be pooled for analysis and to only separate to explore heterogeneity and also to pool all types of sham in the analysis. The committee agree it is important to detail the different arguments for the effects that different types of acupuncture, and different shams may have. The committee's conclusion from the

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				In the linking of evidence to recommendations, more emphasis should have been given to it being far more likely that the difference between so-called real and sham acupuncture relates to how long the needles were left in place, whether or not they were moved, re-inserted, twirled, etc. Additionally, the practitioner, who clearly could not be blinded to the nature of the treatment, might have given verbal or non-verbal cues which affected the subject's responses. The danger is that this guideline (and NICE itself) will make itself ridiculous in the scientific world by giving validity to Qi and acupoints. Of course, we don't understand everything, but the idea that acupuncture itself 'works', has no scientific or biological basis. The particular, small systematic review that NICE has done produced very low to low quality evidence that flies in the face of over 50 negative reviews of acupuncture done by the Cochrane Collaboration in other conditions. Even if it is the 'best available evidence', it should be treated with much more caution.	review was not to specify a type of acupuncture and not that despite the potential limitations and variation it was also appropriate to pool different types of sham. The fact that sham acupuncture may itself have a therapeutic effect, would reduce any effects of acupuncture in a comparison. Although the mechanisms through which acupuncture produces effects are not understood and may also include non-specific effects of the therapist, the committee agreed that the fact that benefits of acupuncture were seen compared to sham was promising. They agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual

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					care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.
Healthwatch UK	Guideline	020	001 - 002	The guideline says: "*[t]he committee agreed that the type of acupuncture or dry needling should depend on the individual needs of the person with pain*". Nothing further is said about this, which seems remarkable. There is nothing in the evidence review to suggest that there is any rational way of determining the "individual needs" of the person with pain, even less a sensible method of selecting the type of acupuncture or dry needling which might address those needs. What the guideline is essentially saying is that the details of treatment should be worked out according to the prejudices/financial interests of the provider and the impulses of the sufferer.	Thank you for your comment. The committee acknowledged in the discussion of the evidence (in Evidence report G) that the review. included a wide range of acupuncture methods. There was no heterogeneity seen in the evidence that could be explained by the different types of acupuncture, and this was considered when wording the recommendation. The committee considered that clinical judgement by the healthcare provider delivering acupuncture

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					would inform the most appropriate type of acupuncture according to the type of pain.
Healthwatch UK	Register of interests	General	General	This document is appalling badly laid out and almost impossible to read, as the name of each committee member is not carried over in column 1 when her/his declared interests go over onto the next page. Indeed, the whole idea of putting the information into a table, as has been done here, is a nonsense. For future reference, please give a list of the committee members at the beginning of such registers, then give each member one or more pages on which relevant interests can be declared, with a table of contents at the start of the document to indicate to the reader where to look, e.g. "Dr Jens Foell, pp12-14".	Thank you for your comment. This is the standard template used for the declarations of interest register across all NICE guidance. We will note your suggestions for consideration in future updates to the template.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	1	4	Implies that the guideline is for all chronic pain rather than the main focus which is chronic primary pain as defined in ICD-11. This needs to be much clearer at the outset. The current layout of the guidance is confusing and misleading. It might be better if the guidance were just aimed at chronic primary pain?	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant

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					recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	10	1	No guidance on how often and when patients already taking these medicines should be reviewed	Thank you for your comment. The committee agree that it is important to acknowledge that some people will already be receiving these medicines. More detail has also been added to the recommendation with considerations for people already taking these however as the guidance recommends against their use the committee have not recommended how they should be used and reviewed, but do state if a shared decision is made to continue, this needs to be done safely.

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Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	5	3	To include questions about what makes the pain better or worse.	Thank you for your comment. The scope included the identification of factors that may be barriers to the pain improving, and each intervention reviewed focussed on whether or not this improved pain.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	6	2	Pain Management Programmes – could this be more definitive ie. are they recommended or not? Giving consideration to: 1. Widespread existence of PMP in the NHS 2. What else can patients be offered; the interventions are limited, particularly for complex type patients? This guidance contradicts numerous national documents/organisations who recommend PMP eg. National Back Pain Pathway, which has been used to inform commissioning of local services. This feels like a national u-turn.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For

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					chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review.

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					The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	6 10	8 15	In discussion with numerous general practitioners they were not familiar with the term "Chronic primary pain" and explained this would be difficult to identify Presumably, chronic pain is a diagnosis of exclusion .ie everything has been tried, and possible explanations / causes ruled out – by this point it may be too late, and medications which are difficult to wean are missed off	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received the guideline has been renamed and subheadings have been added throughout the guideline as well as adding wording to relevant

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					recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The assessment recommendations have now been amended to include consideration of other causes of the pain and when to consider a diagnosis of chronic primary pain.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	7	2	Local access to CBT locally is limited to people with pain leading directly to a mental health disorder; so this will be difficult and expensive to implement. May need re-thinking in terms of how and where the service is offered.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement

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					some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	7	7	Large proportion of evidence for acupuncture is seen in osteoarthritis patients rather than chronic primary care patients. Limited numbers in fibromyalgia etc. So should it be used at all? Will be difficult to ensure that: 1. Acupuncture is delivered as described Delivery is limited to patients with chronic primary pain (most other indications limited evidence and ? should not be commissioned)	Thank you for your comment. Studies in people with osteoarthritis were excluded from this review as the population of interest is chronic primary pain. Osteoarthritis is considered in another NICE guideline. The evidence base was mainly from studies in people with fibromyalgia and chronic neck pain, but there was also evidence for myofascial pain, chronic pelvic pain, vulvodynia and shoulder pain.
Herefordshire and Worcestershire Clinical	Guideline Evidence	8 21	1 18	Electrical physical modalities for chronic primary pain: Could this section include a recommendation for: - Laser therapy – *just because the evidence is promising is insufficient justification not to make a recommendation. Indeed in the absence of sufficient*	Thank you for your comment. The committee agree the evidence base for laser therapy isn't sufficient to recommend it's use for people with

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Commissioning Group	Evidence	22	11	*evidence for safe and effective use should there be a recommendation either to i. only use in the context of research or 2. Only use provided that standard arrangements are in place for clinical governance, consent and audit.This would mirror the advice for IPG guidance issued and seems reasonable approach.* PENS and transcranial direct current stimulation – *just becauseneither intervention is widely used in current practice for chronic primary pain does not mean a recommendation should not be made. There are providers wishing to use these modalities. We would suggest a recommendation as for IPGs above.*	chronic primary pain within the NHS. They agree that highlighting this as an area for future research may be useful to inform future updates of the guideline. Research recommendations are made based on those most likely to be high priority to the NHS and to inform future updates of the guideline. The committee agreed that as at present this is being explored as an option for secondary chronic pain rather than chronic primary pain, it was not a priority area for a research recommendation within the guideline.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	8	14	Depression is a common comorbidity with chronic pain. Patients should be monitored and treated for depression when necessary.	Thank you for your comment. We agree that depression is a common comorbidity with chronic pain. Recommendations for the monitoring and treatment of depression are beyond the scope of this guideline. The NICE pathway will link to this and other relevant NICE guidelines when published on the website.

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Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	8	8	Would be more helpful if the committee could make a recommendation about use as for IPGs as above.	Thank you for your comment. The committee agreed there was insufficient evidence to make a recommendation for the use of manual therapies, although the evidence was suggestive of a possible benefit and therefore further research was warranted to inform future updates of this guideline. The committee's consideration of the evidence is detailed in the rationale for this topic.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	9	10	This will be challenging as many patients are already on a combination of these medicines and it will involve a large time commitment in primary care to reduce and stop these medicines in this cohort of patients. Also there are limited alternative medications or interventions to offer these patients. One GP interpretation of this was that as long as the patient doesn't have chronic primary pain then they can have these medications. Whilst we realise that this is not the case and other guidance needs to be referred to it highlights the confusing nature of this guidance and likely interpretation by GPs.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged

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					and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee agree there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed

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					the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	9	13	There is evidence that NSAIDs have a beneficial effect in patients with non-specific lower back pain. Whilst the section applies to Chronic Primary Pain, the messages are getting confusing when a clinician needs to refer to so many different NICE guidelines when a patient present with chronic pain. It would be helpful if NICE could summarise, by intervention, when it should and should not be used drawing on all guidance documents.	Thank you for your comment. Subheadings have been added throughout the guideline and clarifications where populations are excluded to make this clearer. A visual summary has been added clarifying what populations are covered by each recommendation. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	9	15	There is evidence that pregabalin can be of benefit in patients with fibromyalgia (although it doesn't have marketing authorisation for this).	Thank you for your comment. The committee agreed that the evidence reviewed within this guideline did not support the use of gabapentinoids for chronic primary pain.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	General	General	No mention of when to refer to a pain specialist or any criteria	The committee agree that specialist assessment for diagnosis and management of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The committee have included one recommendation to seek specialist advice if pharmacological management is being

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					considered for young adults aged 16-17.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	General	General	General issues of concern: 1. The number of people with chronic pain (primary or other) 2. The lack of sufficient specialist pain services to support patients; where services exist they are unable to cope with demand. Perhaps the guidance could also define the patient circumstances that warrant referral. 3. The limited number of effective treatment options The burden on primary care practitioners to facilitate management and implement guidance	Thank you for your comment. The committee acknowledge that there are a large number of people with chronic pain, which is also true of chronic primary pain although this is a subsection of the chronic pain population. The committee agree that specialist assessment for diagnosis and management of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for

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					specialist advice or assessment might need to be considered The committee agree people should have treatment options and take an active part in their care. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, as detailed in the guideline recommendations. It should be noted the management section applies to chronic primary pain only, not all chronic pain. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE

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					pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	General	General	Suggested additions that would benefit the guidance: - more emphasis needs to be put on deprescribing medications which have been tried but not made any perceptible benefit to the patient – how do you address the situation where the patient believes that the medication is helping them to some extent? more emphasis should be placed on key messages when some of these secondary medications are commenced, before the diagnosis of chronic pain is reached e.g recommending a short trial period / demonstration of objective benefits, so expectation regarding continuation is managed from the outset	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
Herefordshire and Worcestershir	Guideline	General	General	1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.	Thank you for your comment. The guideline reflects the evidence for

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e Clinical Commissioning Group				- Prescribing and de-prescribing recommendations – general practitioners who have little else to offer patients. Many other interventions ineffective or not recommended either. - Psychological therapy for chronic primary pain – insufficient resource available providers/commissioners - PMP – if it were to be decommissioned, depending on recommendation – providers/commissioners Acupuncture access for chronic primary pain with limitations defined – not currently available in the described capacity - commissioners	best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	General	General	2. Would implementation of any of the draft recommendations have significant cost implications? - Psychological therapy - Acupuncture De-prescribing advice	Thank you for your comment.
Herefordshire and Worcestershir	Guideline	General	General	3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)	Thank you for your comment.

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e Clinical Commissioning Group				Time and money	
Herefordshire and Worcestershire Clinical Commissioning Group	Guideline	General	General	4. The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication. Any changes to clinical practice at this time of restoration (and potential second wave COVID-19) will be a challenge as all sectors of healthcare are struggling to engage with and deliver core functions and many resources have been diverted or there is limited capacity. This will impact on the ability to implement any new guidance.	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
Homerton Hospital NHS Foundation Trust	Guideline	005	General	It is unclear whether the recommendations for chronic primary pain apply to other causes of chronic pain, including endometriosis. A separate pharmacological management section in '1.2: Managing all types of chronic pain' would be beneficial for clarity. There is evidence that endometriosis-related chronic pelvic pain is likely to be caused by a combination of nociceptive, inflammatory and neuropathic mechanisms. Significantly increased nerve fibre densities have been identified in	Thank you for your comment. Endometriosis was excluded from the scope of this guideline for the specific management reviews due to there already being existing NICE guidance on this topic. We have amended the headings and subheadings in the guideline to define

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				deep endometriotic nodules, peritoneal lesions, and ovarian endometriomas. This is likely to contribute to the occurrence of severe and neuropathic pain that characterises these lesions. Furthermore, women with endometriosis have substantial numbers of unmyelinated C-type nerve fibres in the functional layer of the endometrium, which are rarely present in unaffected women. As clinical trials of gabapentinoids for endometriosis pain are lacking, we believe this should be a research recommendation. If neuropathic pain mechanisms or pelvic nerve endometriosis is suspected, a trial of gabapentinoids may be reasonable, extrapolating clinical evidence of efficacy from other neuropathic pain syndromes. References: Anaf V, El Nakadi I, De Moor V, Chapron C, Pistofidis G, Noel JC. Increased nerve density in deep infiltrating endometriotic nodules. Gynecol Obstet Invest. 2011;71(2):112-117. doi:10.1159/000320750 Howard FM. Endometriosis and mechanisms of pelvic pain. J Minim Invasive Gynecol. 2009;16(5):540-550. doi:10.1016/j.jmig.2009.06.017 Bellessort B, Bachelot A, Grouthier V, et al. Comparative analysis of molecular signatures suggests the use of	more clearly what each section of recommendations apply to. We hope this improves clarity.

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				gabapentin for the management of endometriosis-associated pain. J Pain Res. 2018;11:715-725. Published 2018 Apr 10. doi:10.2147/JPR.S163611 Wattier JM. Antalgiques et alternatives thérapeutiques non médicamenteuses pluridisciplinaires, RPC Endométriose CNGOF-HAS [Conventional analgesics and non-pharmacological multidisciplinary therapeutic treatment in endometriosis: CNGOF-HAS Endometriosis Guidelines]. Gynecol Obstet Fertil Senol. 2018;46(3):248-255. doi:10.1016/j.gofs.2018.02.002 Miller EJ, Fraser IS. The Importance of Pelvic Nerve Fibers in Endometriosis. Women's Health.	
Homerton Hospital NHS Foundation Trust	Guideline	026	015-017	Suggest that this section includes the need for patients to be assessed on a case by case basis. For some patients a small amount of opioid or gabapentinoid may have been prescribed for many years with no escalation of dose or cause for concern. It is important that a thorough assessment is taken of what the medication is enabling the patient to do, that they may not be able to do without it. We recommend that Patients are not placed on enforced reduction programmes, this may lead to the use of illicit substitutes and risk life.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a

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					shared plan to continue safely can be agreed.
Homerton Hospital NHS Foundation Trust	Guideline	General	General	There needs to be consideration to trauma focus and Adverse Childhood events (ACE) within these guidelines. https://scholar.google.co.uk/scholar?q=adverse+childhood+experiences+chronic+pain&hl=en&as_sdt=0&as_vis=1&oi=scholart&fbclid=IwAR2NZl7UNKJykaWn4F4roMgRvDILPmLd5kx3iCJ2upwB45Lth8nD5WaxBO8#d=gs_qabs&u=%23p%3DOlLDn9TflT8J	Thank you for your comment. The committee have included a recommendation in the assessment section (1.1.) to highlight the need to consider stressful life events, including previous physical or emotional trauma.
Homerton Hospital NHS Foundation Trust	Guideline	General	General	In the summary documents there are a lot of different interventions all rolled into one, it would be useful to have in the final a table with the different interventions and whether the committee (NICE) found some evidence which supports the use of that intervention to be recommended for some cases or not – as otherwise it's a lot of text on different unrelated drug groups to go through.	Thank you for your comment. The guideline sets out individual recommendations for the assessment of chronic pain, and the management of chronic primary pain, highlighting both those that are and aren't recommended. The committee agree that shared care and support plans developed with the person with chronic primary pain should be based on an informed discussion of the risks and benefits of all of the available treatments and therefore it is important they are all included in the guideline text.

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Homerton Hospital NHS Foundation Trust	Guideline	General	General	Largely in support of this document and we believe that it is a very timely resource that is a positive step to help support clinicians in avoiding medication which has repeatedly been shown to be ineffective and often counter-productive leading to drug dependency. The strong recommendations go towards empowering clinicians to make these difficult decisions.	Thank you for your comment.
Homerton Hospital NHS Foundation Trust	Guideline	General	General	Implementation of this guideline would benefit on advice regarding a public campaign with accompanying patient support tools/decision aids to explain risks of medication and lack of evidence of effectiveness. Potentially with information for patients on living with chronic pain.	Thank you for your comment which will be considered by NICE where relevant support activity is being planned.
Hope 4 ME and Fibromyalgia Northern Ireland	Guideline	006	010-017	We are concerned that there are many patients diagnosed with fibromyalgia who may have undiagnosed Myalgic Encephalomyelitis or post-viral syndromes in whom exercise programmes may cause harm. (NICE guidelines for ME/CFS currently under review & caution issues re: using GET in post-COVID syndrome). It is estimated up to 80% of patients with ME are undiagnosed. In our experience many patients with a diagnosis of fibromyalgia have ME & were misdiagnosed or have both.	Thank you for your comment. The exercise recommendation is for people with chronic primary pain. These recommendations do not apply for the management of ME/CFS. For management of ME/CFS, recommendations in the upcoming NICE guidance on that topic should be followed. Recommendations in each guideline are also hoped to improve identification of these conditions and reduce misdiagnosis. The NICE pathway will also link to all the

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					relevant guidelines to enable more easy navigation between the recommendations for different topics.
Hope 4 ME and Fibromyalgia Northern Ireland	Guideline	006 & 007	010-017 001-015	We are concerned that the treatments recommended instead of pharmacological measures, including acupuncture, group classes, and psychological therapies are going to be inaccessible to patients who have ME as well as fibromyalgia or another primary pain disorder who are predominantly housebound.	Thank you for your comment. The committee acknowledge that access to services can be challenging for some people. They agree it is appropriate to recommend the treatments with best evidence of effectiveness. The means of delivery can vary to ensure these services accessible, and this should be determined by local commissioning.
Hope 4 ME and Fibromyalgia Northern Ireland	Guideline	009	012	Some patients with fibromyalgia have comorbid Ehlers Danlos Syndrome and Postural Orthostatic Tachycardia Syndrome. In these patients there is a negative cycle or pain, sleep, mood and fatigue. In some cases getting the pain under control using opiods temporarily can lead to improvements in sleep and fatigue as well, which can allow cautious increase in physical activity, which can then lead to improvements in pain and the opiods can be weaned off again. We are concerned that the current draft guideline may prevent benefits that would otherwise be seen in specific patient groups.	Thank you for your comment. Management of conditions that co-exist with types of chronic primary pain is not covered within this guideline. The pharmacological recommendations in this guideline only apply to the specific management of the chronic primary pain condition being treated. Clinical judgement should be applied when managing comorbid conditions, as well as

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					following guidance in other NICE guidelines where appropriate.
Hope 4 ME and Fibromyalgia Northern Ireland	Guideline	017 - 018	021 (p17) – 015(p 18)	We are concernedthat the heavy focus on psychological and behavioural causes for sleep issues, may also be due to an overgeneralisation of the evidence i.e. while they may help some groups of patients with chronic pain, they cannot be generalised to all those with CPP, including patients with comorbidities, like ME, where the pathophysiology of sleep disturbance is more complex.	Thank you for your comment. The committee do not comment on the causes for sleep issues. Some evidence reviewed suggested promising results for CBT for insomnia and sleep hygiene. This was not sufficient to inform a recommendation but the committee agreed that it warranted further research and included a research recommendation for CBT for insomnia to inform future updates of the guideline. These recommendations are for chronic primary pain only. For management of ME the recommendations in the NICE guideline for Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) should be followed.
Hope 4 ME and Fibromyalgia	Guideline	16	012-014 & 026-027	We are concerned that While it may be the case that many Chronic Primary Pain (CPP) sufferers could benefit from some form of exercise or physical activity therapy, such guidance cannot be generalised to all those with	Thank you for your comment. The committee agreed that the recommendation should apply for the

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Northern Ireland				CPP, including patients with other conditions, like ME, that are largely made worse by exertion.	management of all types of chronic primary pain as the benefit of exercise was likely to be the same. However it was also considered that the most appropriate type of exercise may depend on the type of pain condition and it should therefore be tailored to individual needs and preferences. For management of ME/CFS, recommendations in the upcoming NICE guidance on that topic should be followed.
Hope 4 ME and Fibromyalgia Northern Ireland	Guideline	7	001-004	We are concerned that psychological therapies are being recommended yet waiting lists for psychological therapies and acupuncture can be over 12 months in some areas. Patients being left untreated in pain while waiting for these therapies (if nothing else is offered, or no extra service provision secured) will lead to worsening of the pain, fatigue, depression, poor sleep cycle.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where

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					resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Hywel Dda Pain Team		General		The Hywel Dda Pain Team consists of multidisciplinary professionals, working and developing services to treat acute and chronic pain in South West Wales. We are concerned that this guidance is aimed at the 2019 publication of the ICD-11 for Chronic Primary Pain risks also becoming applied to Chronic Pain. This is will lead to confusion for commissioners, staff and patients. The ICD-11 is due to become effective in January 2020 and we are concerned about the quality of the evidence supporting this document. It is estimated that 5% of the population have CPP, and we suspect that the conclusions are based on data which includes all patients with chronic pain, 45% of the population. CPP and secondary pain can easily co-exist. The key recommendations throughout the document, for further research is noted and we question how this extensive piece of work will be funded and how long it will take. The guidance downgrades interventional approaches to managing pain, and therefore, despite a robust and comprehensive assessment procedure, undermines the patient with regard to shared decision making and developing a care plan.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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				There is concern that the implementation of the guidance as it stands may serve to decommission pain services. The conclusions within PMP section of the document challenges the clinical outcomes that we see in practice. As there is limited guidance regarding the specifics of how PMPs should be delivered and on its content, will this be reflected in the consulted evidence?	clarifying what populations are covered by each recommendation. The committee agree that the recommendations reflect best practice, recommending those treatments where there is evidence that they benefit people with chronic primary pain. This will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Hywel Dda Pain Team		006		Many pharmacological interventions are licensed for specific indications and as yet there are few (if any) good quality clinical trials for CPP. The guideline is based on low to moderate quality evidence from clinical studies that are mainly not applicable as populations, indications or duration are limited. Some studies are included whose evidence is considered to be very low quality due to risks of bias or imprecision and would therefore challenge how NICE can develop a guideline based on this poor methodology.	Thank you for your comment. The quality of the evidence base is taken into account in the systematic reviews of the evidence, including risk of bias, imprecision, sample size, applicability etc. Details on the committee's considerations of the evidence quality are included in the discussion of the evidence in the relevant evidence

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				NICE have recognised that the medications are not licensed for CPP and by advocating the use of anti-depressants outside of their license puts the clinician in a difficult position. There is some concern of side effect such as serotonin syndrome. The inclusion criteria from PICO of the conditions (,chronic widespread pain, CRPS, chronic visceral pain, chronic orofacial pain and chronic primary MSK pain other than orofacial) appears to be so specific that very few trials (n=33) would have met these criteria. 49 Cochrane reviews were identified that were relevant to the review question, but were excluded due to the inclusion criteria not being met. The excluded trials have got specific indications such as neuropathic pain, pain (other than CPP) and short trials duration which are not representative of patients with chronic pain. The included studies include a large proportion for women with FMS (N=20) with relatively small cohorts without a stated 'duration of pain'. How can this be applied to patients with chronic pain ? On pages 62-63 of the full guidelines, the committee's response to the efficacy of pharmacology treatment options is based on opinions rather than critical evaluation of trial evidence, so current practice should not be changed. There is poor confidence in the credibility, reliability and transferability of the recommendations made within this guideline in relation to pharmacological treatment.	review (evidence review J for pharmacological therapies). Details of the full methods followed for the review and consideration of the evidence for decision making is consistent with Developing NICE guidelines: The manual, and detailed further in the methods chapter for this guideline. There are no medicines licensed for chronic primary pain in the UK. The evidence review included those that are commonly used off license for this type of pain. The committee agree it is important that the side effects associated with antidepressants are considered when making a decision on whether to use these. They state in the recommendation that this should be made after a full discussion of the benefits and harms.

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				Similarly, some of the dose of meds used in the studies contain a low dose/ high dose/ not used in practice (Amitriptyline 5mg/day , Pregabalin 75mg/day, Clonazepam 0.5mg. Ibuprofen 2400mg/day, topical lidocaine) hence it is difficult to understand why these were used to justify the decisions made.	The PICO table at the beginning of the evidence review is a shortened form and cross refers to the full protocol in appendix A, and also the search strategy in appendix B. The search terms were not limited to those in the PICO and were much more broad to ensure different types of chronic primary pain that fall under the umbrella term would be identified where available. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has

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					also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Hywel Dda Pain Team		018	026,027	There is considerable concern that the document states that pain education is 'not clinically important'. This is a considerable oversight and pain education is a most powerful and valued clinical intervention.	Thank you for your comment. This statement in the rationale relates to the evidence reviewed where pain education did not demonstrate a clinically important difference compared to usual care.
Hywel Dda Pain Team		019	005	Concern that the committee is not recommending sleep hygiene as it is no more effective than CBTI. This statement is vague and worrying	Thank you for your comment. The committee discussed that there were some promising effects observed for sleep hygiene, but only from 1 small study and therefore it was not sufficient to inform a recommendation. They discussed whether further research should be recommended, but considered that evidence demonstrated it not to be as effective as CBT for insomnia, and it is one of the components of CBT for

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					insomnia, that the research recommendation for CBT for insomnia adequately covered this. The rationale has been edited to clarify that this also relates to the research recommendation. Further detail is provided in the committee's discussion of the evidence in Evidence review F.
Hywel Dda Pain Team		018	021-024	From a clinical perspective it is hard to comprehend that there is insufficient evidence for the use of relaxation mindfulness and psychotherapy,	Thank you for your comment. These reviews were for chronic primary pain only. The committee are aware that there may be more research for chronic secondary pain, but for this specific population the evidence is limited. The population covered was detailed in the scope and the protocol for each review, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation

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					topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Hywel Dda Pain Team				CBT and ACT were recommended but there was such variability within the document that the content was vague.	Thank you for your comment. The committee agreed that there was sufficient evidence to warrant recommendations to consider these for chronic primary pain, but the variability in evidence was part of the reason the committee agreed a stronger recommendation to offer CBT or ACT to all people with chronic primary pain could not be made.
Hywel Dda Pain Team		019	022 on	This recommendation is incongruous within the document, a seemingly short term and cost counting approach to the treatment of pain. It is some concern to note that acupuncture has been excluded from all other NICE guidelines related to pain.	Thank you for your comment. The committee were aware of the recommendation and evidence review underpinning the recommendation in the current NICE low back pain guideline (NG59) and that in CG177 for osteoarthritis. However, the review for this guideline excluded

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					evidence in people with low back pain and osteoarthritis and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica and was supported by a large evidence base. The osteoarthritis guideline is currently being updated. Consistent benefits were observed for quality of life, and pain compared to sham as well as usual care as well as some benefits in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This

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					research recommendation has been made high priority in response to stakeholder comments.
IBritish Association for Behavioural and Cognitive Psychotherapies	Evidence review F	125	035	It may be helpful to be clearer what is meant by 'general CBT'; and to clarify whether a distinction was made between CBT delivered for depression or anxiety associated with persistent pain, as this can differ from or be delivered alongside CBT aimed at self-management of persistent pain. The evidence for varying modes of delivery, number of sessions, whether group or individual; type of setting, levels of training of therapists is all included under 'CBT'. It would be helpful to make more specific research recommendations so that these elements can be evaluated.	Thank you for your comment and for highlighting this. This has been amended to clarify that this is CBT for pain. All evidence identified in this review was either CBT for pain, CBT for insomnia or CBT for pain and insomnia. The committee did not include a research recommendation to determine the more specific elements of the programme as this review did not consider that level of detail in the comparison. Research recommendations can only be made on topics that have been directly reviewed within the guideline.
Imperial Healthcare NHS Trust				https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2752362/#!po=14.5833	Thank you for your comment. We have responded below.
Imperial Healthcare NHS Trust	General	General	General	I would like to highlight some studies that show significant and consistent benefit for the use of clinical hypnosis for the management of Chronic pain. ...see below: 7-10	Thank you for your comment. Responses are given in the relevant rows below.

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					It is important to note that the reviews for specific interventions included in this guideline are for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Imperial Healthcare NHS Trust	General	General	General	The absence of inclusion of data related to the use of clinical hypnosis would be a great disservice to patients. The paucity of current use of hypnosis reflects an	Thank you for your comment. Hypnosis was included within the psychological therapies review, and

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				educational gap in many medical curricula, which is in the process of being addressed.	evidence included where relevant to the review protocol. We have reviewed the additional references received in the stakeholder comments, but have identified no additional evidence for hypnosis specific to people with chronic primary pain that can be included within this review.
Imperial Healthcare NHS Trust	General	General	General	There is a misapprehension that clinical hypnosis is a 'complementary therapy', but this is not substantiated by the World Health organisation. It is already integrated into medical practice as an 'adjuvant intervention', that is versatile, highly cost effective, and needs to be acknowleged as a highly valuable asset which requires on-going study within different settings. As a clinician who uses clinical hypnosis in the Oncology setting, I can vouch that patients who choose to use self-hypnosis techniques through treatment benefit markedly, in pain management, and mental health and quality of life measures. Although not a universal tool as yet, the evidence supports that NICE guidance should include its role as a valid option with a consistent evidence base, albeit of smaller studies which though often underpowered, nevertheless show statistically significant benefits in many arena.	Thank you for your comment. Hypnosis was reviewed in this guideline within the psychological therapies review. There was insufficient evidence identified for chronic primary pain to recommend its use in this population.

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Imperial Healthcare NHS Trust	General	General	General	For chronic pain, particularly challenged with difficult trade-offs with addiction and escalating polypharmacy to deal with side-effects, any intervention which lessens dependency, has few if any side effects, and empowers patients to manage their symptomatology independently is to be highlighted, and endorsed in order to support further research. There are studies siting significant cost savings, but not within the chronic pain setting to my knowledge, however this should not be a barrier to endorsing its possible role for future investigation.	Thank you for your comment. The committee agreed such outcomes are desirable in the management of chronic primary pain. There was insufficient evidence identified for hypnosis for chronic primary pain to demonstrate this however.
Imperial Healthcare NHS Trust	General	General	General	"This review indicates that hypnotic interventions for chronic pain results in significant reductions in perceived pain that, in some cases, may be maintained for several months. Further, in a few studies, hypnotic treatment was found to be more effective, on average, than some other treatments, such as physical therapy or education, for some types of chronic pain. These findings are encouraging for an initial wave of studies, but a more sophisticated body of research including larger sample sizes and more rigorous controls would be far more convincing....."	Thank you for your comment. The population relevant to the guideline review is chronic primary pain only (as stated in our responses above), not all types of chronic pain as in the cited review. The conclusions reached therefore may differ due to the different evidence base reviewed.
Imperial Healthcare NHS Trust	General	General	General	***International Journal of Clinical and Experimental Hypnosis***	Please see our response in row 354.
Imperial Healthcare NHS Trust	General	General	General	Volume 62, 2014 - Issue 1	Please see our response in row 354.

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Imperial Healthcare NHS Trust	General	General	General	A Meta-Analysis of Hypnosis for Chronic Pain Problems: A Comparison Between Hypnosis, Standard Care, and Other Psychological Interventions	Thank you for your comment. As per the response detailed in your earlier comment, the guideline review of psychological therapies was for chronic primary pain only. This cited review was therefore not included due to being in all types of chronic pain. The reference list was checked for any studies relevant to the review protocol, but no additional studies were identified.
Imperial Healthcare NHS Trust	General	General	General	https://www.tandfonline.com/doi/abs/10.1080/00207144.2013.841471	Please see our response in row 354.
Imperial Healthcare NHS Trust	General	General	General	Abstract	Please see our response in row 354.
Imperial Healthcare NHS Trust	General	General	General	Hypnosis is regarded as an effective treatment for psychological and physical ailments. However, its efficacy as a strategy for managing chronic pain has not been assessed through meta-analytical methods. The objective of the current study was to conduct a meta-analysis to assess the efficacy of hypnosis for managing chronic pain. When compared with standard care, hypnosis provided moderate treatment benefit. Hypnosis also showed a moderate superior effect as compared to other psychological interventions for a nonheadache group.	Please see our response in row 354.

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				The results suggest that hypnosis is efficacious for managing chronic pain. Given that large heterogeneity among the included studies was identified, the nature of hypnosis treatment is further discussed.	
Imperial Healthcare NHS Trust	General	General	General	The effectiveness of hypnosis for pain relief: A systematic review and meta-analysis of 85 controlled experimental trials	Thank you for your comment. As per the response detailed in your first comment, the guideline review of psychological therapies was for chronic primary pain only. This cited review was therefore not included due to being from a broader population. The reference list was checked for any studies relevant to the review protocol, but no additional studies were identified.
Imperial Healthcare NHS Trust	General	General	General	Neuroscience & Biobehavioral Reviews. Volume 99, April 2019, Pages 298-310	Please see our response in row 358.
Imperial Healthcare NHS Trust	General	General	General	https://doi.org/10.1016/j.neubiorev.2019.02.013	Please see our response in row 358.
Imperial Healthcare NHS Trust	General	General	General	The current meta-analysis aimed to quantify the effectiveness of hypnosis for reducing pain and identify factors that influence efficacy. Six major databases were systematically searched for trials comparing hypnotic inductions with no-intervention control conditions on pain ratings, threshold and tolerance using	Please see our response in row 358.

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				experimentally-evoked pain models in healthy participants. Eighty-five eligible studies (primarily crossover trials) were identified, consisting of 3632 participants (hypnosis nö=ö2892, control nö=ö2646). Random effects meta-analysis found analgesic effects of hypnosis for all pain outcomes (gö=ö0.54-0.76, p's<.001). Efficacy was strongly influenced by hypnotic suggestibility and use of direct analgesic suggestion. Specifically, optimal pain relief was obtained for hypnosis with direct analgesic suggestion administered to high and medium suggestibles, who respectively demonstrated 42% (pö<ö.001) and 29% (pö<ö.001) clinically meaningful reductions in pain. Minimal benefits were found for low suggestibles. These findings suggest that hypnotic intervention can deliver meaningful pain relief for most people and therefore may be an effective and safe alternative to pharmaceutical intervention. High quality clinical data is, however, needed to establish generalisability in chronic pain populations.	
Imperial Healthcare NHS Trust	General	General	General	Jensen, M. P., & Patterson, D. R. (2014). Hypnotic approaches for chronic pain management: Clinical implications of recent research findings. *American Psychologist*, *69*(2), 167–177. https://doi.org/10.1037/a0035644	Thank you for your comment. As per the response detailed in your earlier comment, the guideline review of psychological therapies was for chronic primary pain only. This cited review was therefore not included due to being in all types of chronic pain. It is also a literature review rather than a

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					systematic review so would not have met the criteria for inclusion. The reference list was checked for any studies relevant to the review protocol, but no additional studies were identified.
Imperial Healthcare NHS Trust	General	General	General	Abstract	Please see our response in row 362.
Imperial Healthcare NHS Trust	General	General	General	The empirical support for hypnosis for chronic pain management has flourished over the past two decades. Clinical trials show that hypnosis is effective for reducing chronic pain, although outcomes vary between individuals. The findings from these clinical trials also show that hypnotic treatments have a number of positive effects beyond pain control. Neurophysiological studies reveal that hypnotic analgesia has clear effects on brain and spinal-cord functioning that differ as a function of the specific hypnotic suggestions made, providing further evidence for the specific effects of hypnosis. The research results have important implications for how clinicians can help their clients experience maximum benefits from hypnosis and treatments that include hypnotic components. (PsycINFO Database Record (c) 2016 APA, all rights reserved)	Please see our response in row 362.
Imperial Healthcare NHS Trust	Guideline	Section F	Table 013	I question that the recommendations on the use of hypnosis are based on merely 1 study when there are other reviews and meta-analyses that summarise findings	Thank you for your comment. As highlighted, this review was for

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				showing a significant impact and benefit in favour of the use of clinical hypnosis.	chronic primary pain only, and therefore there was a smaller more defined evidence base available. All references provided have been checked, but none were for chronic primary pain specifically.
Inagene Diagnostics Inc	Guideline	8	14	Question 3: The Pharmacological Management of chronic primary pain indicates antidepressants as first step for management. White paper – Pharmacogenetics and Mental Health Crisis June 2020 highlights the following evidence: "What has not been widely known until recently, is that individual variations in response to drugs is largely due to genetic factors. Over 98% of the population carry gene variations that can cause varying responses to drugs and that could be used to inform the choice of medication prescribed.[28,29,30,31]Genetics accounts for between 20 – 95% of individual variability in drug response [24,25]and 42 - 50% of antidepressant response rates[26,27]." Should this guideline include pharmacogenetics as a support tool for decision making either as part of the recommendations in 'Pharmacological management of chronic primary pain' or 'Recommendations for research'? [24]Broadhead WE, Blazer DG, George LK, Tse CK. Depression, disability days, and days lost from work in a	Thank you for your comment. Pharmacogenetics was not included within the scope of this guideline as a topic to consider, and therefore we are unable to make recommendations on this topic.

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				prospective epidemiologic survey. JAMA. 1990;264(19):2524–2528. [25]Simon Ge, VonKorff M, Barlow W. H [26]Smetanin et al. (2011). The life and economic impact of major mental illnesses in Canada: 2011-2041. Prepared for the Mental Health Commission of Canada. Toronto: RiskAnalytica. [27]Lim et al. (2008). A new population-based measure of the burden of mental illness in Canada. Chronic Diseases in Canada, 28: 92-8. [28]Crisafully C, Fabbri C, Porcelli S et al, Pharmacogenetics of Antidepressants. Front. Pharmacol. 2,6 (2011) [29]Bush WS, Crosslin DR, Owusu-Obeng A, et al. Genetic variation among 82 pharmacogenes: the PGRNseq data from the eMERGE network. Clin Pharmacol Ther. 2016;100(2):160-169. [30]Ji Y, Skierka JM, Blommel JH, et al. Pre-emptive pharmacogenomic testing for precision medicine: a comprehensive analysis of five actionable pharmacogenomic genes using next-generation DNA sequencing and a customized CYP2D6 genotyping cascade. J Mol Diagn. 2016;18(3):438-445. [31]Van Driest SL et al. Clinically actionable genotypes among 10,000 patients with pre-emptive pharmacogenomic testing.Clin Pharmacol Ther. 2014:95(4):423-431	

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Inagene Diagnostics Inc	Guideline	9	6	Question 2: NICE Guidelines on Medicines optimisation state 1.6.3'Apply the principles of evidence based medicine when discussing the available treatment options with a person in a consultation about medicines. **Use the best available evidence when making decisions**with or for individuals, together with clinical expertise and the person's values and preferences.' 1.6.4In a consultation about medicines, offer the person, and their family members or carers where appropriate, the opportunity to use a patient decision aid (when one is available**) to help them make a preference-sensitive decision that involves trade offs between benefits and harms**. Ensure the patient decision aid is appropriate in the context of the consultation as a whole.[3] In view of NHS strategy to move towards personalised medicine and targeted therapy, should this guideline include the option for the prescribing clinician to utilise the best available evidence, in the form of individual pharmacogenetic data; to support decision making and efficiently optimise treatment whilst also enabling the clinician to fully support the patient with data that reduces the trade off between benefits and harms? [3]https://www.nice.org.uk/guidance/ng5	Thank you for your comment. The guideline reviews present the best available evidence for all of the interventions that were considered most relevant at the scoping stage for this guideline. This is based on reviews undertaken according to the methods set out in Developing NICE guidelines: The manual.

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Inagene Diagnostics Inc	Guideline	General	General	We would like to commend NICE on the development of this guideline and the wholistic approach taken including both 'Non-pharmacological management of chronic primary pain' and 'Pharmacological management of chronic primary pain'. It is well documented that early and effective intervention in Chronic Pain has both Improved Outcomes for patients and significant Health Economic benefit.	Thank you for your comment.
Inagene Diagnostics Inc	Guideline	General	General	We are concerned that this guideline has not mentioned Personalised Medicine / Pharmacogenetics as an approach to aid clinicians and their patients make informed decisions about their pharmacological treatment options. 'Personalised medicine offers the opportunity to move away from 'trial-and-error' prescribing to optimal therapy first time round'[1]. NHS Plan: A New Service Model for the 21st Century: 'We will focus targeted investment in areas of innovation that we believe will be transformative, particularly genomics'[2] In view of NHS strategy to move towards personalised medicine and targeted therapy, should this guideline include the option for the prescribing clinician to utilise	Thank you for your comment. Pharmacogenetics was not highlighted as an area to focus on during the scoping of this guideline and has not been considered in the systematic reviews of the evidence to inform recommendations.

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				the best available evidence in the form of individual pharmacogenetic data to support decision making. [1]https://www.england.nhs.uk/wp-content/uploads/2016/09/improving-outcomes-personalised-medicine.pdf [2]https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/	
Inagene Diagnostics Inc	Guideline	General	General	Question 1: There is evidence that the science of pharmacogenetics offers a personalized treatment approach that is PROVEN to: • minimize drug costs • prevent adverse reactions/hospitalizations/deaths • optimize analgesia, minimize time to remission • minimize drug/healthcare utilization costs, and help people get better and back to work sooner (significant savings to the healthcare system/payers) Should this guideline include pharmacogenetics as a support tool for decision making either as part of the recommendations in 'Pharmacological management of chronic primary pain' or 'Recommendations for research'?	Thank you for your comment. Pharmacogenetic panel testing was not prioritised during scoping as an area to include within the guideline and therefore we have not reviewed the evidence for this.

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Inagene Diagnostics Inc	Guideline	General	General	The evidence clearly demonstrates the clinical and health economic benefits of pharmacogenetics in pain management and associated mental health problems. We would like to bring to your attention that Pharmacogenetics is not considered in this guideline under either Pharmacological management of chronic primary pain' or 'Recommendations for research'. White paper – Pharmacogenetics and Mental Health Crisis June 2020: • The impact of pharmacogenetic testing in terms of health care system savings is well documented, with savings ranging between USD$1000 – 10,000 per year. In a review of 44 economic evaluations of pharmacogenetics, 30% were found to be cost-effective and 27% cost-saving.[41] • One study showed that patients who received PGx testing saved USD$1035.60 in total on medication costs over a 1 year period compared to standard care[42] • When patients were switched to medications congruent with pharmacogenetic medications, Pharmacy cost savings averaged USD$2774.53 compared to those who were not.[42] • A recently published analysis using clinical patient outcome data and published health care	Thank you for your comment. Pharmacogenetics was not highlighted as an area to focus on during the scoping of this guideline and has not been considered in the systematic reviews of the evidence to inform recommendations.

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				costs to model the cost savings associated with pharmacogenetic-guided treatment for depression resulted in a savings of USD$5,962 annually per patient tested.[43] • 50% of patients don't take medications as prescribed, and one third of prescriptions are never taken, and the top reasons for lack of drug adherence are fear of side effects and or lack of perceived effect (often driven by previous disappointing experience with medications), and depression [40]. [40]Brown MT et al. Medication adherence – WHO cares? Mayo Clin Proc. 2011 Apr; 86(4): 304–314 [41]Verbelin M et al. Cost-effectiveness of pharmacogenetic-guided treatment: are we there yet? The Pharmacogenomics Journal (2017) 17, 395–40 [42]Winner J et al. Combinatorial pharmacogenomic guidance for psychiatric medications reduces overall pharmacy costs in a 1-year prospective evaluation. Current Medical Research & Opinion. Volume 31, 2015 - Issue 9, Pages 1633-1643 [43]Maciel , Cullors , Lukowiak , Garces . Estimating cost savings of pharmacogenetic testing for depression in real-world clinical settings. Neuropsychiatr Dis Treat. 2018 Jan 8;14:225-230	

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				We are willing to provide NICE with a full list of clinical studies and publications.	
Inagene Diagnostics Inc	Guideline	General	General	COVID-19 There is emerging evidence that COVID-19 has generated an additional burden and layer of complexity for the Chronic pain patient. The enforced isolation and reduced access to support services increasing the risk of mental health issues. With restricted access to the full range of support services, clinicians may, in the short term, need to consider prescribing treatment for mental health issues (anxiety & depression) alongside the treatment for pain. Combined Pharmacogenetic profiling looking at pain and mental health can support a targeted approach to medical management, reduce the risks associated with polypharmacy, optimise medication quickly, aiding the best outcome for the patient. Should this guideline include pharmacogenetics as a support tool for decision making either as part of the recommendations in 'Pharmacological management of chronic primary pain' or 'Recommendations for research'?	Thank you for your comment. Pharmacogenetics was not highlighted as an area to include within the guideline during scoping and therefore recommendations on its use cannot be made.
Inhealth Pain Management	Evidence review F	126	022	The guideline group reportedly felt that the research may underestimate the effects of CBT. In relation to CBT is seems uncharacteristic in the guideline development group's otherwise discussion of the evidence. Perhaps the argument could be used in other areas of research?	Thank you for your comment. The comment in the discussion of CBT specifically relates to the committee's discussion about the limitations of some of the studies and the variability

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					in the methods of delivering CBT, including internet delivered programmes which may have underestimated the effects of CBT delivered face to face. The committee discuss limitations and applicability of the interventions in all of the reviews and discuss the potential effects it may have had on the results, where relevant, in the discussion of the evidence section of the review chapter.
Inhealth Pain Management	Evidence review G	043	036	The Evidence Report's describes the problems with the studies included; "high risk of bias" due to selection or attrition bias and "quality of evidence being low or very low", lack/difficulty of blinding and "wide variation in the of and intensity of interventions applied". The detailed recommendation of the use of acupuncture is not consistent with this description of the literature. In other interventions in the guidance (for instance Pain Management Program or laser therapy) a recommendation of further research has been made. A recommendation for better quality research would be consistent with the evidence base and also other recommendations in this specific guideline.	Thank you for your comment. The committee agreed that overall the large body of evidence was demonstrating a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and

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				Suggested Action: Can the guideline development group please discuss if reconsideration of their recommendation based on their own interpretation of the quality of the evidence base?	psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost effectiveness evidence supporting the recommendation.
Inhealth Pain Management	Evidence Review J	045	048	There is recognition of the expansion of the cost of care with this intervention. To recommend 5 hours of individual treatment might equal all other aspects of a chronic pain service's input with an individual so this is in	Thank you for your comment. This is registered as relating to Evidence

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				some cases doubling the cost of their care. Commissioning is not a zero-sum scenario as investment in one area might reduce the need for care in another area. However, this could lead to reduced resources for other forms of care. **Suggested Action: Perhaps the cost and impact on services and the effect this has on treatment availability should be reconsidered with longer term or real life implications considered.**	review J although appears to relate to Evidence report G about acupuncture. Acupuncture in addition to usual care was found to be cost effective compared to usual care alone. The analysis was undertaken in line with NICE methodological guidance (see the NICE website for details). It is acknowledged that where cost effective interventions will increase resource use in the NHS, this will require disinvestment elsewhere. However, where this occurs is considered a local decision and not specified in NICE guidance.
Inhealth Pain Management	Guideline			Opioids: The messaging in this guidance is understandably similar to that in other public health guidance on the management of Chronic Primary Pain. I am not clear why Opioids were not included in the literature search for the question "What is the clinical and cost effectiveness of pharmacological interventions?"	Thank you for your comment. Opioids were included in the literature search for this question. This is detailed in the review protocol and search strategy in appendices A and B respectively. There was however no evidence identified for the use of opioids in

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				Welcome the advice not to prescribe opioids- very clear and helpful during consultations with patients. However, this is not entirely consistent with Opioid Aware guidance who suggest that opioids are of some help to a minority of patients. **Suggested Action: Include Opioids in the literature review on effectiveness.**	people with chronic primary pain that met the review protocol.
Inhealth Pain Management	Guideline	004	001	We understand that the diagnosis of chronic pain is made following exclusion of other possible causes. However, there are conditions that have guidelines on diagnosis Fibromyalgia (recognised by the ICD as a offspring condition of Chronic Primary Pain in the 2010 ACR (American College of Rheumatology) or Chronic Fatigue Syndrome 2015 IOM (Institute of Medicine). It is not clear in the guideline if these are recommended. There might be healthcare professionals who would clinically use these diagnostic criteria to offer a further diagnosis to a sub-section of Chronic Primary Pain patients. It is also foreseeable that there would be patients with symptoms that fall under these classifications that might wish to make use of these diagnoses. Chronic Fatigue Syndrome and Fibromyalgia are more recognised in society and by employers,	Thank you for your comment. A recommendation has now been included for when to consider a diagnosis of chronic primary pain. Diagnosis of types of pain that fall under the umbrella of chronic primary pain was not included within the scope as an area to review, and therefore the diagnostic criteria used in other guidelines have not been reviewed or recommended. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most

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				educational institutions and benefits agents more specifically. In addition to this it is the practice of some healthcare professionals to seek specific professionals (Pain Specialist Anaesthetists or Rheumatologists) to make a final diagnosis of Chronic Primary Pain. In other areas diagnosis is made by primary care physicians. It would perhaps be helpful for the guideline development group to give guidance on how the diagnosis of Chronic Primary Pain is made. **Suggested Action:** What is the guideline development group view on the diagnosis of Chronic Primary Pain? Further what are the thoughts on use criteria to diagnose subsets of Chronic Primary Pain.	people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered.
Inhealth Pain Management	Guideline	004	002	The sections on what is included as part of an assessment of someone with Primary Chronic Pain is excellent and specific in a way that is immediately useful to clinicians.	Thank you for your comment.
Inhealth Pain Management	Guideline	006	001 and 005	That the sections on Pain Management Programs and Social Prescribing are for all chronic pain types and the rest is specific instead for Chronic Primary Pain is confusing and likely to lead to misunderstanding. **Suggested Action: Can the distinction between all chronic pain and chronic primary pain be clarified?**	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received

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					we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The sections on pain management programmes and social prescribing are now addressed in the rationales and research recommendations only.
Inhealth Pain Management	Guideline	006	004	The outcome of not being able to recommend for or against Pain Management Programs is rational based on the evidence review and discussion presented. What is notable is that the outcome is different to other guidelines (British Pain Society 2013: Fwww.britishpainsociety.org%2Fstatic%2Fuploads%2Fresources%2Ffiles%2Fpmp2013_main_FINAL_v6.pdf&usg=AOvVaw2-biW2sYk60RQBKqeLUCXuor SIGN (Scottish Intercollegiate Guidelines Network) 2013	Thank you for your comment. The committee were aware of the existing guidance from other organisations and Cochrane reviews on related topics, primarily due to different review protocols and different methods followed to develop the recommendations. A statement has

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				www.sign.ac.uk%2Fassets%2Fsign136.pdf&usg=AOvVaw2uW6iVEbtByGmc4N-jsYRw) or in Systematic Reviews of the literature (Joypaul et al 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6774525/or Cochrane 2017 (lay people led groups: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005108.pub2/full) That there this conflict is unclear and a source of potential misunderstanding. **Suggested Action:** The outcome is reasonable but perhaps the above should be recognised in contextualising the recommendations in this guideline?	been added to the discussion of the evidence in the review chapter acknowledging this.
Inhealth Pain Management	Guideline	006	010	We have no concerns with the guidance around Exercise. They are consistent with my understanding of the literature.	Thank you for your comment.
Inhealth Pain Management	Guideline	007	001	The recommendation of ACT on the basis of evidence is surprising as a Cochrane review that was looking at the Psychological therapies in the management of chronic pain found insufficient evidence to recommend ACT. This review was published after the literature search for the guidelines was conducted and is understandable it was not included, however it's predecessor was identified in reference 142 (https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007407.pub4/full). It was excluded as it was looking at all Chronic Pain and not Primary Chronic Pain	Thank you for your comment. The protocols of these two reviews differ. The Cochrane review is for all types of chronic pain but specific to ACT, whereas the guideline review is specifically for chronic primary pain but for a range of psychological therapies. as detailed in the PICO table at the beginning of the evidence review and full protocol in appendix A,

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				and was considered to be too broad. It is surprising that they found 5 suitable studies yet the literature review conducted for this guideline included 47 studies. Inclusion/Exclusion criteria and search strategy can account for differences in included studies but the difference is large and surprising considering the present draft guideline is looking at a subset of the population covered by the Cochrane review. Given that Amanda Williams was on the guideline development group and is the lead author in the Cochrane Review I expect that there is a plausible reason for this unexpected difference? **<u>Suggested Action:</u> Can the group clarify and establish that their guidance around ACT is in keeping with the literature?**	A total of 47 studies are included in the guideline review for psychological therapies, 5 of which are for ACT. The committee agree that for chronic primary pain the evidence is sufficient to inform a recommendation to consider using this. They agree it is not strong enough to offer ACT for everyone with chronic primary pain.
Inhealth Pain Management	Guideline	007	007	To recommend a treatment on the basis that it delivers up to 3 months of benefit for some individuals seems short sighted in a condition that is by it's nature Chronic and lifelong for many that experience it. After the 5 hours of care have been delivered is there any recommendation on how individuals should continue to fund such care? The recommendation and the condition it is for are not compatible. This places services in a difficult position where they have to rationalise decisions made by a guideline development group to individuals living with conditions that make even well evidence-based decisions harder.	Thank you for your comment. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with

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					chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
Inhealth Pain Management	Guideline	007	012	Use of the Agenda For Change banding in the recommendation on acupuncture as this is a loose way to categorise different professionals and their skill-set. It is assumed that the use of this criteria is based on the economic evaluation and that the implication is that the treatment is not effective if delivered by a clinician who is paid more than a band 7 level? How this might be applied in practice is made more difficult by the way that healthcare is commissioned in the UK. Organisations that do not follow the agenda for change terms can provide services for people with Primary Pain. Subsequently it is less clear who is recommended to provide this treatment.	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.

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				On the other side banding in agenda for change is updated yearly and would allow the recommendation to remain relevant in the future.	
Inhealth Pain Management	Guideline	008	001	Recommendations for further research seem consistent with the description of the literature.	Thank you for your comment.
Inhealth Pain Management	Guideline	008	008	Further research recommendation is reasonable given the uncertainty in the evidence base. Has decision to exclude chronic low back pain populations (whilst including populations including other forms of single site pain) of chronic low back pain affected available studies?	Thank you for your comment. The reviews for specific interventions included in this guideline (including manual therapy) are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of

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					this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. This does have an impact on the studies included, but this is consistent with the population in the scope of the guideline and with the review protocols.
Inhealth Pain Management	Guideline	019	024	The guideline rational recommendation implies an effect **at** 3 months. Where the Evidence Report uses the term **up to**3 months. The former indicating meaningful benefit at three months the latter at any time leading up to 3 months. There is a lot of difference between these two descriptions of time. **Suggested Action: Can the guideline development group make their use of language consistent across their guidance and supporting rational?** **Can clarification on the meaning of their rational as these two time frames are quite different.**	Thank you for your comment. The evidence review included results reported up to 3 months. This has been amended in the rationale.

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Inhealth Pain Management	Guideline	024	018	It was interesting and sobering (as ever) to read the all cause mortality and adverse effects of Opioids in long-term use. However the quality of this evidence sounds to be poor and I wonder if a recommendation for research could be made? It is different to say "the evidence suggests that it has no benefit" compared to "there is no evidence to suggest it has a benefit". Suggested Action: **Consider making research recommendation on the long-term effects of Opioids in this population.**	Thank you for your comment. The committee agreed that there was sufficient knowledge of the harms of long term use of opioids and that recommending research specifically for this population was not valuable and also raised ethical concerns when it is thought that these medicines do not benefit the majority of people with chronic primary pain but are likely to lead to long term harms.
Inhealth Pain Management	Guideline	025	008	Anti-epileptics: The thinking behind the lack of support for Gabapentinoids is clear and understandable. If there is no evidence of benefit then this is rationalised. However, this does conflict with the guidance given in the EULAR (European League against Rheumatism) Fibromyalgia guideline which does find evidence for the use of Pregabalin. It could be that this is an artefact of different search criteria. It is also interesting to note that the committee discussed averse effects which are understood through practice and drug information but there was not study which identified this. Perhaps it would be useful to recommend observational studies to offer some guidance? **Suggested Action: Research recommendation of observational studies into safety of Gabapentinoids?**	Thank you for your comment. The committee were aware of the EULAR guideline for fibromyalgia. The methods used to develop each guideline differ, and the protocol for the review also differed. A key difference was the inclusion of studies with an enriched enrolment design / placebo run in phase. When setting the review protocol for the pharmacological review included in this NICE guideline the committee

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					agreed these should be excluded, the reasons are set out below. Placebo run in studies: While this can be a useful methodology employed in a proof of concept study, it does not provide a generalizable estimate of the efficacy of the medicine in the general population. There are two main concerns: 1, such trial designs will likely increase the observed magnitude of effect of the medicine compared to the placebo group as placebo responders are removed. Whilst the placebo response in pain is known to be high, this is reflective of how the general population are likely to respond, and so excluding these gives a biased estimate of effectiveness gained from these trails compared to those without a placebo run in phase. 2 – the side effect profile of many of these medicines (including pregabalin)

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					are notable. Having a placebo run in phase can effectively unblind study participants as they are able to notice the difference between tablets received. This again biases the results of the study, generally in favour of the active intervention when in a clinical trial setting. Enriched enrolment design: The committee considered that including enriched enrolment design studies would not provide the committee with an overview of the effect of pharmacological interventions for people with chronic primary pain and would not support their decision making for this population as a whole. By including studies that only recruit known responders there are difficulties with interpreting the data for a patient population, particularly for people that have not been prescribed the drug of interest previously. By the nature of these studies people that don't respond (but are diagnosed with

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					chronic primary pain) are not included. The effect of this is to likely increase the observed magnitude of effect of the medicine in a population when it is known not to be effective for some people. It does not provide a generalizable estimate of the efficacy of the medicine in the general population. In addition, the concerns re the side effect profile stated above (in our discussion about placebo run in studies) also apply here. The committee are aware this has resulted in the exclusion of some studies of pregabalin in people with fibromyalgia. For the reasons stated above, they believe this is appropriate when making evidence based medicine for a population with chronic primary pain. Unfortunately these studies do not provide detail to identify characteristics of responders to enable more targeted prescribing if there is a subgroup who do benefit.

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					The committee don't agree that a research recommendation for safety of gabapentinoids would be beneficial as the recommendation is also based on evidence not demonstrating these medicines to be clinically effective as well as concerns about their safety.
Inhealth Pain Management	Guideline	026	005	Paracetamol: The decision not to recommend based on no evidence is understandable and limited anecdotal effect from clinical experience is reasonable. However, I wonder if further research could be conducted given the more limited risk profile than compared to some other medications? **Suggested Action: Could a research recommendation be considered?**	Thank you for your comment. The committee considered that it was unlikely that further research would add value for this area. They considered that paracetamol has been available and widely used for a long time and if a beneficial effect for chronic primary pain was expected, this would be evident from clinical expertise.
Inhealth Pain Management	Guideline	026	005	Anaesthetics: The guidance seems relevant to topical use of local anaesthetics. This could be made more explicit as some of these medications are used in infusions for Primary Chronic Pain. I understand that use of this type of intervention is not supported by a strong evidence base but remains practice in many areas. Might it be useful to comment on this in the guidance? The evidence is limited in the effectiveness of topical	Thank you for your comment. The review considered topical and intravenous use of local anaesthetics. Although the only evidence identified was for topical administration, the committee agreed that their expert consensus opinion was that intravenous use was also not of

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				anaesthetics and it is also impractical to see it used in widespread chronic pain. It is understandable that there is a research recommendation for use in CRPS due to variation in the biology for this condition as with Gabapentinoids. **Suggested Action: Can the guideline be extended to consider Anaesthetic infusions?**	benefit to the majority of people with chronic pain. The routes of administration considered have now been clarified in the recommendation, rationale and discussion of the evidence.
Inhealth Pain Management	Guideline	General	General	Within the Shortened version of the guidance the recommendation for research is mentioned in some interventions in the recommendations (Pain Management Programs and Manual therapy) but in the case of others this was only included in the recommendations for research. I am unclear on the inconsistencies and how this might reflect the different interventions? **Suggested Action**: **Be more consistent in how recommendations for research are represented in the guidelines.**	Thank you for your comment. All references to research recommendations have now been removed from the recommendations and appear in the research recommendation section and related rationales only.
Inhealth Pain Management	Guideline	General	General	Although there is guidance from NICE for low back pain this is not necessarily Chronic Low back pain. It is not clear although it could be assumed that evidence relating to Chronic low back pain has been excluded as it is assumed that this is covered in the prior guidance. However neck pain is included in the literature review. It is not clear the distinction between pain in one part of	Thank you for your comment. The population for NG59 for low back pain and sciatica does cover chronic low back pain. The committee acknowledge that chronic neck pain is also part of the axial skeleton, but this is not already included in other NICE

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				the axial skeleton and another? Given that Non-Specific Chronic low back pain is often cited as the most common form of chronic pain that excluding this form of chronic pain reduces the evidence base and makes it harder to make evidence informed decisions? **Suggested Action: Can the exclusion of low back pain as a form of Chronic Primary Pain and inclusion of neck pain be justified?**	guidance and so is included as it falls under the definition of chronic primary pain.
Inhealth Pain Management	Guideline	General	General	I would agree with the statements in the BPS (British Pain Society) response that individuals might have a mixture of Primary Chronic Pain and other conditions and it is not clear on how to reconcile guidance in these situations. I would also agree that it is not clear on how Chronic Primary Pain is to be diagnosed and a more clear pathway would be greatly appreciated to ease clinical journeys. **Suggested Action: Can an algorithm of diagnosis be developed? Does the evidence base and understood clinical practice allow us to do that?**	Thank you for your comment. Recommendations have been added to the assessment section to highlight that chronic primary pain and chronic secondary pain can coexist. In such cases clinical judgement should be used to determine management according to the relevant NICE guideline. A recommendation has been added on when to consider a diagnosis of chronic primary pain.
Inhealth Pain Management	Guideline	General	General	NICE guidance for Neuropathic pain and low back pain to run concurrent to new guidance and experience would suggest that a number of patients with long term pain	Thank you for your comment. The committee acknowledge that chronic

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				also have secondary pain and this may confuse the issue in regards to prescribing pain medication.	primary pain and chronic secondary pain can coexist, and have included a recommendation to highlight that. In those cases, clinical judgment should be used to determine management for the type of pain being treated according to the appropriate NICE guideline. The committee discussed that there are many similarities in the pharmacological recommendations in the guidelines.
Inhealth Pain Management	Guideline	General	General	Other guidelines are changing as well and one of those is around safety and stimulant laxatives. Any patient that does stay on opioids, Gabapentinoids or even when changed to an antidepressant etc may also need a laxative review. Maybe that could be rolled into assessment of current patients whose pain medication may be under scrutiny. Might save them double or triple appointments and conflicting advice?	Thank you for your comment. If a shared decision is made to stay on one of these medicines the recommendation highlights that a shared plan should be made to continue safely. The guideline also cross refers to the NICE guidelines on Medicines optimisation and Medicine adherence for guidance on medicine reviews.
Inhealth Pain Management	Guideline	General	General	In General we wanted to welcome the effort to offer guidance in a condition that can make up a range of descriptions. We support many of the messages around the value of good communication and the importance of treating the person dealing with Chronic pain as an	Thank you for your comment.

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				individual and considering them as a human being in assessment and treatment plan. We support the role of movement and supporting the psychological wellbeing of the individual. We hope that our comments can be considered in the manner the are meant; in good faith and in the interest of building on an excellent and highly worthwhile project.	
Inhealth Pain Management	Guideline	General/p 1	007	1. Title and press releases refer to condition the guidance advises on as "Chronic Pain". This is misleading as it is referring to the broader sense of chronic pain in parts and for a majority it is infact referring to Chronic Primary Pain ICD classification of: "Chronic primary pain is chronic pain in one or more anatomical regions that is characterized by significant emotional distress (anxiety, anger/frustration or depressed mood) or functional disability (interference in daily life activities and reduced participation in social roles). Chronic primary pain is multifactorial: biological, psychological and social factors contribute to the pain syndrome. The diagnosis is appropriate independently of identified biological or psychological contributors unless another diagnosis would better account for the presenting symptoms. Other chronic pain	Thank you for your comment. We agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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				diagnoses to be considered are chronic cancer-related pain, chronic postsurgical or posttraumatic pain, chronic neuropathic pain, chronic secondary headache or orofacial pain, chronic secondary visceral pain and chronic secondary musculoskeletal pain." This diagnosis is not universally known in specialist areas to treat chronic pain, let alone in the broader healthcare and public as a whole. Contrast this to guidance on Diabetes or Osteoarthritis where members of the public would likely have some recognition of the term. Due to this ambiguity there is a risk of misinterpretation by the public, healthcare professionals and even commissioners. This has been manifest in some press reporting of the guidance. This could lead to misinterpretation that these guidelines are entirely about ALL kinds of Chronic pain. This could mean that those with conditions with other guidance (low back pain, neuropathic pain etc) are not treated in the way that is ideal for these conditions but rather treated under blanket term of Chronic pain rather than Chronic primary pain.	clarifying what populations are covered by each recommendation. The assessment recommendations have now been amended to include consideration of other causes of the pain and when to consider a diagnosis of chronic primary pain.

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				Suggested Action:The diagnosis should be explained in press releases, guidance (short versions and long) and repeated in sections of the guidance.	
Inhealth Pain Management	Guideline and Evidence review J	008	014	Anti-depressants: The evidence base is similar to other literature such as the EULAR (European League against Rheumatism) guidance https://ard.bmj.com/content/76/2/318. Although there is variation on the effects identified. It might be anticipated that a common question might be as to how these medications benefit a person dealing with chronic pain. The name of the medication groups leads you to assume that this might be due to altered mood. The evidence seems to vary on the basis of each group: • Duloxetine improved quality of life, reduce psychological distress and improved sleep. • Tricyclics: improved quality of life, function, sleep and pain. • SSRIS reduced pain, psychological distress and improved quality of life. **Suggested Action: Could slight changes in the brief recommendations reflect these outcomes as this might**	Thank you for your comment. We do agree that the evidence varied between each in which outcomes benefits were observed, however there was considerable overlap, and the committee considered the body of evidence across all outcomes for each intervention. This detail is included in the full evidence review for readers and we have stated in the rationale the range of outcomes benefits was observed in to highlight that this is not just effects on mood. Sleep has been added to the list of outcomes where benefit is seen as this was not previously stated in the rationale.

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				assist reader's understanding on how anti-depressants might impact someone with chronic pain and subsequently on how they are used?	
Inhealth Pain Management	Guideline, Evidence review J	005	019	CRPS (Complex Regional Pain Syndrome) seems to be included in Primary Pain Syndrome but could also be considered to be within Neuropathic pain. Whilst it is understandable that there will be some overlap perhaps this is another aspect of the broad nature of this guidance. This is clarified in the pharmacological management evidence review. **Suggested Action: Can some clarification on what conditions are included in the ICD (International Classification of Disease) definition and which are not assist those using the guidance, particularly the brief versions?**	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised, but it is the committee's view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there is no reason not to consider this with other types of chronic primary pain.

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ISRM Institute of Soft Tissue Therapists	Guideline	General	General	The Guidelines make it clear that the chronic pain patient should be treated as an individual and that their biological, psychological and social contexts should all be taken into account in a complete and well-rounded approach to management and treatment of their pain. Yet the layout of the guidelines immediately breaks down into individual categories, separating out social, psychological and physical approaches with no reference to combining interventions, and the risks or benefits of such a combined approach. Instead, one could view the updated guidance as broadly replacing pharmaceuticals with exercise, rather than guiding on a true biopsychosocial approach. By way of example in a given clinical appointment; manual therapy may first be used to alleviate a patients state anxiety and facilitate some supported movement into painful ranges, whilst some appropriate pain education is provided and social factors discussed. The patient may then be in a better psychological state to engage in physical exercise and a supportive, collaborative relationship will have been fostered. Instead, the Guidelines appear to suggest that exercise or acupuncture should be used in isolation to other interventions as they have a direct affect on pain, and other interventions such as manual therapy should not be used. We recognise the challenge in providing guidance on treating a, by definition, multifactorial condition, but	Thank you for your comment. The committee agree that in the assessment of chronic pain a holistic approach is required. However the evidence for chronic primary pain demonstrated effectiveness of exercise, acupuncture and CBT or ACT as standalone interventions.

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				feel that more emphasis can be given to a combination of interventions perhaps working better for the individual biopsychosocial patient than a single standalone treatment.	
ISRM Institute of Soft Tissue Therapists	Evidence Review I	006	General	The introduction to Evidence Review I [Manual Therapy] states that the aim of manual therapy is "to alter the physical and/or neurophysiological properties of the tissues". We would suggest that the implication that therapeutic manual therapy is capable of altering the physical properties of the tissues to any clinically significant degree is outdated and not supported by the wider evidence base. However, this statement appears to have informed the criteria for inclusion of studies assessed for this review, which in turn may have resulted in the significance of manual therapies in the treatment of chronic pain being missed. The primary outcome measures of 11 of the 15 included studies were Pain Reduction and Physical Function, suggesting the focus was on the proposed physical tissue changes brought about by manual therapy. Of the neurophysiological effects, whilst pain reduction and to a certain extent physical function could be categorised as such, psychological distress was only measured in 4 of the 15 studies. In addition, 9 of the 15 studies compared specific manual therapy techniques to each other. We would suggest	Thank you for your comment. The introduction to the chapter is intended to give background to the review only. It is not related to the inclusion criteria for the studies, which is defined in the protocol in appendix A. The protocol defines outcomes of interest for decision making. Pain reduction and function were 2 of the 9 outcomes listed for this review. Psychological distress was also considered a critical outcome but was not reported in many of the included studies. The committee also agreed that while they were interested in comparisons to usual care, head to head comparisons that may be able to inform whether one manual therapy

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				that the trend in modern musculoskeletal healthcare is moving away from specificity of approach and towards general effects. We see analyses that demonstrate specific exercise being no more effective than general exercise in rehabilitation. This suggests a far more general mechanism of effect, and one that we suggest alsoapplies to manual therapy as a whole, rather than being technique specific. In particular we suggest that a more contemporary view of manual therapy would be taken through a psychological lens, whereby meta-analyses by researchers such as Moyer et al (2004) demonstrate general massage reducing self-reported state and trait anxiety and depression substantially - comparable to the well established effects of psychological therapies. Acknowledging that we cannot attach studies to this document for copyright reasons, we will instead refer more generally and provide references upon request. Pinheiro et al (2015) have demonstrated that depression has a significant dose-response relationship with chronic pain (Non-specific lower back pain in this case). The systematic review by McLean et al (2010) concluded that anxiety and depression are significant barriers to patient compliance to treatment adherence in physiotherapy (e.g exercise). Thus we would suggest that manual therapy	was more effective than another was also of interest. It should also be noted that the reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more

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				(specifically general massage in reference to Moyer et al (2004)) can be used to alleviate the symptoms of anxiety and depression in chronic pain patients, lowering the barrier to patients complying with exercise prescription. This takes a more rounded biopsychosocial approach to the patients treatment than any single intervention manages alone. We make the suggestion that Manual Therapy's role in chronic pain may be reviewed in this context, ie as a significant component ofa multifaceted biopsychosocial interaction with a patient, in alleviating symptoms of anxiety and depression and supporting the end goal of self-efficacy through physical exercise.	easy navigation between the recommendations for different topics. The references supplied all relate to chronic pain more generally rather than chronic primary pain.
ISRM Institute of Soft Tissue Therapists	Evidence Review G	006	027	In Evidence Review G [Acupuncture] it is noted that "Recent research demonstrated that contextual factors, such as therapeutic setting, interpersonal skills of the therapist or even the therapist themselves ("practitioner-effect") have a significant influence on the outcome of the intervention. In the context of chronic pain, acupuncture treatments are often delivered in sequences of several sittings over time, which can facilitate building a therapeutic relationship." Given that this statement appears to be included by way of rationalising the otherwise limited and low quality evidence for acupunctures effects, it is disappointing that the same observation is not made for manual therapy in Evidence Review I [Manual Therapy] where the same is patently true. If this example of a fully biopsychosocial approach to treatment has influenced the committees inclusion of a	Thank you for your comment. This comment is included as part of the introduction of the review chapter providing some background information, not as a means of rationalising the evidence. The committee's discussion and interpretation of the evidence is detailed in section 1.7 of the evidence review. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by

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				recommendation for use of acupuncture, then might it be prudent to consider recommendations regarding manual therapy in the same context?	some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost

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					effectiveness evidence supporting the recommendation.
ISRM Institute of Soft Tissue Therapists	Evidence Review I	035	018	The committees discussion of the evidence of Manual Therapy, in particular regarding the quality of the evidence, is so similar to that of acupuncture [Evidence Review G, Page 43, Line 30] as to be essentially the same. In the "Overall" discussions [Evidence Review I, Page 37, Line 43 and Evidence Review G, Page 45, Line 25 respectively] the similar reflections on variations amongst interventions results in a recommendation for clinical use for acupuncture and no recommendation for clinical use for manual therapy. This is despite the introduction to Evidence Review G [Page 6] clearly stating significant differences in approach between Western and Traditional Chinese acupuncture methods, resulting in significantly different placement of needles for a given condition, and later in the review "the belief system of the practitioner giving the acupuncture is an important aspect of the intervention" [Page 44, Line 29]. We would suggest that collectively this information suggests a far more general, potentially neurophysiological/psychological, effect from acupuncture rather than any specific biological effect. We make the case that Manual Therapy may also be considered a non-specific neurophysiological/psychological intervention when viewed through a contemporary evidence based lens.	Thank you for your comment. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost effectiveness evidence supporting the recommendation. The evidence base for manual therapies was limited for each type. The committee did agree that encouraging benefits were observed compared to usual care however and that this warranted further research.

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				Yet the Guidelines appear to explain away difficulties in the data for acupuncture ["Sham acupuncture could also be therapeutic by involving both validation of the person's pain and by an empathic approach from the clinician" - Evidence Review G, Page 44, Line 38] whilst not giving Manual Therapy the same consideration. It would appear that two closely related interventions have not been given the same level playing field under review.	
Kent Community Health NHS Foundation Trust	Guideline	General	General	This guideline is called 'Chronic Pain', but then very quickly deviates to 'Chronic Primary Pain'. Chronic Primary Pain is a very new term, in fact it has not even been officially adopted, with the planned adoption date set for 2022. Neither doctors, patients nor Commissioners are familiar with this terminology. Currently, we teach our patients (and their doctors!) in depth about the different types of pain; namely Nociceptive, Neuropathic, Nociplastic and the fact that they could have Mixed pain, along with the concepts of peripheral and central sensitisation. This helps them understand their experiences, as well as how to judge the appropriateness and action of a medication for instance. Even 'Nociplastic' is a new term that has only been defined by IASP in late 2018. Why not incorporate these terms in the guideline for familiarity and explain concepts accordingly?	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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					clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications.
Kent Community Health NHS Foundation Trust	Guideline	General	General	The general wording in the guideline makes it appear as if patients with chronic pain have either primary or secondary pain. However, in practice, it is very seldom this clear and a large number of our patients have more than one type of pain, or cause for their pain. Treatment planning should be holistic and individualised, as it currently is in our multidisciplinary service. Demarcating it this sharply is not only not representative of patients' experience but may also mean they do not get access to treatments they need, if it was left to commissioners who are not specialists, to try and determine what is "allowed" and what not.	Thank you for your comment. A recommendation has been added to highlight that chronic primary pain and chronic secondary pain can coexist. The guideline cross refers to other relevant NICE guidelines for management of chronic secondary pain. Where they coexist clinical judgement should be used to determine management for the type of pain being treated, according to the relevant guideline. The committee agree there should be a holistic

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					individualised approach to assessment and development of a care plan for chronic pain. Amendments have been made to the assessment sections to highlight this approach.
Kent Community Health NHS Foundation Trust	Recommendation 1.3.5	007	011-015	Regarding acupuncture: We gratefully acknowledge that acupuncture is accepted here as a useful modality, but there seems to be many restrictions to its use. Within the East Kent model, Acupuncture had been offered for almost 2 decades when it was a secondary care service only, and more than another decade since the non-interventional modalities moved into the Community. We thus have a wealth of experience with its use and had audited and adapted how we offer it over the years. There is rightly question about its long term benefits in people with chronic pain, and hence we offer it as a modality to primarily facilitate goal-setting (and thus self-management) through the reduction in pain it affords. Our recent audit indicated that 79% of patients who responded to acupuncture and thus completed a course, either partially or fully achieved the goal they chose to work on. Traditionally, as per the British Medical Acupuncture Society, a trial of acupuncture is regarded as 3—4 sessions, once per week. We use Dolotest®, VAS(visual analogue scores), PSEQ(pain Self-Efficacy Questionnaires) to determine whether any changes. If responding, a course will then be completed.	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation. This evidence review was only for people with chronic primary pain. This is detailed in the protocol and in the scope but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations

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				It seems to be restricted to people with 'primary' pain only: many different types of pain respond to acupuncture. It seems to be restricted to not more than 5 hours worth of sessions. From our experience and auditing over the years, we had settled on offering up to, but not more than 12 sessions. In the recent audit, 26 % of patients required 11+ sessions. A quarter of patients would thus have been denied achieving their goal with this restriction, for 30 min sessions (if note taking, dressing and undressing, inserting needles, indwelling of needles and removal of needles + safe disposal is accounted for, it is difficult to do sessions shorter than this.) You are very prescriptive with the banding of staff performing it, seemingly for cost-effective reasons. In our service, multiple different clinicians are trained in acupuncture, including higher bandings. We have found that what is more important than the profession or banding of staff member performing acupuncture, is a thorough understanding of the principles of self-management , to be discussed and progressed on with patients during their sessions. 23% of the patients who achieved their goal, felt no further need to continue their pathway in the service and elected discharge. Thus effective patient education, not necessarily banding, will also save money—leave it to the services to decide.	are covered by each recommendation topic.

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Kent Community Health NHS Foundation Trust	Recommendation 1.3.6	008	004.	Re TENS This modality is widely used be people in pain and many find it beneficial, for multiple different types of pain. Quite correctly, there is no need to provide the apparatus, as these are readily available for very reasonable prices on the high street. The wording makes it appear as if this was a worthless modality and not to be discussed. Perhaps the wording could be changed to indicate that services could teach the use /trial TENS, but for patients to provide their own machines. This is a modality we have decades of experience in its use. In the most recent audit, 646 patients were taught in groups (as part of Pain Education) on the use of TENS over one year, of these 58 % decided to trial it after hearing the talk and explanation. Of those that trialled it, 57 % found benefit across a wide range of pain conditions (the most common, being beneficial in low back pain)—83 % of these patients who found it helpful, then purchased their own machines. That is a large number of patients in just one year in one service, who found a simple treatment to be beneficial.	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
Kent Community Health NHS	Recommendation 1.3.8	009	015	Pharmacological management of chronic 'primary' pain, not to offer gabapentinoids:	Thank you for your comment. The recommendation not to offer

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Foundation Trust				This advice ignores the fact that so many of our patients have many reasons for their pain, or mixed pain, and oversimplifies the groups of patients. Most commonly, these patients with widespread pain, may display central sensitisation. Anti-depressants may not be the solution for all of them and the gabapentinoids trialled and used appropriately, may be very useful drugs in this situation. These could then also often treat the anxiety that so many of these patients have(which is actually a licenced indication of pregabalin). Not being "allowed" to use it, narrows the possibilities of finding a suitable treatment for a patient down considerably.	gabapentinoids is based on the evidence reviewed for chronic primary pain. This evidence did not demonstrate a clear benefit for pain for this population and no benefit in any other outcomes, but there are harms associated with gabapentinoids use. The committee noted that there was more uncertainty as to whether gabapentinoids may be beneficial for CRPS and included a research recommendation for this type of chronic primary pain, but for all other chronic primary pain they agreed that it was appropriate to recommend against their use. This recommendation only applies to the management of chronic primary pain. The committee acknowledge that there will be overlap in painful conditions in many cases. Clinical judgement should be used to determine the appropriate treatment option relevant to the type of pain being treated.

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Lancashire and South Cumbria Medicines Management Group	Guideline	General	General	The Lancashire and South Cumbria Medicines Management Group (LSCMMG) is part of the collaborative commissioning arrangements between the eight Lancashire and South Cumbria Clinical Commissioning Groups (CCGs). Its purpose is to provide a platform for a consensus decision making process relating to the use of medicines across the Lancashire and South Cumbria NHS footprint, to ensure equity in access to medicines and optimisation of medicines use. The group has recently revised and replaced the LSCMMG chronic non-cancer pain guidelines. As part of this programme of work the group engaged extensively with local pain consultants and clinicians. Additionally, at the August meeting of the LSCMMG, the draft NICE chronic pain guidance has been discussed. The group recognised that the draft guideline is a significant shift from current practice. Certainly, whilst drafting the new LSCMMG chronic pain guidance, pain specialists were clear that if used correctly additional pharmacological agents, such as opiates, did have a place in the management of chronic pain. Whilst it was clear that there are issues with the overuse of analgesics, such as opioids, in primary care the group felt that to limit the management of chronic pain to one class of medicines is unduly restrictive given that there	Thank you for your comment. The assessment section of the guideline covers all types of chronic pain. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The committee agreed that the

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				may be significant delays before patients can access specialist services. Non-pharmacological interventions, including pain management programmes and social prescribing, are supported by local pain management teams. Consequently, these form the basis of the non-pharmacological measures that are promoted by the LSCMMG. When the draft guideline was discussed, doubts were expressed about the accessibility and capacity of CBT services for such a large cohort of patients. The group also questioned the availability of acupuncture services in the NHS. Whilst the evidence base for pain management programmes and social prescribing in the literature is lacking, pain specialists did feel that these interventions had an important role to play. There is a drive to implement these services in Lancashire and South Cumbria. The group does recognise that the guideline follows the evidence. However, members have commented that the guideline offers only one approach to manage a very complex cohort of patients and this would not be sufficient to achieve adequate outcomes for their patients.	evidence did not support recommending the majority of medicines reviewed for chronic primary pain due to lack of evidence of effect and evidence of harm. Social interventions and pain management programmes were considered for all chronic pain. There was no evidence in people with chronic pain for social interventions and the committee agreed it important to recommend research in this area. They agreed the evidence for pain management programmes did not enable a recommendation to be made for or against their use. For the recommended interventions, the committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment to implement some recommendations in the guideline. However, this will ensure

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					that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Lancashire and South Cumbria NHS Foundation Trust	Evidence review C	053	1.7.12	"The outcomes that matter most". We would like to see included in the call for research, research that focuses on 'wellbeing' outcomes – rather than a focus on 'reducing anxiety/depression', a focus on, for example measuring wellbeing, hope, satisfaction with life etc. For example Warwick Edinburgh Mental Wellbeing Scale; Sneider Hope scale. N=1 studies may also be important, so as to capture what meaningful change looks like for invididuals. This may allow the benefits of PMPs to become clearer and better evidenced. In our experience working clinically with people with chronic pain, we suspect that it is difficult to conduct research that meets the quality required by NICE, possibly due to the complexity of this condition.	Thank you for your comment. This section of the guideline is the committee's discussion of the evidence that was reviewed. 'The outcomes that matter most' describes the outcomes the committee ideally wanted evidence for to inform recommendations, and details what evidence was available. The suggested protocols for the research recommendations are detailed in the appendices where relevant. In the case of the pain management programmes review, on consideration of stakeholder comments that there had already been extensive research in this area, this research recommendation has now been

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					removed. However, all of the existing research recommendations include health related quality of life as a critical outcome. The committee agree this is important to include in all research. N of 1 trials are not suggested as the proposed study design in the research recommendations where it is feasible and reasonable to perform a higher quality research study with randomisation, a control arm and larger participant numbers amongst other factors to minimise bias and give the best estimate of the true effect of the intervention. The committee agree that research in complex conditions requires additional considerations, but controlled trials have been conducted in this area and are feasible.
Lancashire and South Cumbria NHS	Comment form question 1	N/A	N/A	***Question 1: Which areas will have the biggest impact on practice and be challenging to implement?***	Thank you for your comment. The guideline reflects the evidence for

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Foundation Trust,				Reducing the number of options for pain medication will have the biggest impact on practice. With limited options for GPs there will likely be increase demand for pain and physiotherapy services. This will increase demand for support with providing manual therapy, acupuncture (services physiotherapists have evaluated to be of limited long term value for CPP) and establishing research for PMP's - a service we have good guidelines for from British pain Society. There will be a big (and backward, we feel) impact on the shift in focus of physiotherapists from developing psychologically informed practice and supported self management to a more interventional focus i.e. acupuncture and manual therapy. A lot of work has gone into getting physiotherapists confident in psychologically informed practice yet the guidelines appear to focus more on a shift towards pain treatments, which we feel is not helpful.	best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The guideline does recommend CBT and ACT as well as acupuncture and exercise and acknowledges the importance of providing information on self-management (in the assessment recommendations). Manual therapy is not recommended for chronic primary pain in the current guideline, but a research recommendation has been

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					made to inform future updates of the guideline.
Lancashire and South Cumbria NHS Foundation Trust,	Comment form question 2	N/A	N/A	***Question 2: Would implementation of any of the draft recommendations have significant cost implications?*** Training costs will be involved in updating acupuncture and manual therapy skills as physiotherapists have generally invested more time in making sense of the complexity of pain, psychological informed practice and physical/functional rehab rather than 'pain interventions'. More physiotherapy staffing investment will be required to ensure those with limited medication options do have access to physiotherapy services.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Manual therapy is not recommended for chronic primary pain in the current guideline, but a research recommendation has been made to inform future updates of the guideline.

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Lancashire and South Cumbria NHS Foundation Trust,	Comment form question 3	N/A	N/A	***Question 3: What would help users overcome any challenges?***We note (and are pleased to see) that the assessment of the patient's strengths is documented as vital to the assessment. Work lead by clinical psychology colleagues at Southport (Ainsdale) and Preston community pain services help support patients in identifying those strengths and moving towards their personal goals. Solution Focused Brief Therapy/Solution Focused approaches (in the context of MDT work) are very useful when 'treatment options' are limited or hope for a cure/fix is low. This would be good training for all staff to have to help clinicians deal with patients who feel stuck with no apparent medication solution.	Thank you for your comment. Your comment will also be considered by NICE where relevant support activity is being planned.
Lancashire and South Cumbria NHS Foundation Trust,	Comment form question 4	N/A	N/A	***Question 4:The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.*** Please take into account that a lot of the cost effectiveness data may have changed as there was a rapid shift to virtual working. We are unable to deliver acupuncture and Manual therapy but as physiotherapists we have been able to adapt and deliver Interdisciplinary PMP's, TENS, group based exercise sessions and psychologically informed practice (virtually). NICE should take this into account when finalising the documentation.	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain with considerations of where evidence demonstrates interventions are clinically and cost effective.

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				These new mechanisms may allow for greater patient choice in future, something which our patients have highlighted as important.	Implementation of these should take the current context into account.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	004	011	What evidence was considered to support the value of the therapeutic relationship in patient assessment and management? Does this press home a need for the role of psychology in supporting non psychology colleagues to understand and optimise this relationship for the benefit of the patient? I.e. we strongly feel that psychology is not just 'separate' CBT/ACT treatment for patients, physiotherapists value this co-working to provide those effective therapeutic relationships with patients.	Thank you for your comment. This recommendation has been reworded, removing 'therapeutic' focussing on the supportive collaborative aspect of the relationship which was agreed as the key element. This was a theme identified from evidence in the qualitative review of communication between patients and health care professionals. There was high confidence in this finding. It did not particularly relate to psychological involvement.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	005	002	Asked to assess what would be meaningful quality of life changes for patients yet usefulness of treatments are evaluated upon what standard QOL measures deem meaningful. This means treatments such as psychology/PMP may have been judged as having little significance in impact on QOL as perceived by a questionnaire but of huge importance for the individual at the heart of the intervention.	Thank you for your comment. The review protocol prioritises validated quality of life measures which are all patient reported measures. It is important that outcome measures used in systematic reviews are valid and reliable for the population of interest to provide the best estimate of effect for what is being studies.

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Lancashire and South Cumbria NHS Foundation Trust,	Guideline	005	004	Suggest that we acknowledge that the pain may improve or get worse but it is likely be something that will be with them for the forseeable future. Provide some hope with the reality of living with CPP.	Thank you for your comment. A sentence has been added to the recommendation to highlight that quality of life can improve even if pain remains unchanged.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	005	007	There is no reference to Interdisciplinary working or use of biopsychosocial model throughout the document. Was this a choice on behalf of the committee?	Thank you for your comment. Interdisciplinary working was not specifically considered within the evidence review. The guidelines do highlight the need for assessment to be based on a person-centred assessment and the assessment recommendations reflect a biopsychosocial approach.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	005	018	Needs reference to making sense of pain/ understanding the condition/ understanding self management/lifestyle approaches as well as interventional /therapist lead treatments. This doc appears to focus more on the interventions that can be therapist lead.	Thank you for your comment. Recommendations included in this section include exploring people's understanding of the pain and a section has been added to clarify recommendations on developing a care and support plan where we include consideration of what management strategies people use that are helpful, as well as discussing all management options available.

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Lancashire and South Cumbria NHS Foundation Trust,	Guideline	006	003	Were the British Pain Society PMP guidelines considered in the development of these guidelines?	Thank you for your comment. The committee were aware of the British Pain Society PMP guidelines.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	006	003	Many PMP's are often an integration of CBT principles and supervised group exercise (which are recommended separately in the guideline) – yet it appears there was inconsistent evidence for benefit of PMPs. Was PMP not recommended over group exercise because of cost effectiveness?	Thank you for your comment. The decision to recommend pain management programmes was based on the inconsistency in the evidence of clinical effectiveness. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain

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					management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which

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					were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	006	005	Group exercise can also provide a social intervention. It will add to the experience and feeling of support. Is group exercise only recommended because of cost effectiveness or was social intervention considered valuable?	Thank you for your comment. The majority of evidence was for group exercise (both clinical and economic evidence). The committee do agree that there may also be value from the social intervention aspects. Social interventions for chronic pain were considered in a separate review (evidence report D) but no evidence relevant to the review protocol was identified. A research recommendation has been made for this area.

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Lancashire and South Cumbria NHS Foundation Trust,	Guideline	006	010	Was the research on Cognitive Functional Therapy considered when looking at the role of exercise? We find this highly useful and efficacious in our practice.	Thank you for your comment. This review focussed on exercise as a standalone intervention. Evidence for cognitive functional therapy was not included.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	007	007	Concerns over levels of staffing to provide this input. Passive, reliant on therapist,. Short term not supporting long term patient self management. We would welcome more research and allowance in practice of self acupuncture projects Does the definition of Chronic primary pain include persistent LBP? If so how has the evidence analysed changed from the NICE guidance for LBP which specifically stated NOT to use Acupuncture?	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also

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					be considered by NICE where relevant support activity is being planned. The evidence reviewed didn't inform effectiveness of repeat courses of acupuncture. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments. The committee acknowledged in their discussion of the evidence that they were aware of self-acupuncture techniques. No evidence was available to inform this from the review and therefore a recommendation was not included. Chronic pain already covered in existing NICE guideline (such as low back pain) was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the

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					headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The evidence base reviewed was therefore different to that included in NG59.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	008	004	As a group of physiotherapists working in pain, we feel that TENS is a choice for patients that holds low risk/harm/cost for patient. It is less passive. Promotes independent self-management of pain and is readily available. This we would endorse over a course of acupuncture or manual therapy.	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are

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					for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	008	004	US and IFT have not been used for these patients by physiotherapists in the mainstream NHS for some time. It is good to see that these passive electrotherapy interventions are not recommended.	Thank you for your comment.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	009	001	Interesting to see that drug intervention requires 'a full discussion of the benefits and risks' but other treatment modalities do not have this included. We would like to see this added to every intervention offered to patients.	Thank you for your comment. The assessment recommendations include a recommendation stating that the risks, benefits and evidence for all treatment options should be considered in the development of the care and support plan and at all stages of care. It was agreed important to restate this in the recommendation for antidepressants due to the side effect profile of the medicines.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	014	008	Appreciate the inclusion of honesty relating to the uncertainty of prognosis. We feel that uncertainty can be expressed in a more balanced way that offers hope and potential for rehabilitation /recovery. We suggest including an acknowledgement that pain is likely to be	Thank you for your comment. The committee agree that some people do successfully manage their pain. The committee agree the statement about telling people that pain may not

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				with them for the foreseeable future. For some people the pain never goes away but for others they find ways to modify, reduce or control the pain and lessen the impact it has on their life.	improve or get worse needs to remain, as evidence demonstrated that people valued honesty in communication about prognosis, but a sentence has been added to the recommendation to highlight that quality of life can improve even if pain remains unchanged.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	015	004	• How valuable and meaningful to the patient was this small improvement in quality of life following PMP? • Were any of the interventions evaluated for reducing future use of the healthcare services? • Research recommendations should include evaluation of Pain Management Programmes as these are considered to be the 'gold standard' for pain teams. Yet, their mention in the guidelines is more like a suggestion rather than an emphasis and an evidence based alternative. Such programmes are pivotal in reducing reliance on medications and should be at the forefront of management.	Thank you for your comment. The clinical importance of all effects is considered by the committee based on the minimum difference that may be considered important to a patient. The outcomes of interest for each review are detailed in the protocol (in this case, evidence review C, appendix A). Healthcare utilisation was not an outcome that was reported. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have

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					decided not to recommend further research.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	007	1.3.3	There is growing evidence as to the efficacy of solution focused brief therapy / solution focused therapy (SFBT) and solution focused approaches (SFA) in long term conditions, such as pain; SFBT/SFA is a 'younger' therapy, however, and published evidence may not meet NICE criteria? We would welcome a call for research. SFBT/SFA and ACT have many therapeutic commonalities. SFT is recommended as an intervention in the NICE Guidance on Cancer Services : Improving Supportive and Palliative Care for Adults with Cancer (page 80, 5.30). Our trust has experience of implementing SFA with people with pain and other LTCs, and would be willing to submit experiences to the NICE shared learning database. Contact pmp@lancashirecare.nhs.uk	Thank you for your comment. Solution focussed therapy was included as an intervention of interest in the review protocol and evidence was searched for. No evidence relevant to the review protocol for chronic primary pain was identified however. This is detailed in the committee's discussion of the evidence in evidence report F. The committee agreed not to include a research recommendation as it was unclear whether this would add value for this population.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	General	General	Section 1.1 (Assessing all type of chronic pain) appears to firmly embed the importance of working with patient preferences. Section 1.2 (Managing all types of chronic pain) however, appears highly guidance driven; we would hope for a strong statement in Section 1.2 saying interventions must be guided but not determined by the guidance .. otherwise preference, person-centredness etc means nothing. (Useful source: Patient's Preferences Matter, Kings Fund, 2012: "standardisation guarantees preference misdiagnosis).	Thank you for your comment. The guideline recommends that there should be a care and support plan developed between the healthcare professional and the person with chronic pain, based on the person's priorities, abilities and goals. All management options should be considered within this, and all

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				The addition of the following statement could be helpful: "When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients. It is not mandatory to apply the recommendations and the guideline does not override the responsibility to make decision appropriate to the circumstances of the individual, in consultation with them and their families/carers/guardian" (source from page 2 of NICE guideline Depression in adults with a chronic physical health problem: recognition and management CG91)	decisions to use an intervention should be shared decisions. This is an overarching principle of all NICE guideline recommendations. The NICE guideline on patient experience in adult NHS services highlights this and is cross referred to from this guideline. This is also detailed on the NICE website section on Using our guidelines.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	026	020 - 029	We have concerns that, although welcomed, given the evidence base, the reduction in drugs available to GPs may result in increased referrals to specialist pain management services. Resource investment in early intervention pain management would be welcomed.	Thank you for your comment. This guideline should help ensure resource is directed towards the interventions and services that have been demonstrated to be effective for chronic primary pain.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	General	General	We are curious about the terminology. In recent times there has been a shift to use of the term 'persistent pain'. Why is the term 'chronic pain' used for the guideline? There is no reference to the rationale for this.	Thank you for your comment. During the scope consultation for this guideline a specific question was asked of stakeholders regarding whether the term persistent or chronic should be used. The majority of stakeholders said that chronic pain

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					should be used for consistency with ICD-11 terminology.
Lancashire and South Cumbria NHS Foundation Trust,	Evidence review 4	006	1.3	In clinical practice, patients frequently cite the benefits of peer supports and social interventions. We would like to see included in the call for research, research that focuses on 'wellbeing' outcomes – rather than a focus on 'reducing psychological distress - anxiety/depression', a focus on, for example measuring improvement in wellbeing, hope, satisfaction with life etc . For example Warwick Edinburgh Mental Wellbeing Scale; Sneider Hope scale. This may allow the benefits of social interventions and peer support to become clearer and better evidenced. N=1 studies may also be important, so as to capture what meaningful change looks like for invididuals.	Thank you for your comment. All of the research recommendations include health related quality of life as a critical outcome. The committee agree this is important to include in all research. N of 1 trials are not suggested as the proposed study design in the research recommendations where it is feasible and reasonable to perform a higher quality research study with randomisation, a control arm and larger participant numbers amongst other factors to minimise bias and give the best estimate of the true effect of the intervention.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	Gene ral	General	In our clinical experience, psychologically informed care should be provided by all staff at all tiers (rather than seen as a stand-alone therapy) and we would hope to see this expressed more clearly in the guideline. In the main guideline there is little reference to multi-disciplinary working, something we see as a key strength when working in pain management.	Thank you for your comment. The reviews in the guideline did not generally inform who should deliver the interventions. There is an assumption that this should be a healthcare professional who is

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					appropriately trained to deliver the relevant intervention. Implementation of the recommendations should be determined locally.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	General	General	We would hope to see reference in the guidelines to those with lived experience contributing to the design and development (and facilitation) of pain services and interventions and research; there is some reference in the guidelines (eg page15) but we felt this needed stronger emphasis given the audience for the guidelines and the way it might affect decisions about service delivery – commissioners, GPs etc.	Thank you for your comment. It is beyond the remit of the guideline to inform on the design and development of services. The committee do agree that experience of people with lived experience is important in these aspects.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	001	007	There should be more clarity around the definitions – chronic primary pain (IASP adopted ICD-11 definition) refers to sub-categories of chronic secondary pain conditions. To ensure clinicians understand the recommendations are around medication use in chronic **primary**pain not chronic secondary pain conditions. This would alay some fears of clinicians who may misunderstand or confuse chronic primary pain with chronic pain as a whole. See: https://www.iasp-pain.org/PublicationsNews/NewsDetail.aspx?ItemNumber=8340#:~:text=The%20chronic%20pain%20classification%20was,for%20more%20than%20three%20months	The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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					included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	001	007	'This guideline covers…' should also include reference to the NICE neuropathic pain guidelines CG173.	Thank you for your comment. Neuropathic pain has been added to the list of other relevant NICE guidelines.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	010	1.3.12 and 1.3.13	"If a person with chronic primary pain is already taking any of the medicines in recommendation 1.3.11, explain the risks of continuing"… and 'withdrawing medicines' section:- There is a risk here that GPs and primary care physicians may stop these medications abruptly, with the best will in the world, we have seen this before with opioids, gabapentinoids, lidocaine, benzodiazepines etc. There should be absolute clarity that patients already on them should be called in for review rather than blanket bans and stopping of prescriptions from the surgery. This leads to patient distress and then has a knock on effect on patients reporting to A&E, demanding urgent appointments with pain teams and resorting to 'risky' medicines use etc.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible.

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Lancashire and South Cumbria NHS Foundation Trust,	Guideline	General	General	The guideline will support primary care physicians but then if specialist services make different recommendations, where they feel it is clinically appropriate, often this is met with reluctance or sometimes refusals to prescribe something often quoting/misquoting NICE guidelines. So it should be clear that specialist services especially may do things differently based on their assessments.	Thank you for your comment. This guideline recommends the evidence for best practice for all healthcare professionals in NHS settings, or where NHS services are commissioned.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	008 - 010	1.3.8 to 1.3.14	Pharmacological management for chronic primary pain: Sertraline, fluoxetine, citalopram and paroxetine – are now being recommended as potential options. Clearly there is a risk that we are simply shifting the problem with opiates/gabapentinoids/benzodiazepines to another class of drugs. In a few years time we risk having the same conversations, saying we now have an antidepressant prescribing problem. This has already been identified last year in the Prescribed Medicines Report, which highlighted the risks with antidepressant therapies too (https://www.gov.uk/government/publications/prescribed-medicines-review-report).	Thank you for your comment. The committee agree that it is important side effects and harms of antidepressants are considered in any decision of whether to start using these. They recommend a decision is made only after a full discussion of risks and benefits. They also include a recommendation to discuss with the person the problems associated with withdrawal from these. The committee's discussion of these factors is included in the discussion of the evidence in Evidence review J.
Lancashire and South Cumbria NHS	Guideline	General	General	The overall tones of the guideline seem to suggest the blanket bans when clearly the fine print suggests little of lack of evidence at times. Many have	Thank you for your comment. Underneath each recommendation section in the guideline there is a link

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Foundation Trust,				highlighted already that the problem isn't with opioids inherently rather it's with inappropriate prescribing, lack/infrequent monitoring, lack of counselling/education for GPs and patients etc. Where it is clinically appropriate there should be scope for clinicians to use their experience, judgement and data to use opioids. Emphasis should be put on primary care clinicians prescribing opioids more appropriately i.e. not starting them unless appropriate and seeking advice otherwise the patients end up on high doses before the pain teams even see them. Removing opioids for primary care clinicians is likely to make things worse and a stigma associated with prescribing them where appropriate.	provided to the rationale for the recommendations, linking to the evidence underpinning it. Whilst there may be certain situations where they can be prescribed safely and appropriately, the committee agreed that there is insufficient evidence to recommend opioids for chronic primary pain, and their expert consensus opinion agreed that these are not appropriate to recommend for chronic primary pain.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	General	General	GP advice lines for medication related queries should be recommended as a research recommendation perhaps, or as a standard of good practice for pain teams to offer, so GPs can ask for advice at the point of care rather than waiting for a referral and starting opioids or other medication in the meantime - which might not be entirely appropriate.	Thank you for your comment. Medicine advice lines was not a topic that was reviewed within the guideline.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	009	1.3.11	Mention of gabapentin and local anaesthetic in CRPS trials only – it is already sometimes used and recommended by specialists for CRPS with sometimes good effect so this should be recognised. If it doesn't work of course it should be stopped but	Thank you for your comment. The committee acknowledge in the discussion of evidence in the review chapter and in the rationale that their expert opinion was that these may be

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				again blanket ruling saying not to prescribe it leaves little room for clinicians to even trial.	of some benefit for people with CRPS, despite there being no evidence identified for this. The inclusion of research recommendations in this topic is a recognition of this, and hopefully will inform future updates of this guideline.
Lancashire and South Cumbria NHS Foundation Trust,	Guideline	026	020	'How the recommendations might affect practice' – to suggest the recommendations will reduce prescribing over the long term is quite simplistic. It may reduce opioid and gabapentinoid prescribing but antidepressant prescribing will go up and also the financial burden of the patients attending Out of Hours services, A&E and using other illicit substances or relying more heavily on OTC or internet sourced products is likely to go up. Also stating that this is likely to result in people returning to the workforce is a really simplistic viewand may give the misleading impression that reduction of pain drugs will enable people to return to work. With such little medication options and support for other pain services one could argue it's likely to have the opposite effect. This statement seems to suggest the medication is what has been keeping patients off work when clearly this is not the case as mentioned in the 'key facts and figures' section later on that it's the pain that has been keeping people off work...not the medication	Thank you for your comment. The committee agree that there is likely to be an increase in antidepressant prescribing but believe that overall the recommendations are likely to lead to a reduction in the use of drugs for managing chronic pain in the longer term. The costs associated with implementing the recommendations are considered within the resource impact assessment produced by NICE alongside the guideline. The sentence regarding return to work has been removed from the guideline.

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				itself. In fact medication has allowed people to return to work or lead somewhat normal lives. There needs to be reference to (and investment in) other interventions and support structures that might help facilitate a return to work, when needed.	
Loughborough University	Evidence review B	General	General	We welcome this consultation. Our collaborative research and training work with healthcare professionals involved in pain assessment indicate that there is real need for guidelines in this area. Our response is built on cutting-edge communication science research on language and social interaction – in particular on studies using conversation analysis – where (recorded) naturally-occurring interactions are examined so as to specify the structure and functioning (the anatomy and physiology, as it were) of human communication practices and problems. There is a large body of valuable communication evidence published (even languishing) primarily in linguistics and social sciences journals and books. Parry, Jenkins and team work at the interface between such foundational communication science research and clinical practice, policy and training. Our expertise is in making communication scientific evidence more readily available to policy makers and - through training interventions - to clinical educators and practitioners.	Thank you for your comments. We have responded to your individual comments below.

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				Our comments will point out relevant communication science studies that should be included as evidence informing the NICE guidelines because they provide robust evidence relevant to improving healthcare practitioners' communication skills in providing the best possible support for people dealing with chronic pain.	
Loughborough University	Evidence review B	006	003	The literature in the Evidence Review overwhelmingly relies on patient and practitioner reports on what they believe to be barriers and facilitators to good communication. There is no reference at all to direct evidence, that is, to research based upon direct observation of (recorded) actual practice wherein practitioners and patients (and sometimes those patients' companions) interact in the course of assessment, diagnosis, providing interventions and more broadly managing chronic pain in real-life consultations. A small number of published studies have directly observed and analysed (video-recorded) pain-related healthcare conversations between staff and patients. A much larger body of published studies have directly observed and analysed (recorded) healthcare conversations relating to other conditions, but involving topics and activities that are highly relevant to the core components of chronic pain communication – including effective information gathering, sensitive and effective shared decision making, maximising uptake of advice and	Thank you for your comment and for this information. The review included all evidence that met the protocol for the qualitative review. We are not aware of any literature of conversational analysis that was directly relevant to include.

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				treatment recommendations, persuasive communication, and managing of patient resistance to diagnosis or to interventions (including psychologically-based interventions). Evidence from conversation analytic studies that have directly observed chronic pain communication in a palliative care context Conversation analysis is rapidly becoming the gold standard approach for studying healthcare communication. It allows a detailing of the structure and functioning of communication practices not possible through gathering post hoc accounts of communication. People may come away from conversations with a sense that it "went well", that the healthcare professional was "empathetic", or in other situations, that they felt "misunderstood" or "not listened to". Very small, and usually unnoticed, details of the way we talk have a huge impact on how well a consultation goes, as well as upon what patients do thereafter. However, we know that people are not able to articulate these details in ways that help others learn and improve on their communication. Conversation analytic studies spell out these details. Our conversation analytic studies analysing actual consultations involving experienced palliative medicine doctors and people suffering long-term pain (Jenkins and	

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				Parry, 2020; Jenkins, Parry and Pino, in press) found the following: • Practitioners use listening techniques – head nodding, and 'continuers' like mmhm, yes, in particular places during the consultation as ways to encourage patients to report their pain as fully as possible. • Practitioners design their questions to show or imply what they already know and understand about the patient's pain. • Practitioners' responses will inevitably convey messages to the patient about the nature and origins of their pain, its severity, its authenticity, and potential remedies (Jenkins, 2015). Thus, people's sense of "feeling believed" about their pain results from specific moments in consultations where practitioners say things that convey an assumption that the patient's pain and their reports of it are 'real'. • When patients talk about their pain, or answer questions about their pain, even brief responses such as "okay" or "right" from the practitioner show the patient that	

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				they are treating what they say about their pain as valid, apposite, meaningful. • When practitioners repeat an answer a patient has given, they show the patient that they are treating what the patient has said as clinically relevant (Jenkins, Parry and Pino, in press). • Repeating a patient's answer can provide an opportunity for the patient to say more about their pain (Jenkins, Parry and Pino, in press). • When practitioners repeat a question they have already asked a patient (e.g. "so tell me a bit more about it"), this can prompt the patient to provide more detail; at the same time, the repeated question works to show the patient that what they have to say is important and relevant. • When practitioners administer a pain intensity scale (such as the 0-10 numerical scale), patients often capitalise on it as an opportunity to provide information not only about intensity, but also about other features, including its variability, and effects on their functioning. If practitioners insist on	

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				a specific number, they can close off such opportunities and lose out on clinically valuable information. When practitioners administer a numerical pain intensity scale, if a patient shows themselves to have misunderstood (for instance, they may take 10 to mean no pain, and 0 to mean very severe pain – the opposite to convention for this scale), clearing up this misunderstanding can bring new difficulties into the conversation and the therapeutic relationship. We found practitioners worked hard to avoid implying that the patient is at fault in such misunderstandings. This takes both subtle interactional skills and time. Evidence from direct observational (conversation analytic) research on pain communication in primary care consultations • It is possible to optimise how questions are asked in ways that increase the chances of patients providing a rich and detailed account of their pain symptoms. The current consultation guidance provides good advice on what patients should be asked about, although it does not cover how to ask questions. Evidence shows that how questions are posed has a substantial impact	

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				on what the patient will say next, and how easy it is for them to answer with information that is clinically relevant. (Heritage, 2010)This is unsurprising – a large body of work on naturally-occurring human interactions across various settings shows that the way in which a speaker seeks information from another person profoundly affects what information is actually provided – regardless of what they actually 'know'. • The timing of patients' descriptions of pain gives clues to the practitioner. In particular, patients regularly provide additional, new information, or information that the practitioner might not have sought out themselves (and thus had not anticipated as relevant) by 'inserting' pain reports outside the section of the consultation that comprises assessment question and answer sequences, and outside specific 'slots' for reporting pain during physical examinations (Heath, 1989; McArthur, 2018). Practitioners should be alert to the fact that:	

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				○ patients may communicate in this way ○ practitioners can make it more or less easy for patients to do so ○ if patients do 'insert' such reports, practitioners should pay attention and (if needed) change tack so as to focus on enabling patients to expand on what they have begun to report / disclose. Evidence from direct observational (conversation analytic) research on healthcare interactions A wealth of relevant research is available, but it is beyond our current scope to review this here. However, we note one finding about how different ways of delivering (and ordering) treatment recommendations can impact on patients' acceptance of or resistance to these: • Research on primary care consultations (Stivers, 2005)found that, overwhelmingly, when practitioners start with specific and positive recommendations, these are much more likely to be agreed to compared with negative 'rule out' recommendations. • If practitioners start out with 'rule out', negative recommendations (e.g. 'you don't need X'), then even if the practitioner goes on to recommend	

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				something else, they are more likely to be met with resistance and arguments. • This finding has formed part of a recently trialled communication training programme in the US which was found to be effective in reducing antibiotic prescribing for viral infections (Kronman et al., 2020) and a report of an associated economic evaluation currently in preparation found significant cost savings as a result.	
Loughborough University	Evidence review B	015	006	Implications of evidence from direct observational (conversation analytic) research on 'functional' neurological disorders A body of research on optimal practice for doctor/patient communication surrounding non-epileptic seizures and 'functional' neurological disorders is relevant to some chronic pain contexts. A summary of practical implications of this work is provided by Stone et al. (2016). This guidance is quoted and summarised below: On explaining and arranging investigations: • Preparing patients to anticipate that their investigations are likely to be negative can have a positive effect on outcome.	Thank you for your comment and for this information. This evidence was not included in the review as it is not directly relevant to chronic pain, but many of the aspects highlighted are reflected in the assessment recommendations in the guideline and the committee agree these are important.

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				• Many doctors believe reassurance is a goal of treatment, but fail to realize that: (1) the best form of reassurance is to provide an explanatory model of what has happened ... and (2) in patients with health anxiety, reassurance is a "drug" that provides short-term relief but actually fuels the problem. On explaining 'functional' disorders: 1. Take the problem seriously. In practical terms, this may translate to saying to the patient during the assessment, "this is familiar, I'll explain at the end" or "this is a genuine problem/I believe you" during the explanation.... Such simple measures may overcome barriers of health professional interest and questions of malingering in patients who may have had previous experience of being dismissed or held in contempt. Clearly, such an approach will probably not be successful if delivered by a doctor who holds an ambivalent attitude. 2. Make it clear that there is a diagnosis.... There is a tendency for doctors to overemphasize the diagnoses that patients do not have, often by introducing these before the actual diagnosis.... We would argue that a diagnostic label, whether functional or psychogenic, is an essential signpost to direct the patient to information, explain the condition to family, friends, and employer, and access correct treatment....	

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				3. Demonstrate the rationale for the diagnosis. Much of the literature from primary care on "explaining medically unexplained symptoms" (an oxymoron) emphasizes sharing clinical uncertainty about the presence of disease. In neurologic practice, however, functional disorders should be diagnosed on the basis of positive features and the patient can be invited to understand this process. Our own experience is that sharing clinical signs, such as the tremor entrainment test or Hoover's sign, with patients is a powerful way of persuading the patient that the diagnosis is correct, that there is the potential for reversibility, and that the consultation is a transparent process….. 4. Convey the potential for reversibility. A diagnosis of functional disorder can be presented in an empathetic and transparent way, but has arguably failed if the patient is left feeling that there is no potential for improvement… A functional diagnosis can be interpreted as "something in the brain I can't influence" and a psychogenic diagnosis can be interpreted as "it's all down to me and my personality and there's no changing that." Patients and doctors often fixate on whether the problem is psychologic or neurologic when arguably it is more useful to consider whether the problem is reversible or not reversible, software or hardware. 5. Provide written information. Most patients recall only a fraction of the medical consultation ….. As a generic recommendation, therefore, and arguably especially	

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				when there is complex and new information, it is essential to provide written information. This may take the form of a copy of the clinic letter supplemented with printed or online information specific for functional neurological disorders… In the last few years, patient organizations such as www. fndhope.org have also appeared, providing a perspective that has been missing in comparison to other conditions seen in neurologic practice.	
Loughborough University	Evidence review B	018	002	Implications of evidence from direct observational studies of interactions involving specialist terminology ('jargon'), including in healthcare Conversation analytic research directly examining human interactions 'in the wild' has closely examined use of specialist terminology (sometimes called jargon) and the consequences of using it (Kitzinger and Mandelbaum, 2013) and has also examined healthcare episodes where practitioners underestimate or overestimate patients' and their companions' knowledge of terms (Seuren et al., 2020). Relevant findings: • Using specialist language and terms that a patient does not know and understand can lead to problems of engagement and understanding. • However, use of specialist language also adds important nuance. For some patients, specialist language and terms should be used, and if not,	Thank you for your comment. The committee agree that use of jargon should be avoided wherever possible.

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				this can negatively impact knowledgeable expert patients, and cause problems in the consultation. • Using non-specialist language when a patient does actually know and understand the specialist terms regularly causes trouble in interactions. In such cases, patients treat the practitioner as underestimating their competence and knowledge. Unsurprisingly, patients (and their companions) treat this as an important matter, and they often interrupt the ongoing conversation and business of the consultation in order to clear this matter up. • Practitioners should be alert to the fact that patients with chronic pain are likely to have quite specialist knowledge and know specialist terminologies. Through how they interact, they should work to establish what patients know. • Practitioners should be alert to the fact that they should avoid using specialist terminology IF THE PATIENT DOES NOT ALREADY KNOW IT. BUT practitioners also need to know that, if they avoid specialist terminology when the patient actually has specialist knowledge, this can be perceived as patronising and as underestimating the patient's competence. Moreover, it is likely to lead to a (temporary) disruption of the ongoing clinical agenda because patients often interrupt the conversation in order to correct the	

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				practitioner's understanding about their competence and knowledge. • Practitioners should work, towards the start of a conversation with a patient with chronic pain, to ascertain what the patient knows about their condition, its treatment, and so on. Practitioners can also endeavour to make it easy for patients to alert the practitioner to difficulties of understanding, and conversely to alert the practitioner if they have greater understanding and technical knowledge than is being assumed. With regards to enabling patients to let the practitioner know if they are having difficulty understanding, there are different ways to do this, some better than others, as follows: o Do not ask the patient something like, 'Do you follow me?' or 'Do you understand?' because this asks the patient to claim knowledge but not to demonstrate it. Patients are likely (for various good reasons) to claim they do understand something even where they do not. o Do not ask the patient to repeat back or summarise what you have said. This implies that the practitioner is the one with full knowledge and competence, and that the patient is possibly not. It	

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				risks putting the patient in a vulnerable position by obliging them to expose their lack of understanding. o Instead, practitioners should use some form of words that puts the 'blame' for any possible misunderstanding at their own door – with something like, "I've gone through a lot of information there, and I might not have explained it properly, so can you tell me what you are clear about from what I have said?" (and/or, "So, are there things that are not very clear, or that you have questions about?").	
Loughborough University	Guideline	011	006	Key recommendations for research The style and content of practitioners' communication with patients profoundly impacts the therapeutic relationship, as well as patients' adherence, outcomes, quality of life, and satisfaction with care (Haverfield et al., 2020). Empathic communication and inducing positive expectations reduce pain (Howick et al., 2018).	Thank you for your comment. The committee agree these are important areas to consider in the assessment of people with chronic pain. The review of evidence for communication between healthcare professionals and people with chronic pain identified a lot of good quality research in the area. Although there are always more areas that could be addressed, the committee did not identify this as a particular area where the need for

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				Almost all interventions for pain will be delivered or initiated through interaction between practitioner and patient. The key recommendations for research should therefore include: Interactional practices for pain assessment, diagnosis delivery, delivery of treatment recommendations, and administering (talk-based) interventions What are the optimum practices for asking questions, responding to patients' pain reports, discussing pain, shared planning and decision-making, providing advice, and communicating test results? (i.e. for implementing the guidance 1.1.1-1.1.8). Given that indirect evidence (post hoc reports) of communication is insufficient for characterising the specifics of effective verbal and non-verbal communication practices, new research should involve systematic, direct observational research on (video recorded) real-life chronic pain consultations between practitioners and patients (and companions, where relevant). Given that, in the coronavirus pandemic, much care has moved to being remotely delivered, this research will ideally include comparison of face-to-face in-person	more research needed to be highlighted.

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				consultations with remote consultations, and should include an aim of identifying patient and chronic pain characteristics and clinical tasks and activities which cannot be adequately assessed and managed via remote consultations.	
Loughborough University	Specific question			What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) Resources on communication components: 1. Health Education England's Person-Centred Approaches framework (https://www.skillsforhealth.org.uk/services/item/575-person-centred-approaches-cstf-download), to support formal and informal training and development. In particular, the Core skills and behaviours, 'Conversations to engage with people', 'Conversations to enable and support people', and Behaviours and learning outcomes. For organisations, the sections on education and on the organisational enablers for embedding a person-centred approach would be useful. 2. Real Talk Training resources: Pain communication training	Thank you for your comment. Thank you for your response. We will pass this information to our resource endorsement team. More information on endorsement can be found here: https://www.nice.org.uk/about/what-we-do/into-practice/endorsement

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				www.realtalktraining.co.uk; realtalk@lboro.ac.uk These comprise evidence-based learning materials for training and development of healthcare trainees and staff. The resources are based on a series of cases built from recorded real-life healthcare conversations, with transcripts and learning points based on published communication science research, blogs, and 'in a nutshell' accessible versions of scientific papers on communication. These are freely available online. In addition, video clips of the original recordings of cases are available for use by professionals who deliver (not for profit) communication skills training within the NHS, universities, and hospices, provided that those trainers register to use the clips and agree to safeguard the personal data they include. Two modules of the materials are specific to pain assessment: 1) Asking patients about pain, and responding to patients' reports of pain, and 2) Howto administer pain intensity scales and support patients to provide as much information about their pain as possible.	
Loughborough University	Specific question			The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to

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				There is a small but growing body of direct observational research on communication problems and practices specific to remotely-delivered healthcare (by phone and by video). We would encourage the committee to conduct an evidence review on relevant literature on this. This would enable the committee to formulate guidance on best practice on both technical and clinical procedures. Key authors include Seuren, Shaw, Greenhalgh, (all Oxford) Femoe Nielsen (Copenhagen), Stommel (Radboud, the Netherlands). Specific points include: • Video consultation is optimal compared with telephone calls. • Video consultations where physical examinations are conducted are optimised if the patient and/or a technically proficient companion is able to move and guide the camera, and take and send still images from their phone (Seuren). • In video consultations, communication is improved if the full upper body of the participants is in view, so that gesture and body positioning components of communication are available to the other party. • Physical examinations place additionaland new demands on all parties when done remotely (Stommel, Seuren).	COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.

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				• Practitioners are likely to feel less certain of their findings and diagnoses carried out via remote consultation (Stommel). • Remote consultations may save time and costs for care recipients (Shaw) but they place additional burdens of skill, judgement, and workload on practitioners (Shaw, Seuren).	
MEAction UK	Guideline	1	7	"It should be used alongside NICE guidance for specific conditions that cause pain" "Alongside" needs to be defined in this sentence. It is unclear whether this guideline should be considered a secondary or primary resource for health professionals treating people with chronic pain. It should be defined as a secondary resource.	Thank you for your comment. The assessment section of this guideline is for all types of chronic pain, although the management recommendations are specific to chronic primary pain. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. A recommendation has also been added to highlight that chronic primary pain and chronic secondary pain can coexist.
MEAction UK	Guideline	1	7	The list of conditions that cause pain is not exhaustive – "and others" should be added to the end of this statement to make that clear.	Thank you for your comment. This list links to the other NICE guidelines that are most relevant and is not intended

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					to be an exhaustive list of conditions that cause pain.
MEAction UK	Guideline	1	7	"The guideline aims to reduce distress and improve quality of life by ensuring a care plan informed by a person's individual priorities, strengths, preferences, interests and abilities." If this were true, the guideline would acknowledge that where there is insufficient evidence, individual preferences should be reached through open discussion of the evidence base of **all**treatment options. Instead the guideline committee have chosen blanket bans.	Thank you for your comment. NICE guidelines provide recommendation for the NHS. Recommendations should reflect best practice and focus on those where there is evidence of benefit rather than those that do not have evidence of benefit, and in some cases, evidence of harm. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas.
MEAction UK	Guideline	10	11	Defining chronic pain and chronic primary pain at the end of this document causes significant confusion while reading it. These definitions must come at the beginning of the document.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
MEAction UK	Guideline	10	14	The definition of chronic primary pain as "appropriate unless another diagnosis would better account for the presenting symptoms" could impede necessary further investigation unless it is explicitly said that it should not.	Thank you for your comment. The context section highlights that the decisions about the search for any

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				At present people with ME/CFS and other diagnoses such as fibromyalgia commonly experience a premature end to investigations when they receive their diagnosis. Thorough investigation, especially when pain changes, must be actively promoted in this guideline.	injury or disease that may be causing the pain, and about whether the pain or its impact are out of proportion to any identified injury or disease, are matters for clinical judgement in discussion with the patient.
MEAction UK	Guideline	10	14	There is no recommendation for the time frame at which the diagnosis of chronic primary pain should be considered "appropriate" – is it also 3 months?	Thank you for your comment. The widely accepted timeframe for 'chronic' pain is at least 3 months. The committee agreed this should be followed within the guideline and is defined in the 'terms used in this guideline'.
MEAction UK	Guideline	4	2	At no point in this section is a thorough investigation of the possible causes of pain mentioned. This omission will leave many at risk of causes of their pain being overlooked.	Thank you for your comment. Additional recommendations have been added to this section, including stating the need to consider other causes for the pain and considerations for diagnosis of chronic primary pain.
MEAction UK	Guideline	5	20	As stated previously, this list of conditions that cause pain is not exhaustive – "and others" should be added to the end of the sentence to make this clear.	Thank you for your comment. This list is included to provide a link to other relevant NICE guidelines. It is not intended to list all other types of pain.
MEAction UK	Guideline	5	9	"Discuss the possible benefits, risks and uncertainties of all management options for the person's condition when first developing the care plan and at all stages of care."	Thank you for your comment. This section applies to all people with

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				This guideline then goes on to itself counter this statement by issuing a blanket ban on various low management options.	chronic pain – including secondary pain where management options are recommended in other NICE guidelines. We have now included a recommendation to highlight this. Although the management section in this guideline for chronic primary pain recommends against the use of management options that do not have evidence for their effectiveness, there are also interventions recommended that can be considered for this population.
MEAction UK	Guideline	6	10	Despite pain being secondary to ME/CFS, there are many people who have diagnoses of both ME/CFS and certain "chronic primary pain" conditions as defined in this document. Exercise is not appropriate for all people with chronic primary pain, and has various risks for those with certain comorbidities. This must be clearly stated. NICE guidelines for ME/CFS state that simple advice to exercise, as well as programmes delivered by professionals with no experience of the condition, should not be offered to people with ME/CFS. However for many years, people with ME have been advised to undergo graded exercise therapy and experienced significant harm from this. All advice must now clearly	Thank you for your comment. This recommendation is for management of chronic primary pain only. For management of ME/CFS, recommendations in the upcoming NICE guidance on that topic should be followed.

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				state that exercise programmes including graded exercise therapy have the potential for harm. It can no longer be considered that advice to exercise is always innocuous.	
MEAction UK	Guideline	7	2	How will this interact with existing guidelines for CBT in ME/CFS, IBS or other conditions? Will patients be advised to do CBT twice?	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more

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					easy navigation between the recommendations for different topics. Where conditions coexist, the healthcare professional should use their clinical judgement to determine the appropriate treatment, according to relevant guidance, based on a holistic assessment and as part of a shared decision with the person.
MEAction UK	Guideline	7	2	There are no recommendations on waiting times for patients in pain. In the event that patients are given a long waiting time to access CBT/ACT, are they expected to simply suffer during this period with no pain management at all?	Thank you for your comment. A review on waiting times was not undertaken within the guideline and therefore specific recommendations cannot be made. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources

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					should be focussed and those interventions that should not be recommended, saving resource in other areas. It is hoped that by highlighting these areas for focus, waiting times could reduce.
MEAction UK	Guideline	8	14	The wording is obtuse. Instead of referring to treatments like amitriptyline as analgesics, the guideline simply calls them antidepressants. This has caused a significant media interest in painkillers apparently being replaced with psychological treatments, which is stigmatising to patients. Amitriptyline and duloxetine have been used for decades for their analgesic properties and standard practice has been to advise patients that this doesn't imply their pain is only psychological. Why has the committee taken a different approach, which could potentially increase stigma and prejudice against patients, or encourage them to refuse treatments they feel are inappropriate (e.g. if they are given a psychological explanation for pain they feel has a physical cause)?	Thank you for your comment. In the guideline the names for the medicine class have been used consistent with their use in the BNF. In the rationale for the recommendation we have stated the range of outcomes benefits were observed in (pain, quality of life, sleep and psychological distress) to highlight that this is not just effects on mood. A recommendation has also been added to highlight that antidepressants have been recommended for their effects on the symptoms of chronic primary pain. The committee believe the aim should be to move away from the stigma associated with antidepressants and the recommendations in 1.1 of this

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					guideline highlight that the benefits, risks and uncertainties of treatments should all be discussed between the healthcare professional and person with chronic primary pain when making a joint decision about their use. In this case this should include that evidence suggests the benefits are not just for mood.
MEAction UK	Guideline	9	10	This blanket ban on management options that have been used for centuries defies sense. Our knowledge of the causes of pain is still very limited, and to issue a blanket ban requires that people in pain who could be helped will instead be forced to live debilitated and diminished lives. NICE should strive towards tailored care for individuals. This recommendation flies in the face of that.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended

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					to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The committee agree that there should be tailored care for individuals, and recommend in the guideline that there is a holistic assessment and development of a shared care and support plan with full discussion of the benefits and harms of all treatments. However they also believe this should be based around those treatments demonstrated to be effective for the type of pain being treated and where benefits outweigh the harms, to ensure best patient care.
MEAction UK	Guideline	9	21	Putting management options such as paracetamol on a list that also includes drugs with considerably more harmful side effects implies an equal potential for harm from these drugs. The evidence base clearly demonstrates this is not true, and this should be differentiated in the guideline.	Thank you for your comment. The committee agreed that for clarity for readers, all pharmacological options that are not recommended should be included in one recommendation. The

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					rationale that accompanies this recommendation details the committee's reasoning for each, and this is further expanded on in the committee's discussion of the evidence in evidence review J.
MEAction UK	Guideline	General	General	We stand with the more than 24,000 signatories (as of 16:00 14th September 2020) of the petition "Stop the Proposed Cruel Changes to Chronic Pain NICE Guidelines" - https://www.change.org/p/national-institute-for-health-and-care-excellence-stop-the-proposed-cruel-changes-to-chronic-pain-nice-guidelines This draft guideline has caused great concern for people with ME (myalgic encephalomyelitis) and others with chronic pain, whether it is primary or secondary in nature. There is a lack of clarity as to what this guideline is intended to address throughout. The guideline pays lip service to patient centred care whilst ignoring the reality that we still understand little about the causes of chronic pain, and finding management options commonly requires a trial and error approach. Where a treatment is successful in helping to manage pain for one person, it will not be for another. Blanket recommendations that don't take into account	Thank you for your comment. The committee acknowledge that there was confusion regarding the populations covered by the recommendations in the guideline. They agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in

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				how little we understand about an individual's chronic pain will cause great harm over the years. #MEAction UK concludes that this guideline needs significant revision.	the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. Management of CFS/ME is covered by the NICE guideline on this topic that is currently in development. The committee agree that a holistic individualised assessment is critical to good management of chronic pain. The recommendations in section 1.1 of this guideline have been amended to emphasise the importance of this.
Medtronic	Guideline	005	018	We suggest that TA159: Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin is also included as a link here.	Thank you for your comment. This list links to the other NICE guidelines that are most relevant and is not intended to be an exhaustive list.
Mindfulness Initiative	Guideline	18	21	It was surprising to see the committee's conclusion that "*There was not enough evidence for .. mindfulness .. for the committee to make recommendations*". The studies noted in the NICE Guidance template are very small scale and do not reflect the broad range of research investigating	Thank you for your comment. It is important to note that the reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather

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				the impact of structured mindfulness practice for a diversity of conditions. It is also important to note the review and meta-analysis of mindfulness for chronic pain by Hilton et al, Mindfulness Meditation for Chronic Pain: Systematic Review and Meta-analysis (ann. behav. med. (2017) 51:199–213). This concluded that while "*more well-designed, rigorous, and large RCTs are needed in order to develop an evidence base that can more decisively provide estimates of the efficacy of mindfulness meditation for chronic pain; nonetheless* ***mindfulness meditation interventions showed significant improvements for chronic pain, depression, and quality of life"***and *"Chronic pain continues to pose a tremendous burden on society and individuals.* ***A novel therapeutic approach for chronic pain management such as mindfulness meditation would likely be welcomed by patients suffering from pain***. The Systematic Review and Meta-analysis by Goldberg et al, Clin Psychol Rev 2018 Feb:59:52-60 looking across 142 samples and 12,005 participants, found that the evidence ***"supporting the use of mindfulness for treating pain conditions"*** and ***"mindfulness performed on par with other active therapies" .***	than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The systematic review by Hilton et al is for all types of chronic pain. Their conclusion also notes that more RCTs are needed, and so it is unsurprising that the committee's interpretation of this review of a smaller more defined

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				Zeidan and Vago's review of the evidence of mindfulness meditation-based pain relief (ann. New York Academy of Sciences (2016) 1373:114-127 concludes " *Mindfulness meditation is a technique that has been found to significantly reduce pain in experimental and clinical settings. The present review delineates findings from recent studies demonstrating that mindfulnessmeditation significantly attenuates pain through multiple, unique mechanisms"*	population of chronic primary pain came to the conclusion that further research was needed. Goldberg et al. reviews mindfulness for psychiatric disorders. They examine the effects of disorder type for moderator of the effect, but do not review studies for chronic primary pain separately. Zeidan and Vago's review is a literature review, it does not review the effectiveness of mindfulness as an intervention for chronic pain, nor for chronic primary pain. The committee agree the review conclusion that more research is required for mindfulness in chronic primary pain is correct, and will hopefully inform future updates of this guidelines.

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Mindfulness Initiative	Guideline	18	23	We welcome the committee's decision to make research recommendations on mindfulness for pain management to inform future guidance. Give the recognition that *"what evidence there was suggested there may be some benefit*." We would suggest that the NICE guidance additionally includes a reference to mindfulness-based treatments for pain similar to the one included in the current NICE depression guidance p.186: "(*MBCT … is derived from) mindfulness-based stress reduction*, ***a programme with proven efficacy in ameliorating distress in people suffering chronic disease***(Baer, 2003; Kabat-Zinn, 199") " This could be brief but would show a willingness to highlight an area of patient support with good evidence of benefit, over and above the more specific guideline recommendations. Indeed this would be particularly helpful for clinicians in discussion with patients, given the level of public interest in alternatives and complements to long term medicatio". " *The committee were aware that mindfulness is often used in clinical settings to help with symptoms associated with chronic pain, and that people are actively enquiring about "t.*"A reference to the evidence could be a great help to those currently short of treatment and support options.	Thank you for your comment. The committee agree that the statement included in the rationale in the guideline and the inclusion of a research recommendation do highlight that this is an intervention that has some promising effects that require more research to recommend on the NHS.

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Mindfulness Initiative	Guideline	2	1	Recent experience is that COVID-19 has created a new "Long COVID" condition associated with fatigue, poor mental health and pain, most commonly in older people, that is likely to require long-term clinical support. the 2019 Public Health England Review of Dependence and Withdrawal Associated with some Prescribed Medicines. This showed that in a 12 month period about a quarter of the population (11.5m adults) had been prescribed one of the drugs considered. 1 million people had been using antidepressants for at least three years and for the other drugs, there was only a minority of cases where long-term use was appropriate. It emphasised that "*effective, personalised care should include shared decision making with patients*" and the need for "*increased public and clinical awareness of other interventions*". Professor Paul Cosford, PHE Medical Director, emphasised the need to make sure people are helped to access alternative treatments.The President of the Royal College of GPs noted *" the severe lack of alternatives to drug therapies for many conditions"*. The Mindfulness Iniative has cited alternatives in the briefing paper The Mindfulness Initiative briefing paper on Mindfulness-based alternatives to long-term prescription drugs. These are needed now more urgently than ever.	Thank you for your comment. NICE has recently developed a rapid guideline on COVID-19: Management of the long-term effects of COVID-19 [NG188]. Recommendations in that guideline should be followed.
Mindfulness Initiative	Guideline	28	6	This adds to the importance of identifying alternatives to long -term use of the many medications identified as	Thank you for your comment. The committee agree that research into

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				problematic in the 2019 Public Health England Review of Dependence and Withdrawal Associated with some Prescribed Medicines. Structured mindfulness based programmes offer such an alternative and with lower risk of creating additional morbidity from treatment compared to pharmacological interventions.	interventions such as mindfulness that show some promising results may help inform future guidelines and enable positive recommendations in future if shown to be beneficial for chronic primary pain.
Mindfulness Initiative	Guideline	5	7	It's important to recall"" *The committee were aware that mindfulness is often used in clinical settings to help with symptoms associated with chronic pain, and that people are actively enquiring about it."* There is a social gradient in exposure to pain and to mental health problems, which also affect BAME and older populations more highly. The cost of accessing mindfulness programmes without NHS support disadvantages those on low incomes. Testimonials reveal patient value for the courses they can subscribe to including these cases of people experiencing Long COVID symptoms:: *"As a sporty 47 year old and former international triathlete, I have taken good health and abundant energy for granted. When illnesses have come, they have soon passed.* *So I have been shocked to still be suffering recurrent Covid symptoms of fatigue, body and head aches, mood swings and brain fog after four months. The Mindfulness for Health course has helped me to develop patient acceptance of my condition, as well as a new skill of mindful 'pacing' that is helping me to steadily return to work and life."*	Thank you for your comment. This review and recommendations for interventions for management are for chronic primary pain only, not for other conditions such as long COVID. The committee agreed there was not sufficient evidence to recommend mindfulness for chronic primary pain. This guideline is both for healthcare professionals and people with chronic pain, their families and carers. The committee therefore would not recommend that people pay for an intervention for which there is insufficient evidence to recommend at present for the management of chronic primary pain.

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				"Despite lifelong asthma and related health issues, I was unprepared for the long-term debilitating effects of contracting Covid-19. Ongoing fatigue, neurological issues such as confusion and "brain fog", head and body aches, as well as mood swings have all contributed to the challenges of life beyond the acute phase of illness. *Following the "Mindfulness for Health" course has helped me to develop life-changing new habits in two key areas: firstly, by working with awareness and pacing to begin changing my tendency to override physical exhaustion and discomfort; and secondly, by working with the led meditations to engage more fully, fearlessly and kindly with the anxiety and tension that ongoing ill health can bring."*	
Musculoskeletal Reform (MSKR)	Guidance and Evidence Review B	P004-005 and p013-014.	General	Communication - We liked that there was a strong emphasis on communication particularly in the first section of the guidance. We feel that the future research recommendations should explore optimum time for effective communication at initial and follow up appointments for patients with chronic pain to help direct future funding.	Thank you for your comment. Research recommendations can only be made on areas directly reviewed within a guideline. Although the committee comment on the length of appointments in the implementation of these recommendations, it was not a topic that was reviewed.
Musculoskeletal Reform (MSKR)	Guideline	P004-005	General	Assessment Tools- Why is there no mention of assessment tools such as the standardised use of a visual analogue scale (VAS) or a numerical rating scale (NRS) 0-10 scale as a baseline measure? It would be useful to	Thank you for your comment. Assessment tools were not highlighted as an area of uncertainty to focus on within the guideline during scoping.

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				include measures that help differentiate neuropathic pain such as the S-LANSS or pain detect, particularly if neuropathic medication is being recommended as a means of management. It would be useful to include the use of self-efficacy to understand how an individual with chronic pain is managing their symptoms and performing in daily life e.g. https://www.orthotoolkit.com/pseq/. These tools would allow a better understand of how much an individual is able to do in a quantifiable way. Pain does not have to be crippling to have an adverse effect on mental wellbeing and function, which is not addressed in the guidance. We believe the guidance should advocate that pain outcomes are used to help clinicians (and people with chronic pain themselves) understand if they are improving or not. Could there be a recommendation to use the VAS or NRS at certain time frames e.g. six weeks after starting an intervention?	The reviews consider the results from such tools (VAS and NRS) to inform the recommendations. The committee also were aware of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), which has undertaken a lot of research on outcome measures for pain.
Musculoskeletal Reform (MSKR)	Guidance	P007	General	Acupuncture- It appears that whilst there is evidence that acupuncture supports reducing chronic pain in the short term, the current guidance recommends it for a long-term problem. We feel this needs to be clarified and it explained that using short term solutions for long-term issues might not be the best way forward unless used as an adjunct e.g. to reduce pain enough to more effectively do rehabilitation exercise.	The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee

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					agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
Musculoskeletal Reform (MSKR)	Guidance	P009	Lines 012-017 and 021	Analgesia - The removal of paracetamol, gabapentinoids, opioids is radical. It is understood that these medications are best avoided where possible; however in certain circumstances if used diligently and over a short duration of time in conjunction with another therapy, they can be very helpful. This must be hard to read for people living with pain - there is not a lot left on the shelf for them with this guidance when it comes to medication, especially if they have tried the tricyclic medication without positive effect.	It is important to note the reviews for specific interventions included in this guideline, and relevant recommendations, are all for the chronic primary pain population only, rather than all types of pain. This included the recommendations for pharmacological management. Chronic pain already covered in

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			Lines 018-020 and 023	We believe this section should be written to discourage use for certain groups of people e.g. substance abuse, and provide guidance on suggested periods of use of the stronger medications if required. There is good evidence that the use of local anaesthetics and corticosteroids are effective for certain musculoskeletal conditions. It is of concern to us that this guidance is in contrast to the emerging and consistent evidence for use in this patient population. We urge you to reconsider this being on the 'do not use' list.	existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The committee agreed that the evidence reviewed in this guideline and their expert consensus opinion did not suggest that these medicines were beneficial for the majority of people with chronic primary pain, and there was evidence of long term harm for some of these, both from this

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					evidence review and from their experience.
Musculoskeletal Reform (MSKR)	Guidance and Evidence Review A	P012	Lines 010-011	BMI -There is no mention of any association between chronic pain and BMI. It appears that only one study in those evaluated BMI as a possible confounder. The current evidence seems conflicting in this area. We suggest that BMI is included as an area for future research as potentially this group of patients could need support with their nutritional needs alongside their physical, mental and social requirements. We recommend that BMI is included specifically in the Guidance document in lines 10-11 and lines 22-23.	Thank you for your comment. The committee recommended that further research was required on factors that may impact on the management of chronic pain and therefore help stratify treatment. The research recommendation does not define the specific factors that should be researched and therefore BMI isn't explicitly excluded.
Musculoskeletal Reform (MSKR)	Guidance and Evidence Review A	P012	Lines 010-011	Social Risk Factors- We were unable to find anything in the guidance to support or refute social factors as causing a risk of developing or preventing recovery from chronic pain. We are particularly interested in any associations between poor diet and alcohol as key components and suggest that these are considered areas for future research. We recommend that alcohol intake is included specifically in the Guidance document in lines 10-11 and alcohol reduction therapy/advice in lines 22-23.	Thank you for your comment. No evidence was identified for social risk factors that was specific to the review protocol. The committee agree that further research is required.
Musculoskeletal Reform (MSKR)	Guideline	General	General	Conflicts of Interests- We are concerned by some of the potential conflicts of interests within the development group and how they have been mitigated – this is particularly evident with regard to acupuncture recommendations.	Thank you for your comment. The NICE conflict of interests policy was followed throughout development of this guideline. All committee members

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					abided by this policy and declarations were included on a register and reviewed in accordance with the policy. The declaration of interests register is publicly available with the guideline documents and states what action was taken for each declaration. The minutes of each meeting state where committee members withdrew from discussions. In relation to acupuncture, the committee member with a specific conflict of interest for this topic withdrew from all decision making relating to this topic. This is detailed in the declaration of interest register and the relevant meeting minutes.
Musculoskeletal Reform (MSKR)	Guideline	General	General	Inconsistency in threshold for recommendations- The threshold for recommendations does not appear to be consistent e.g. pain education is not recommended, yet the weight of the evidence is similar to that for CBT/ACTwhich are recommended. Reviewing this prior to full guidance will be important, as there appears to be a discrepancy that could have significant implications for practice.	Thank you for your comment. We do not agree that thresholds for recommendations have been applied inconsistently. The committee were very mindful of comparing levels of evidence across all of the reviews to ensure that decision making was consistent. In the case of pain

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					education for example, no difference was observed for quality of life or psychological distress in the short or long term. There was 1 relatively small study suggesting benefit for pain reduction. All evidence was of low or very low quality. For CBT for pain however there was evidence for improvement in quality of life in both the short and long term, from 8 studies in the short term. There was very mixed evidence for pain reduction, but one study suggesting benefit in function in the short and long term. No difference was observed in psychological distress. For ACT benefit was observed in the short and long term for quality of life, pain and psychological distress. The evidence was again low to very low quality, but the body of evidence was larger and more favourable than for pain education and there was also evidence of cost effectiveness.

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MyPain Ltd	General	General	General	There is evidence for benefit of digital therapeutics in delivery of pain services but there is no representation of digital therapeutics experts on NICE. This may be the reason for lack of recommendation or comments for such services and the role they are likely to play in helping people self-manage chronic pain with clinical support as needed.	Thank you for your comment. Digital therapeutics were not highlighted as a key area for the guideline to include during scoping.
MyPain Ltd	Guideline	004	2.1.1	The assessment may be challenging if done remotely. The use of digital technology to capture lived pain experiences and share them with a multidisciplinary team can be helpful by using appropriately technology for remote monitoring and support.	Thank you for your comment. Digital technology was not specifically reviewed within the guideline and therefore no comments are included on that.
MyPain Ltd	Guideline	007	1.3.3	As there are several randomised controlled trials and meta-analysis already available for the efficacy of online pain management programme or using technology to help people self-manage their pain, It may be helpful to recommend rapid technology appraisal by NICE, especially in view of recommendations on rapid roll out of routine services due to COVID restrictions, published in IASP journal Pain in May 2020. No guidance from NICE in this matter will leave several patients and healthcare providers without any support to manage already challenging life situations and is likely to significantly affect their ability to cope as they are may go into crisis with deteriorating mental health and the social impact.	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain with considerations of where evidence demonstrates interventions are clinically and cost effective.

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					Implementation of these should take the current context into account.
MyPain Ltd	General	General	General	COVID – 19 is likely to further increase the demand for pain management due to chronic fatigue and long-termmusculoskeletal rehabilitation they the more severely affected patients seems to need. A digital solution, used within clinical governance to deliver high-quality long-term support, while providing value for care and resources is essential.	Thank you for your comment. NICE is currently developing a guideline on COVID-19 guideline: management of the long-term effects of COVID-19. When available, recommendations in that guideline should be followed. Your comment will also be considered by NICE where relevant support activity is being planned.
MyPain Ltd	Guideline	007	1.3.3	Delivering ACT / CBT in chronic pain in a traditional way is a challenge limited by resources (clinical psychologists with pain experience and expertise). NHS Scotland has already recognised the need for role of technology and digital therapeutics in such services (Psychology / CBT) and the inability for them to be delivered within a traditional model. Hence, digital innovation challenge has been organised to solve this problem. NICE also recommending such an approach in guidelines will help foster innovation in this field.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and

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					those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Napp Pharmaceuticals	Guideline	24	25	We agree with the recommendation of NICE on the pharmacological management of chronic primarypain in general and the use of opioids in particular, which states there is no evidence for the effectiveness of opioids in patients with chronic primarypain. However, we think it is important to clarify that published guidelines* support the use of opioids for chronic secondarypain (caused by diseases such as osteoarthritis, spondyloarthritis etc.) in appropriately selected patients and with appropriate diagnosis, monitoring and as part of a holistic management approach. Without this clarification, we fear that the NICE document may be subject to misunderstandings and misinterpretation as we have seen in some articles that appeared in the media immediately following the publication of the draft guideline, and may cause inappropriate termination of the use of opioid medicines in some patients. * O'Brien T, Christrup L, Drewes A et al. European Pain Federation position paper on appropriate opioid use in chronic pain management. Eur J Pain. 2017 Jan;21(1):3-19.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.

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				* Scottish Intercollegiate Guidelines Network. SIGN 136 Management of chronic pain. Dec 2013 * CDC Guideline for Prescribing Opioids for Chronic Pain, MMWR Recomm Rep 2016;65	
National Axial Spondyloarthritis Society (NASS)	Guideline	004	002	Other related guidance for diagnosis of specific conditions should be referenced	Thank you for your comment. This list links to the other NICE guidelines that are most relevant and is not intended to be an exhaustive list.
National Axial Spondyloarthritis Society (NASS)	Guideline	006	002	It is surprising that pain clinics are not given recognition as a valuable resource. Many of the treatments and techniques referred to later in the guidance would be introduced to a patient by a pain clinic if they have not responded to conventional treatment.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain

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					management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which

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					were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline.
National Axial Spondyloarthritis Society (NASS)	Guideline	006	009	The role of occupational therapy has been omitted from non-pharmacological management.	Thank you for your comment. Occupational therapy was not prioritised as an intervention to review when the non-pharmacological review questions were agreed in scoping or in the protocol setting.
National Axial Spondyloarthritis Society (NASS)	Guideline	006	009	Hydrotherapy should be considered as an adjunct treatment in particular for those who are unable to cope with the physical impact of land based exercise or exercising in cold water.	Thank you for your comment. The committee agreed that the type of exercise that would be most appropriate was likely to depend on the type of chronic primary pain and individual abilities and preferences and therefore recommended that people's needs, preferences and

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					abilities should be taken into account when determining this.
National Axial Spondyloarthritis Society (NASS)	Guideline	006	015	Managing chronic pain with exercise can be impossible without significant pharmacological pain relief	Thank you for your comment. The evidence review and expert consensus opinion of the committee did not support the effectiveness of the majority of pharmacological treatment options for management of chronic primary pain. The exercise recommendation and rationale highlights the need for the exercise offered to be tailored to the needs and abilities of the individual to ensure it is delivered at an acceptable level for the person.
National Axial Spondyloarthritis Society (NASS)	Guideline	008	004	We are concerned that the omission of use of TENS machines as a recommendation might be taken across the board as meaning that they are not effective for any form of chronic pain.	Thank you for your comment. The committee agree it is important that there is clarity in the guideline as to which population the recommendations apply. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order

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					to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
National Axial Spondyloarthritis Society (NASS)	Guideline	011	003	The inclusion of chronic primary musculoskeletal pain confuses the issue.	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development, this includes chronic primary musculoskeletal pain.
National Axial Spondyloarthritis Society (NASS)	Guideline	022	029	There appears to be little consideration for quality of life in this recommendation.	Thank you for your comment. Quality of life was considered as a critical outcome in all reviews within the guideline. There was limited evidence of some benefit for quality of life, but this wasn't consistent and was from small sample sizes. This contributed to the decision to recommend further

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					research for manual therapies for chronic primary pain.
National Axial Spondyloarthritis Society (NASS)	Guideline	General	General	The document is not clear from the outset how it relates to other guidelines. Currently it states that they should be used 'alongside' other guidance but it is unclear how this would work in practice. It is a concern that a GP with lesser knowledge of specific conditions such as axial spondyloarthritis (axial SpA) wouldn't understand the complexities of the condition and may not see their axial SpA being the primary cause for their pain. For example, someone with fusion in their neck may experience severe nerve pain as a result of bone growth but may no longer be suffering pain as a direct result of their axial SpA. Would the GP then consider their nerve pain chronic primary pain? If so how would this be treated? We have already seen fall out from this, with patients reporting that they have had their naproxen stopped by their GP, despite the fact that NSAIDs are a recognised treatment for axial SpA as per NG65.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. Further clarification has been provided with a visual summary to accompany the guideline indicating what populations

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					are covered by each recommendation topic. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
National Axial Spondyloarthritis Society (NASS)	Guideline	General	General	Additionally it is unclear how this guidance should be used if the patient with, say a diagnosis of axial SpA (AS) develops a complication or progression which cannot be treated solely within the NICE guidance for that condition. Going back to the example of a axial SpA (AS) patient developing nerve pain as a result of their axial SpA (AS), would the GP or rheumatologist be able to prescribe nerve pain medication aside from amitriptyline. Many patients do well on the therapies recommended in the guidance but need additional treatments to manage these complications.	Thank you for your comment. We are unable to comment on management of conditions outside the scope of this guideline. Clinical judgement should be used to determine the appropriate management, according to the relevant guidelines, when presentation changes.
National Axial Spondyloarthritis Society (NASS)	Guideline	General	General	A general feeling from the guidance is that quality of life is not taken into consideration with many of the interventions, seeing short term benefits as irrelevant when quite often those short bursts of being pain free are very important to someone with chronic pain. The only short term treatment is acupuncture which features heavily in the guideline despite evidence for 3 months or less benefit? How can this be explained where many other interventions (TENS machines, hydrotherapy, mindfulness, manual therapy) have been completely disregarded?	Thank you for your comment. Health related quality of life was considered as an outcome for all review questions and was agreed by the committee to be critical to decision making. This is detailed in the protocols and the discussion of evidence sections of each review. The recommendations are based on reviews of the available evidence, and

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					only recommend those demonstrated to be clinically and cost effective. There was a substantial amount of evidence supporting the use of acupuncture for chronic primary pain. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The majority of evidence reviewed within the guideline was based on studies of relatively short courses of treatment given the long term nature of this chronic condition. In the absence of evidence for long term use for these interventions the committee

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					believed it appropriate to recommend those where there was evidence of benefit. For acupuncture a research recommendation has been made for repeat courses of acupuncture to inform future updates of this guideline. The committee agreed there was insufficient evidence of even short terms effectiveness for the other interventions mentioned in the comment. The committee made research recommendations for both mindfulness and manual therapy as there was an indication that there may be some benefit, but further research was needed. Hydrotherapy would have been included in the exercise review where evidence was available that met the review protocol. For TENS the committee agreed the limited evidence demonstrating no difference with sham or usual care for the majority of outcomes was insufficient to recommend this for use within the NHS for chronic primary pain.

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National Axial Spondyloarthritis Society (NASS)	Guideline	General	General	The use of the terms 'chronic pain' and 'chronic primary pain' is confusing. From the outset it should be clear that this is for chronic primary pain which is only defined part way through.	The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Neuromodulation Society of UK & Ireland	Guideline	055	017	Even though the introduction says that this guidance should be used alongside NICE guidance for specific conditions that cause pain, including headaches, low back pain and sciatica, rheumatoid arthritis, osteoarthritis, spondyloarthritis, endometriosis and irritable bowel syndrome, we are concerned that this recommendation	Thank you for your comment. We agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where

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				has significant potential that it may be misinterpreted by commissioners. Often chronic primary pain and secondary pain disorders co-exist. As a result, patients suffering from all types of pain would be treated as chronic primary pain and denied timely, effective and evidence based treatments.	appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. A recommendation has been added to highlight this and to clarify that the appropriate NICE guideline should be followed in these circumstances.
Neuromodulation Society of UK & Ireland	Guideline	007	008	Following previous NICE guidance on various pain conditions, acupuncture or dry needling, within a traditional Chinese or Western acupuncture system was considered as ineffective for most of the conditions except headache. All around the Country Acupuncture services has been decommissioned. The pain clinics /	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that

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				primary care settings do not have capacity or experts to deliver it.	may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Neuromodulation Society of UK & Ireland	Guideline	015-018	009	The recommendations for not using gabapentinoids and local anaesthetics by any route in patients suffering from Complex Regional Pain Syndrome contradicts UK guidelines for diagnosis, referral and management in primary and secondary care issued by Royal College of Physicians in 2018. Including CRPS in the draft guidelines and denying patients with any kind of treatments included in RCP guidance will significantly affect patients' rehabilitation, functional improvement and chances of recovery from this dreadful condition.	Thank you for your comment. The methods used to develop these guidelines differ from those used to develop the Royal College of Physicians guideline. The NICE guideline methods are set out in Developing NICE guidelines: The manual. These differing methods have led to different conclusions in the guidelines. We believe the current NICE guideline is based on robust methodology. The recommendations for chronic primary pain included here do apply to CRPS and do also include

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					specific research recommendations for this population for use of gabapentinoids and local anaesthetics.
Neuromodulation Society of UK & Ireland	Rationale	020-023	025	The committee says that complex regional pain syndrome (CRPS) is sometimes understood as a neuropathic pain disorder. CRPS is a neuropathic pain disorder. It should be under neuropathic pain in the secondary section	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised, but it is their view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there was no reason not to consider this with other types of chronic primary pain.

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Neuromodulation Society of UK & Ireland	Guideline & Evidence	General		CRPS at its core has 100% organic origins, even though imperfectly understood. Although having chronic pain in the ICD 11 is clearly a step forward, the writers of ICD11 have got it wrong in putting CRPS in the chronic primary pain category. We do have class 1 evidence of efficacy of spinal cord stimulation and dorsal root ganglion stimulation, as often the only effective treatments. There are numerous clinical trials published proving superior pain relief, patient satisfaction, improved function, quality of life and cost-effectiveness of this intervention in CRPS. The draft guidelines have completely ignored this evidence. We think this will put patients at risk. 1. Mekhail N, Deer TR, Kramer J, Poree L, Amirdelfan K, Grigsby E, Staats P, Burton AW, Burgher AH, Scowcroft J, Golovac S. Paresthesia-Free Dorsal Root Ganglion Stimulation: An ACCURATE Study Sub-Analysis. Neuromodulation: Technology at the Neural Interface. 2020 Feb;23(2):185-95. 2. Deer TR, Levy RM, Kramer J, Poree L, Amirdelfan K, Grigsby E, Staats P, Burton AW, Burgher AH, Obray J, Scowcroft J. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. 2017 Apr;158(4):669.	Thank you for your comment. Spinal cord stimulation and dorsal root ganglion were not prioritised as interventions to consider when setting the protocol. The committee considered that they are not widely used for chronic primary pain.

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				3. Kriek N, Groeneweg JG, Stronks DL, De Ridder D, Huygen FJ. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: a multicentre, double-blind, randomized and placebo-controlled crossover trial. European Journal of Pain. 2017 Mar;21(3):507-19. 4. Kemler et al. The Cost-Effectiveness of Spinal Cord Stimulation for Complex Regional Pain Syndrome. Value in Health 2010; 13(6):735-742 5. Kemler MA, de Vet PhD HC, Barendse GA, Van Den Wildenberg FA, Maarten van Kleef MD. Spinal cord stimulation for chronic reflex sympathetic dystrophy-five-year follow-up. The New England Journal of Medicine. 2006 Jun 1;354(22):2394. 6. Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol. 2004;55(1):13-18.	

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				7. Kemler MA, Barendse GAM, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med. 2000;343(9):618-624.	
Nevro Corp.	Guideline	001	007	"Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin" and "Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain" should be included in the list of NICE guidance this one should be used alongside also. Rationale: Based on HES data April 2017 to April 2019 a total of 2,732 new SCS devices (OPCS A483) and 315 replacements (OPSC A484 with Y032) FAEs been conducted in total. All patients eligible for SCS are also covered by this guidance on chronic pain: assessment and management	Thank you for your comment. This list links to the other NICE guidelines that are most relevant and is not intended to be an exhaustive list. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline (including neuropathic pain) was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic.

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Nevro Corp.	Guideline	005	020	We suggest adding a new sentence: "For guidance on the treatment of chronic pain with spinal cord stimulation see the NICE guidelines "Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin" and "Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain" Rationale: Based on HES data April 2017 to April 2019 a total of 2,732 new SCS devices (OPCS A483) and 315 replacements (OPSC A484 with Y032) FAEs been conducted in total. All patients eligible for SCS are also covered by this guidance on chronic pain: assessment and management	Thank you for your comment. This list links to the other NICE guidelines that are most relevant and is not intended to be an exhaustive list. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline (including neuropathic pain) was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic.
Nevro Corp.	Guideline	General	General	Chronic Pain guidelines are aimed at managing chronic pain in people aged 16 years and over. However, certain important - minimally invasive, reversible - therapies such as SCS have not been included. Spinal cord stimulation (SCS) is an important treatment alternative to	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain.

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				conventional medical management only, and it is also covered by two NICE guidelines: TA159 MTG41 We do not see a rationale for excluding invasive therapy options for the management of chronic pain in this guidance. We argue that spinal cord stimulation should be included in the evidence review and recommendations as an additional chapter: "Evidence review K – Spinal Cord Stimulation" Rationale: There is a significant overlap of the patient population described in the guidance and the existing NICE guidance on SCS (TA159 and MTG41). Not including a therapy that is based on HES data and is conducted over 1,500 times annually in the NHS* would prevent the publication from providing a complete picture of management alternatives and treatment options. This would limit healthcare professionals' ability to give the best advice possible. Since these proposed guidelines purport to give comprehensive advice on the treatment of all chronic pain conditions, it would not be fully representative of all	Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The population that spinal cord stimulation is recommended for in TA159 and MTG41 is therefore out of the scope for management recommendations within this guideline.

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				the major choices available to a practitioner if SCS were to be omitted. The fact that two guidelines covering this therapeutic area have been published, each with positive findings for the therapy, supports the argument that SCS be given a significant mention in any review of the overall field of chronic pain. *Based on HES data April 2017 to April 2019 a total of 2.732 new SCS devices (OPCS A483) and 315 replacements (OPSC A484 with Y032) FAEs have been conducted in total.	
NHS Bury CCG	Guideline	004	012	This recommendation will be a challenging change in practice particularly due to COVID as the digital approach and lack of face to face contact with services will impeded building patient relationships or the opportunity for peer support	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain with considerations of where evidence demonstrates interventions are clinically and cost effective.

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					Implementation of these should take the current context into account.
NHS Bury CCG	Guideline	006	008	We are concerned about the limited availability of services providing exercise programs, ACT, CBT, acupuncture and Inequalities in provision	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS Bury CCG	Guideline	007	007	Acupuncture has a weak-evidence base for treatment of chronic pain and commissioning acupuncture is therefore against usual policies for alternative treatments	Thank you for your comment. This evidence review was for the chronic primary pain population only, rather than all types of pain. Chronic pain

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					already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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					that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS Bury CCG	Guideline	007	008	Acupuncture for a short course – concerned this does not fit with long-term management, repeat courses are not to be offered. Experience has shown this is passive treatment and does not align with a self-management approach like other treatment options.	Thank you for your comment. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations, The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care.

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					In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
NHS Bury CCG	Guideline	008	013	We would agree with this recommendation, reduced opiate and other medication use particularly section 1.3.11	Thank you for your comment.
NHS Bury CCG	Guideline	008	013	We are concerned of the implications of increasing widespread antidepressant use off label.	Thank you for your comment. The committee agreed that antidepressants were the only medicine where consistent benefits were observed for chronic primary pain that were sufficient to inform the recommendation. They did agree there are some side effects and harms that should be considered. This recommendation was written as 'consider antidepressants…' rather than a stronger 'offer' recommendation reflecting the

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					variability in the quality of evidence and also the potential harms. They recommend that a decision to take antidepressants is based on a full discussion of the benefits and harms.
NHS Bury CCG	Guideline	008	014	We are concerned that this recommendation does not suggest an alternative for patients who are C/I or cannot tolerate suggested pharmacological treatment e.g. class reaction	Thank you for your comment. No evidence was available to specifically recommend trying a different drug within the class (based on differing side effect profiles) if one is not tolerated, but the committee discussed that the recommendation does not preclude this. The recommendation does state that there should be a full discussion about risks and benefits before deciding to use antidepressants. If they are contraindicated, other options in the guideline should be considered instead.
NHS Bury CCG	Guideline	008	014	We are concerned that there is very limited evidence to support use of antidepressants, only applicable to fibromyalgia in women and translating that evidence to the general population feels a step to far.	Thank you for your comment. Whilst it is true that a number of studies included in the review were in women with fibromyalgia, the evidence for antidepressants included other

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					chronic primary pain populations such as chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Heterogeneity was not observed between types of chronic primary pain, so the committee agreed it provided no evidence against making this recommendation to be for all people with chronic primary pain.
NHS Bury CCG	Guideline	008	014	We are concerned there appears to be no evidence of the review of dependence and safety of long-term use of antidepressants been considered. We are concerned that this recommendation in practice will in many cases substitute long-term opiate use with long-term antidepressant use.	Thank you for your comment. The long term safety of antidepressants was not prioritised as a review to include when setting the protocol for this guideline. The committee were aware that the update of the depression guideline is ongoing and that there are harms listed in the BNF and relevant summary of product characteristics that would inform their decision making. They recommend that any decision to use antidepressants should be based on a full discussion of the benefits and harms.

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NHS Bury CCG	Guideline	009	010	This recommendation will be a challenging in practice and felt unrealistic with lack of resources to fund non pharmacological treatments.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS Bury CCG	Guideline	General	General	This guideline will be a challenging change in practice because of capacity for non-drug interventions and the historic commissioning and approach to chronic pain. These would need some time to evaluate and commission, would need additional funding and put increased pressure on existing services given expected demand.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that

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					may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS Bury CCG	Guideline	General	General	We are concerned about the public's understanding and perception of chronic pain, as such implementation of this guideline would benefit from being staggered or extended so the right services can be commissioned to support patients who will be significantly impacted by this change.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This

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					guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. The committee also agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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					clarifying what populations are covered by each recommendation.
NHS Bury CCG	Guideline	General	General	This guideline will be a challenging change in practice in the proposed time scales as health professionals do not have the confidence and experience of treating chronic pain in this manner. Although we agree with a reduction in treatment with pharmacological therapy, there is a need for an education program for health professionals.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS Bury CCG	Guideline	General	General	This guideline will be a challenging change in practice because there is veryy little practical advice about what can be achieved in a GP consultation meaning that the majority of patients are going to need to be referred on to another service.	Thank you for your comment. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most

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					people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. Delivery of some of the interventions recommended may require referral to another service.
NHS Bury CCG	Guideline	General	General	This guideline will be a challenging change in practice as the provision and quality of exercise programmes available varies considerably even within one CCG and although there has been investment in CBT in recent years this is aimed more at depression and anxiety rather than chronic pain. Access to acupuncture is limited.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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					that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS Bury CCG	Guideline	General	General	This guideline will be a challenging change in practice the only medicines advised are off label, no analgesia is recommended but this ignores completely the fact that chronic conditions develop over time and the patient will inevitably have tried some analgesia before being defined as having a chronic pain syndrome. The patient's journey started long before the place the guidelines do, and these don't address that problem. Research recommendations in the guideline are therefore not practical.	Thank you for your comment. There are no medicines licensed specifically for chronic primary pain in the UK. The committee are aware that antidepressants are used off license for this condition, the committee agree that their use of licence for pain is well established in clinical practice and the evidence demonstrates that they may be of benefit for the symptoms of chronic primary pain. The committee do acknowledge that people are likely to have tried treatments previously, and consider that this should be part of the holistic assessment and their experience

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					factored in when making a shared care and support plan. The committee wrote research recommendations where evidence suggested a potential for them to be of benefit, but was insufficient to inform a recommendation. The committee agree research in these areas would be useful to inform future updates of the guideline.
NHS Bury CCG	Guideline	General	General	This guideline will be a challenging change in practice as it will almost certainly lead to most chronic pain clinics having to redesign as they tend to focus on pharmacological management, which is difficult in the time scales and experience of this change.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement	Guideline	005	015	Suggest a greater emphasis on how to sensitively convey information regarding negative or normal test results-this can often impact greatly on a patient's psychological response and they feel they are being told it is 'all in their head' and this can impact of long term recovery - is there a training that NICE can recommend? Also please note this information is usually given by reception staff as these are 'normal' results - the GP will check and sign them off as normal and then patient calls and gets result from receptionist. (AMH)	Thank you for your comment. The committee agree this is important to highlight in the recommendation. It is beyond the remit of NICE guidelines to recommend training, but the committee hope that the inclusion of these recommendations will highlight the importance of factors such as this in the assessment of people with chronic pain.
NHS England and NHS Improvement	Guideline	001, 005, 014		When referring to "a care plan" we would prefer the term "personalised care and support plan" in line with Universal Personalised Care: Implementing the Comprehensive Model. This reflects a personalised conversation rather than a standardised clinical management approach. (RP)	Thank you for your comment. This has been amended to a 'care and support plan'.
NHS England and NHS Improvement	Guideline	Page 008/ 009	1.3.8	"after a full discussion of the benefits and risks" – suggest also including discussion of alternative options to ensure a rounded shared decision making conversation. (RP)	Thank you for your comment. A recommendation to discuss all of the available treatment options is included in section 1.1 when developing a care and support plan.

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NHS England and NHS Improvement	Evidence Review C	General	General	The interventions are termed here under the heading of 'pain management programmes' does not truly reflect the approach and ethos of supported self-management and personalised care. Individuals should be offered interventions based on a discussion of their needs, what's important to them in managing their health and wellbeing, and their current level of knowledge, skills and confidence to manage their condition. There is evidence that has not been included in the review 1. Devan, Hemakumar; Hale, Leigh; Hempel, Dagmar; Saipe, Barbara; Perry, Meredith A., What Works and Does Not Work in a Self-Management Intervention for People With Chronic Pain? Qualitative Systematic Review and Meta-Synthesis., Physical Therapy; May 2018; vol. 98 (no. 5); p. 381-397 - https://doi.org/10.1093/ptj/pzy029 "For self-management interventions to positively influence the lives of people with chronic pain, fostering self-discovery was crucial to facilitating acceptance and improved self-efficacy. However, the sustained efforts to self-manage pain after the intervention can be exhausting and were perceived as a constant struggle. Providing intermittent support in the form of booster sessions and peer support groups may be important. Clinicians	Thank you for your comment. The committee agree that the assessment of an individual's needs, to inform a shared decision of the interventions suitable should be based on a discussion with the person and a full holistic assessment. This is detailed in the recommendations in section 1.1 of the guideline. The references provided have been checked. Both of these are reviews of qualitative studies. Whilst we note that qualitative evidence is of value for certain reviews, it was not included as a relevant study type in this review of pain management programme interventions.

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				involved in the management of chronic pain need to be cognizant of the importance of person-centeredness by means of shared decision making and guided problem solving to facilitate ongoing self-management." 2. Matthias, Marianne S.; Kukla, Marina; Bair, Matthew J.; McGuire, Alan B., How Do Patients with Chronic Pain Benefit from a Peer-Supported Pain Self-Management Intervention? A Qualitative Investigation., Pain Medicine; Dec 2016; vol. 17 (no. 12); p. 2247-2255 - https://doi.org/10.1093/pm/pnw138 "Peer support represents a promising approach to chronic pain management that merits further study. The current study helps to identify intervention elements perceived by participants to be important in achieving positive results. Understanding how peer support may benefit patients is essential to optimize the effectiveness of peer supportinterventions and increase the implementation potential of peer-supported pain self-management into clinical practice." (RP)	
NHS England and NHS Improvement	General			it seems an odd review. I note the exclusions at the start eg low back pain, one of the commonest problems is excluded (MA)	Thank you for your comment. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the

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					headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
NHS England and NHS Improvement	27	013 & 014		p27 13&14. I cannot believe that 8.7 to 64% of the UK have chronic pain (wide figures of evidence) with one third to half of the population having a prevalence of chronic pain ...but half the population do not have pain for 3 m impacting significantly on their QL (MA)	Thank you for your comment. The context section has been edited. The committee acknowledge that there is uncertainty about the prevalence of chronic pain, but provide estimates.
NHS England and NHS Improvement	General			while I appreciate we do not wish to fuel the opiate pandemic, cf USA, some folks need treatment. to say paracetamol and other analgesics do not work does not work seems odd unless they are thinking of the pain group of chronic regional pain / fibromyalgia group. I agree with the statements under those circumstances but that is not half the population (MA)	Thank you for your comment. The pharmacological therapies review and recommendations are only for chronic primary pain. This is true of all reviews for specific interventions included in this guideline. Chronic pain already covered in existing NICE guideline was

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					also excluded from the specific intervention reviews. This is detailed in the scope, but the committee agree it needed to be clearer in the guideline. Further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
NHS England and NHS Improvement	General			appears disagreement within the committee and the requests for more research seem a little excessive, but that may relate to the poorly defined group they are referring too (MA)	Thank you for your comment. The recommendations made represent all of the committee's views. Their debate and consideration of the evidence is detailed in the discussions of each review chapter. The research recommendations reflect areas where potential benefit was observed but

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					was insufficient to inform a recommendation.
NHS England and NHS Improvement	Guideline	004	001.1	I agree with the recommendations in the section as a whole. However it seems odd that there is not an initial line that states that practitioners should complete clinical (i.e. physical assessments) that rule out diagnoses such as those described in section 1.2 that could be causing the pain and supplement the assessment with the elements in the recommendation? The recommendations here are about non-physical,quality of life questions which are valid but alone do not provide a holistic approach? (DF)	Thank you for your comment. The assessment recommendations have been edited to add when to consider a diagnosis of chronic primary pain, including that this is when there is no clear underlying cause or that the pain or its impact is out of proportion to any observable injury or disease. The overview page for the guideline states that this should be used alongside existing condition specific NICE guidelines. These guidelines include recommendations for diagnosis of these conditions. The context section also includes a statement that chronic primary pain should be diagnosed only when there are no underlying causes for the pain. These recommendations have now been edited to more clearly reflect a holistic approach.

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NHS England and NHS Improvement	Guideline	004	010	Shared Decision Making P4 line 10 of the Draft Guideline refers to 'shared decision making,' Shared decision making regarding tapering/stopping some analgesic medication (e.g. opioid or gabapentinoid) may be initially difficult or not possible for patients who have complex issues including those that have led to addiction or circumstances that have resulted in persisting distress. (DF)	Thank you for your comment. The committee agree these discussions may be challenging for some people. They highlight the upcoming guideline on safe prescribing and withdrawal management which will include guidance on such topics.
NHS England and NHS Improvement	Guideline	004-005	018-003	Family, carers and significant others P4 line 18 and p5 line 3 of the Draft Guidelines refers to 'family, carers and significant others' and their 'expectations about the pain' and 'quality of life.' It will be important to include contextualisation and acknowledge complexity in the guidelines e.g. • some people whose pain and disability brings about secondary gain by being attended to by family, carers or • some people whose perpetuation of pain/painful condition brings in financial recompense e.g. litigation, benefit/allowance due to inability to work • family, carers may have caused the pain/persistence of pain due to negative psychological impact during childhood/adulthood • people whose quality of life is poor e.g. in prison which will contribute to their pain experience	Thank you for your comment. The committee understand the important issues raised. However they believe it is still important to discuss these with the person being mindful of issues such as these which may arise from these discussions. A bullet has also been added to highlight that current or past history of substance misuse is also an aspect that might be included in these discussions.

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				• poor mental health influencing physical pain experience (DF)	
NHS England and NHS Improvement	Guideline	006-008	001.3	The implementation of these recommendations requires complete transformation of chronic pain care in all sectors of practice. The services described will require new services to be commissioned, funded and accessed by patients consistently wherever they live. In HJ delivering these services will need development with HMP Prison Service, Home Office (for IRCs) and the Youth Custody Service (YCS) as the non-pharmacological services will have to be delivered as part of the custodial regime and access to exercise facilities (which are currently limited). Any developments in HJ settings would need accessin the community across England to enable effective continuity of care- otherwise the HJ service is pointless. (DF)	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement	Guideline	007	1.3.5.	In HJ commissioned services acupuncture services are not usually provided. .In terms of equivalence this will require a service development and investment to deliver. As with other non-pharmacological services continuity of	Thank you for your comment. Access to services (also raised generally for

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				care will be critical for a successful pathway for released detainees. This treatment would need acceptance of benefit by patients before it can really replace pharmacological options. (DF)	non-pharma recommendations, so this response is used for other topics) The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement		008	008-011	Manual Therapy P8 line 8-11 of the Draft Guideline recommends this as an area for future research. In addition to recommending further research into the specific types of manual therapy it would be useful to make comment about the	Thank you for your comment. The committee note that would be an interesting area for research, however research recommendations included in the guideline can only focus on

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				psychological evidence of the importance of touch and the potential benefits of physical contact/need for further research (with reference to development, childhood brain, trauma, ACEs, including the potential for risk factors and modification through touch in complex pain) (DF)	specific topics that have been included as part of the evidence reviews.
NHS England and NHS Improvement	Guideline	008-009	014 - 002	Trial of Antidepressant P8 line 14 to P9 line 2 of the Draft Guideline recommendation 1.3.8. It would be helpful to suggest 'trial of antidepressant' and give framework for timing of trial of treatment and when/how to stop if not resulting in improvement in pain. Also, other 2nd, 3rd line options. It will be important for secure environments to facilitate an integrated healthcare/prison approach to the regime to allow for rapid access physiotherapy, regular exercise opportunities and to commission non-pharmacological support activities to support pain management including acupuncture and psychological support for people, particularly those who have dependence on prescribed and non-prescribed drugs. It would be helpfulto take into account the NHSE National Prison Pain Formulary and the reasons behind the recommendations. (DF)	Thank you for your comment. The committee have included in the rationale that the initial efficacy of antidepressants should be reviewed after 4-6 weeks. The guideline also cross refers to the NICE guidelines on Medicines optimisation and Medicines adherence for guidance on medicines review. Evidence reviewed in this guideline did not inform recommendations for sequencing. A recommendation is included to link to the depression guideline for stopping or reducing antidepressants; NICE guideline on depression in adults. There are areas that may need support and investment, to implement some recommendations in the guideline, including in different settings. However, this will ensure

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					that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement	Guideline	008-010	1.3.8-1.3.14	I agree with the recommendations but the implementation of them in HJ will be challenging. The approach to managing chronic pain requires a complete transformation of the current care pathway and patient and clinician-held beliefs. In HJ practices where clinicians succeed in reducing and stopping the medicines listed in section 1.3.11, this is investment in care is often reversed on release into the community or after an internal HJ transfer. The NHS DFM programme resulting from the PHE review + the expected NICE guidance may help drive some change. However, without effective mechanisms to change the attitudes and beliefs about effective treatments for chronic pain in the public and clinical personnel + investment in pathways to change treatments without harm and in full partnership with the patient + consultation times that provide the space needed for effective decision-making, there is a risk that	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in

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				these aspirational recommendations will remain un-delivered. That said, if there is a successful programme of change where services are re-modelled to deliver the reduction in prescribed medicines and access to alternative, effective treatment, then HJ commissioners, providers and patients will support this along with our primary care colleagues. (DF)	other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement	Guideline	014	011-013	Structuring patient expectations p14 line 11-13: 'relevant management options should be considered at all stages of care, including first contact' it would be helpful to make comment/provide advice about structuring expectations of pain management and self-management when pain is acute ie acute injury/acute pain onset and before pain becomes persistent. Most 'problems' with analgesia in chronic pain are due to 'inherited' prescriptions. It is very easy for clinicians in A+E or on post-operative wards in hospital to commence analgesia without consideration for those who will be required to 'de-prescribe' often weeks, months or even years down the line. (DF)	Thank you for your comment. Acute pain was outside the scope of this guideline. A recommendation has been included for review of people who are already taking the medicines included in the guideline however.
NHS England and NHS Improvement	Guideline	024 026	004-005	Benzodiazepines, paracetamol and NSAIDs for chronic primary pain	Thank you for your comment. As per our response to your comment number 916. These recommendations

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			003-011	P24 line 4-5, line 26, p26 line 3-11: recommends there is limited evidence for the effectiveness of these medications for chronic pain. Whilst the risks of dependence with long-term benzodiapines are clear, and long term use of NSAIDs can cause GI and cardiovascular effects, without NSAIDs or paracetamol, the prescriber is left with very few pharmacological options which may risk the therapeutic relationship with the patient. Is there no evidence for short term use of NSAID/paracetamol/(benzodiazepine) in acute exacerbation of chronic condition e.g. low back pain exacerbation within limited time frame? Would it be possible to recommend structuring expectations for short trial of simple analgesia in acute exacerbations of a chronic pain condition, where the benefit may outweigh the potential side effects? (DF)	for pharmacological treatment are only for chronic primary pain, not chronic secondary pain, nor chronic pain covered in other NICE guidance. This has been clarified in the guideline. The committee agree that there is no evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up.

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NHS England and NHS Improvement	General			I don't particularly like the term 'chronic primary pain', my feeling is that it's too specific and think that 'chronic pain' is actually all we need to say. I agree that most chronic pain is multifactorial and patients often possess undeniable 'evidence' of their pain such as an arthritic joint, spinal spondylosis, a previous fracture, self harm scars and so on. To separate chronic pain into sections such as chronic back pain, neck pain etc and then add chronic primary pain as another diagnostic category could in my view be counterproductive and overmedicalise the condition unnecessarily. As a practising clinician on the ground I would find it hard to be certain when chronicback pain changes into chronic primary pain for example. It seems to me that chronic pain is a problem of response to an event or situation which undoubtedly had an initial element of acute pain. I've seen many people who cope with conditions which must be very painful but they just don't let it hold them back. One old and wise doctor told me in 1988 that pain is a learned phenomenon- I didn't understand properly what he meant back then but I do now. I think that labelling this scenario or syndrome as 'chronic primary pain' runs the risk of medicalising it too much when what's often needed is support, encouragement, reassurance. I fear that pain clinics have for far too long been so focused on physical interventions (drugs, injections, TENS etc) that it's led to a passive societal response- many people will	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. A recommendation has been added to clarify when to consider a diagnosis of chronic primary pain.

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				just think, "I have pain, GP hasn't sorted it, I need to goto a pain clinic." We need to stop this happening and I would ask that consideration be given to removing the 'primary' designation. (DF)	
NHS England and NHS Improvement	General			There is no mention of drug seeking behaviour and dependency. Based on my experience of working in the community in now in prison I have absolutely no doubt that this is a major problem which compounds the problem. This aspect is not mentioned at all. (DF)	Thank you for your comment. The committee acknowledge that this may be an important issue in some people, the issues of dependence were considered in the evidence reviews of safety of opioids and gabapentinoids and informed the recommendations. The rationale for the recommendation not to use opioid and gabapentinoids highlights this, and points towards the evidence review where it is discussed in more detail in the discussion of the evidence (Evidence review J).
NHS England and NHS Improvement	General			The hardest part for a professional dealing with these problems is going to be explaining the change in approach. Telling people it's no longer appropriate to prescribe opioids and pregabalin is one thing but paracetamol and NSAIDs is quite another. I don't disagree with the evidence but the delivery of the message on the ground will be a challenge. It will be vital that the services which are recommended are available otherwise it'll fall	Thank you for your comment. The committee agree that there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic

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				at the first hurdle. Chronicpain is such a huge and expensive problem as detailed in the guidance that I think a significant public information exercise is needed. (DF)	primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
NHS England and NHS Improvement	General			I think the use of terms 'GPs' and 'specialists' does not help. GPs are undoubtedly specialists in this area, I'm sure we issue 99% of the prescriptions for chronic pain and try to monitor/review patients to the best of our ability. We manage many patients without involving secondary pain service and have followed what is now seen to have been bad advice (use of opioids and pregabalin for example). It has to be recognised that the crisis of over prescription of opioids, gabapentinoids and other medications is to a large extent the result of medication initiation by specialists in pain clinics over the last 30 years something which we now know to be inappropriate and need to start to reverse. I do not have a chip on my shoulder but think it would be more appropriate to refer to the professionals as GPs and pain clinic doctors. (DF)	Thank you for your comment. Unless directly referring to something reported in the evidence, we aim to use the term healthcare professional in the guideline and evidence reviews.
NHS England and NHS Improvement	General			This needs complete buy-in across the profession. As an example I've just seen a patient in clinic today and tried to have an open and supportive discussion about the management of his long term lower back pain. This is	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree

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				known to be due to lumbar spine degenerative disease with no surgical solution. His condition has been stable for 10-15 years and he is currently prescribed dihydrocodeine 120mg twice daily and pregabalin 300mg twice daily. He is undoubtedly dependent on these drugs both physically and psychologically. Last year he had successful cervical spine surgery with an agreed plan that we would discuss medication reduction following the operation. I tried to do this today armed with the draft NICE guidance which says that his current regime is not felt to be appropriate and maybe we could discuss a trial reduction. The conversation did not go well and ended up with him taking great offence and accusing me of malpractice. It was not helped by a recent letter from the spinal surgeon advising continued management of his chronic pain with DHC and pregabalin. Patients place so much emphasis and value on consultant opinions that we all have to be very careful with what we say and howwe say it. GPswho are left with long term prescribing decisions need to be assured that all colleagues are singing from the same sheet. (DF)	that there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement	Guideline	Gene ral	General	In secure environments, some patients present with chronic pain that has a clearcut cause and responds well to a combination of non-pharmacological treatments and intermittent short courses of analgesic medication during 'flare ups'. Many patients with chronic pain however,	Thank you for your comment. The committee agree that the management of chronic pain needs to be based on a holistic assessment of the person. Recommendations have

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				have extremely difficult backgrounds and co-existing drug dependence problems. The more common picture of chronic pain in secure environments is extremely complex, resulting from both physical injury and psychological trauma due to adverse childhood experiences. The picture presented to the clinician can also be compounded by secondary gain drivers, sometimes as a result of bullying, to obtain medication for subsequent diversion or misuse. It would be helpful to have a sub-section for specific populations such as people with a history of dependence or addiction, and for those populationswho may have difficult socio-economic circumstances e.g. prison leading to additional layers of complexity in managing their pain. (DF)	been added to include the importance of discussions of aspects of a person's life that may affect their pain, including, but not limited to, stressful life events, including previous physical or emotional trauma and social pressures such as difficulties with employment, housing and income. An additional recommendation has also been added to highlight the need to take into account the person's socioeconomic, cultural and ethnic background, and faith group, and think about how these might influence their symptoms, understanding and choice of management. A bullet has also been added to recommendation 1.1.5 to highlight that current or past history of substance misuse is also an aspect that might be included in these discussions.
NHS England and NHS Improvement	Guideline	General	General	Other general comments - Studies over-represented by women and ethnicity white (not representative of prison ppn)	Thank you for your comment. The committee note in their discussions of the evidence that much

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				- Very little evidence about post-trauma chronic pain (often presents in HMP) - Have not explored use of analgesia for acute exacerbations of chronic conditions or made recommendations about structuring expectations of pharmacological management - What did the antidepressants treat in the primary pain? Depression? Needs more research into ACEs/persistent pain - Significant risk that will end up with population dependent on antidepressants rather than a population dependent on opioids. (DF) -	of the data was in women. They do not believe there is any reason to believe the effectiveness of the interventions would differ in men however. The ethnicity of the study population is also detailed in the evidence reports where this was reported. The committee note in the assessment recommendations that previous history of emotional or physical trauma should be considered in the assessment of people with chronic primary pain. Although most evidence wasn't specifically in this group, the committee are aware this was not specifically excluded and are aware that it can be a factor in some people's lives with chronic primary pain. The committee agree that there is no evidence that the medicines recommended against for chronic

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					primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up. Antidepressants are recommended for their effects on symptoms of chronic primary pain and benefits observed on patient reported outcomes related to this. A recommendation has been added to highlight this is not for depression but because they may help with quality of life, pain, sleep and psychological distress. The committee consider that antidepressants are not thought to be dependence forming as they do not act on the same central

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					mechanisms, but they do highlight that risks of withdrawal symptoms should be considered.
NHS England and NHS Improvement	Guideline	General	General	The main issue will be moving people off current medication and then having access to other treatment modalities. I don't think any of us dispute the issues around the benefit/harm ratio for opiods in particular. I think what would be helpful would be for NICE to "signpost" the ways in which clinicians can support patients to come off these medications. There will then be access to treatments such as CBT as it is frequently limited. Alongside will be weight loss services in particular for back, knee and hip pain. The guidance could also helpfully guide towards patient facing material as often for long term pain "a pill for every ill" can frequently be seen as much easier than long term lifestyle changes and weight management in particular. (DF)	Thank you for your comment. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline.
NHS England and NHS Improvement	Guideline	General	General	I have read the pharmacological recommendation on this guidance, and I am happy with the content as it is in line with our NHSE Pain Management Formulary for Prisons: acute, persistent and neuropathic.	Thank you for your comment. We will pass this information to our resource endorsement team. More information on endorsement can be

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				I am not sure if this formulary could be mentioned (or a direct link added) within the scope of this NICE guidance, as it will help us to disseminate our practices and the existence of this formulary with our community and secondary care colleagues. From my experience this prison formulary is not well known outside our walls, and occasional causes some frictions within clinical teams. See the link: for the page where is uploaded https://www.england.nhs.uk/publication/pain-management-formulary-for-prisons/ And here the actual formulary: https://www.england.nhs.uk/wp-content/uploads/2017/11/prison-pain-management-formulary.pdf (DF)	found here: https://www.nice.org.uk/about/what-we-do/into-practice/endorsement
NHS England and NHS Improvement	Guideline	001	007	Chronic pain is now such a broad term and includes other diagnosis without pathology, such as fibromyalgia, vulvodynia, TMJ dysfunction, etc then there are other more specific chronic pains such as post herpetic neuralgia, phantom limb syndrome, plantar fasciitis, proctagia which also require a holistic approach (AMH)	Thank you for your comment. This guideline covers both chronic secondary and chronic primary pain. Further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation

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					topic and examples of populations included have now been provided.
NHS England and NHS Improvement	Guideline	001		This is developed for 'People with chronic pain, their families and carers' and because of the radical proposals around drug withdrawal and future drug choices I would advise that service users are a major part of this consultation (AMH)	Thank you for your comment. In advance of the stakeholder consultation the registered stakeholder list was reviewed to ensure relevant service user groups were represented. Groups that were not registered were contacted and encouraged to register and participate.
NHS England and NHS Improvement	Guideline	002		Reference to Covid-access to non-pharmaceutical options will be very challenging during Covid as many of these patients will be shielding and because of the impact of social distancing/PPE on face-face treatments. Therefore, many consultations will be conducted remotely, and drug options will be the only choice (AMH)	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain with considerations of where evidence demonstrates interventions are clinically and cost effective.

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					Implementation of these should take the current context into account.
NHS England and NHS Improvement	Guideline	004	006, 011 and 013	Very good to see reference to 'knowing the patient as an individual' and 'working collaboratively/supportively' and be aware of 'how the pain affects their life and how their life affects their pain'. However, this takes time and is impossible to do properly in the 10-minute GP consultation model. Therefore, further recommendations from NICE might be: 1. Specific GP/ANP within the practice with a special interest who can assess over a 20-30-minute appointment 2. Robust, holistic assessment of the impact of pain on life (and life on pain) using a suitable scoring tool Advise that a baseline pain score tool should also be used to evaluate any treatments used-otherwise how do we measure effectiveness? A reduction in pain from 10 to 5 may make a huge difference to a patient's life (AMH)	Thank you for your comment. The committee discussed the need for longer consultations in their consideration of the evidence. This is detailed in Evidence report B and also highlighted in the guideline under how recommendations will affect practice. The evidence for pain scoring tools was not reviewed within the guideline and so recommendations cannot be made on this topic.
NHS England and NHS Improvement	Guideline	006	001	Good that further research is called for to look at pain management, my experience as a GP is poor outcome but these patients are often referred late in their journey and by then opinions are entrenched. (AMH)	Thank you for your comment. On consideration of stakeholder comments this research recommendation has now been removed as it was considered there has already been extensive amounts of research in this area.

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NHS England and NHS Improvement		006	005	Good further research is called for to look at social interventions. (AMH)	Thank you for your comment.
NHS England and NHS Improvement		007	002	Waiting times for CBT and ACT can be up to 6 months which leave the GP often in a difficult position to deny the patient pharmaceutical help (AMH)	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement		007	007	Acupuncture is not widely available on NHS and not an option for most patients unless they go privately, this recommendation discriminates against those who are socially deprived	Thank you for your comment. Access to services (also raised generally for

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				(AMH)	non-pharma recommendations, so this response is used for other topics) The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement		008	013	If antidepressants are to be recommended as first line there will need to be a communication strategy to both doctors and patients, these are generally the 3rd/4th options prescribed and many patients are put off by the term 'anti-depressant' even when we explain why we are using them.	Thank you for your comment. The committee are aware that some of the recommendations included in the guideline are a change in practice and

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				The patients feel that they are being stigmatised as mentally ill and not believed (AMH)	that the guideline will require careful implementation. The guideline does not recommend a sequence of interventions. All of the treatment options should be considered when developing the care and support plan with the person with pain. This should consider both pharmacological and pharmacological options and a shared decision should be made on which to consider. This approach is detailed in the recommendations in section 1.1 of the guideline. The committee agree that there is a need to move away from the stigma associated with antidepressants. They are recommended for their beneficial effects on patient reported outcomes in people with chronic primary pain, including pain and quality of life, not for their antidepressant effects. This should be included in the shared discussion of the benefits and harms of treatments. A recommendation has

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					been added to highlight these are not recommended here for depression but because they may help with quality of life, pain, sleep and psychological distress
NHS England and NHS Improvement		009	010	This recommendation is basically removing the whole options that we as GPs use to treat chronic pain. Whilst there may not be any robust evidence that they have a positive effect most GPs will report that certain patients do respond to some of these drugs and to remove them from our management plan will seriously hinder our ability to manage these patients. I would strongly urge that to publish this as guidance would require a lot of consultation with service users and doctors otherwise it will not 'land' well (AMH)	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.

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					The committee agree There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement		011	006	Very welcomed that further research is advised for CBT,ACT, mindfulness, acupuncture, physical therapy, TMS, etc. Difficult to evidence but every clinician will have anecdotes of reported success (AMH)	Thank you for your comment.
NHS England and NHS Improvement		013	025	Emphasis on good communication between patient and health care professional but I would also strongly advise that these recommendations need good comms between NICE and patient and NICE and doctor (AMH)	Thank you for your comment.

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NHS England and NHS Improvement		014	010	Agree, self-management is something of a last resort, patients feel very disempowered (AMH)	Thank you for your comment.
NHS England and NHS Improvement		024	011	Many patients in desperate need of a solution turn to illicit drug use and report a positive effect with cannabis (AMH)	Thank you for your comment. There was limited evidence available for the use of cannabis for chronic primary pain. The NICE guideline on Cannabis-based medicinal products (NG144) recommends further research specifically for people with fibromyalgia (or persistent treatment-resistant neuropathic pain).
NHS England and NHS Improvement		024	017	Talk to any GP and they will report patient pain improvement with opiates (AMH)	Thank you for your comment. The committee agreed that their expert consensus opinion was that this is not the case for the majority of people with chronic primary pain, and there was evidence of long term harm, both from this evidence review and from their experience. It is important to note the reviews for specific interventions included in this guideline, and relevant recommendations, are all for the chronic primary pain population only,

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					rather than all types of pain. This included the recommendations for pharmacological management. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
NHS England and NHS Improvement		024	026	As above, diazepam and nsaids are the 'go to' prescription for GPs and they will report positive responses from patients (AMH)	Thank you for your comment. Please see the response to your comment above (ID 953) regarding this recommendation only covering chronic primary pain, and the

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					amendments that have been made to clarify this in the guideline. The committee agreed that for this population there is no evidence that NSAIDs or diazepam are effective.
NHS England and NHS Improvement		025	010	As above, plenty of anecdotal evidence that epileptic drugs help with neuropathic pain such as post herpetic pain, TGN etc (AMH)	Thank you for your comment. Please see the response to your comment above (ID 953) regarding this recommendation only covering chronic primary pain, and the amendments that have been made to clarify this in the guideline. Management of neuropathic pain is covered in the NICE guideline for neuropathic pain in adults, CG173.
NHS England and NHS Improvement		026	012	Whilst it is sensible and good practice to do regular medication reviews on patients in the community who are already established on regular prescription medication, discuss reduction in dose or withdrawal (and side effects), please be mindful that there is often no alternative (excessive wait times for CBT etc). Also patients may be stable and functional on a manageable amount of opiate or anti-epileptic and in that a plan to reduce/stop these drugs will cause a huge increase	Thank you for your comment. The committee agree there is a need to acknowledge people who are already receiving these medicines and benefitting. This recommendation has been reworded to include considerations for both people who are receiving little benefit or

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				demand on primary care which is not resourced. These recommendations will help GPs when considering what medications to initiate but medicalisation of pain has occurred because of a lack of anything else to offer. (AMH)	significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee appreciate the point made that medicalisation of pain has resulted from there being limited alternative management options. However, this guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended non-pharmacological services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those

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					interventions that should not be recommended, saving resource in other areas.
NHS England and NHS Improvement		026	029	Patient may have been enabled to return to the workforce by prescriptions (AMH)	Thank you for your comment. This statement has been removed from the text of the rationale.
NHS England and NHS Improvement		28	4	This statement is not a representation of the experience of most GPs (AMH)	Thank you for your comment. This statement has now been removed from the guideline.
NHS England and NHS Improvement	guideline	General comment	General invited comments	The specialised pain CRG acknowledge that the bulk of the guideline lies outside their remit, however since the recommendations impact on non-specialised pain services we expect these will eventually impact specialised pain services hence the need to comment. The CRG is concerned that the guideline may adversely impact access to secondary and tertiary care pain clinics. If this occurs, it will need a concurrent expansion in medically led primary care pain clinics and facilitated referral to secondary care specialists who can identify patients with chronic secondary pain and also rule out specific causes of chronic primary pain (CPP). Furthermore, the CRG is concerned that the label of chronic primary pain may be, as a result of the guideline, be incorrectly applied to a large number of chronic pain patients where the aetiology of the pain may not be immediately apparent in a primary care setting.	Thank you for your comment. The committee agree that specialist assessment for diagnosis and management of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might

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				Patients expect analgesic medication when they visit a doctor with pain. This guideline will result in conversations between doctors and patients which most patients will find frustrating and unhelpfulc. This will be challenging for physicians in all care settings. There isalso a danger that some treatments might be decommissioned, even though research is recommended, e.g.. PMP therapy. (MS)	need to be considered. Recommendations have been added to the guideline for when to consider a diagnosis of chronic primary pain, but also to highlight that the initial diagnosis may change with time and should be re-evaluated, particularly if the presentation changes. The committee agree that some conversations informing people of the lack of evidence of some treatments may be challenging. However they agree it is important that full discussions are had about the risks, benefits and evidence for each treatment and the lack of evidence of effectiveness for these medicines for chronic primary pain and the risk of harm means they should not be recommended. The committee agree that the evidence reviewed within the guideline did not inform a

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					recommendation for or against pain management programmes. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline.

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NHS England and NHS Improvement				2. Would implementation of any ofthe draft recommendationshave significant cost implications? Reduction in primary care drug costs for chronic pain. Reduction of PMP costs if no longer commissioned (MS)	Thank you for your comment.
NHS England and NHS Improvement				3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) Setting up medically led MDT primary care pain clinics as satellites of secondary care pain services. GP training in chronic pain management particularly the aetiologies of chronic pain. GP and Primary care pharmacist training in medication management for chronic pain including the management of reduction and withdrawal of medication Physiotherapy training in managing chronic pain. (MS)	Thank you for your comment. Your comments will also be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement				4. The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication. No group therapy can take place currently and consequently neither the recommended group exercise therapy nor research into group PMP can be carried out. (MS)	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain

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					with considerations of where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
NHS England and NHS Improvement	Guideline	General	General comments	• There is concern that whilst the document proposes to be a definitive document to cover assessment and management of ALL chronic pain (Section1.1 Title), the guideline emphasises primarily the management of Chronic primary pain. This excludes the lager proportions of chronic pain (secondary pain) patients with a clinical diagnosis. • The CRG are concerned that while the guideline aims to cover a broad remit, it fails to address the multiple aetiologies and mechanisms that may result in chronic pain. This major drawback should be acknowledged. The CRG would emphasise the need for all patients with persistent pain to be assessed by clinicians with expertise in pain management to allow for the appropriate triage into primary or secondary pain. • Chronic pain with an identified cause (e.g. significant osteoarthitis, spinal stenosis, degenerative disc disease, endometriosis, and musculoskeletal pain such as frozen shoulder) may co-exist with chronic primary pain.	Thank you for your comment. The assessment and communication section, and reviews on pain management programmes and social interventions were covering all types of chronic pain. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has now been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has

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				• The lack of existing double-blind randomised trials in chronic pain is NOT equal to absence of therapeutic value. In chronic pain acceptance of consistent clinical practice should be taken into consideration. • There have been concerns raised about the formatting of the guidance. A small part of it applies to chronic pain and major part to primary chronic pain. This has the potential to cause confusion. The CRG are concerned that the guidance may be broadly to all chronic pain patients. • The ICD-11 system is designed for research, coding and monitoring of the prevalence of conditions. It does not purport to indicate homogenous biological mechanisms and thus the evidence for lack of effect in certain subgroups within this classification cannot be expanded to include the whole main classification group. This is highlighted by the consideration of CRPS within the Chronic Primary Pain (CPP) group which has had recent evidence of several immunological mechanisms involved in its pathophysiology. CRPS is diagnosed when no other diagnosis explains clinical presentation. The CRG would advise a similar approach is taken when offering a diagnosis of CPP.	also been amended to reflect that chronic primary pain is also a focus of this guideline. The recommendations have been amended to include the importance of undertaking a holistic assessment of the person, exploring possible causes for the pain and acknowledgement that chronic primary pain and chronic secondary pain can coexist. We agree that absence of evidence is not proof of lack of effect, the evidence is interpreted together with the expert clinical experience and expertise of the committee. In some cases it was agreed that absence of evidence specifically for the chronic primary pain population, alongside expert consensus opinion that the benefits do not outweigh the harms, a 'do not' recommendation was appropriate.

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				• The definition of CPP needs further clarification within the document. The guideline needs to be more specific, regarding the placement of individual diagnoses within the classifications and the biological reasoning for that placement. This guidance risks conflicting with previous guidance published by NICE for specific pain conditions which have now been included in CPP. An example is that Cluster headache is known to be a CPP condition but has specific treatment options which are established. This heterogeneity in aetiology and treatment options for CPP needs to be emphasised n the guideline. • The CRG is concerned about the communication surrounding the release of thedraft guidelines which appears to blur the lines between chronic pain and CPP with press reports and social media stating the CPP recommendations apply to Chronic pain.. (MS)	The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect

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					according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). In response to stakeholder comments, the formatting and layout of the guideline has been revised to help clarify what population each section covers. In addition to this the terms used have been clarified in the opening text of the guideline and more prominence given to the cross reference to related NICE guidelines that cover types of chronic pain that have been excluded from the chronic primary pain reviews (including cluster headaches which are covered in the NICE Guideline for Headaches in over 12s, CG150). For these topics, recommendations in existing NICE

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					guidelines still stand. The NICE pathway that will accompany the guideline will directly link to these related guidelines. We hope that this improved presentation and clarity will result in more accurate communication about the guideline and the populations covered by each recommendation.
NHS England and NHS Improvement	Guideline	004, 005	Page 004 lines 002-020, Page005 lines 002-016	Section 1.1: Assessing all types of chronic pain (Page 4 Lines 2-20, Page 5 Lines 2-16) We agree with this section but in addition have following comments. • The committee are to be commended for the very welcome and overdue emphasis on careful, sensitive and collaborative working in their recommendations on the assessment of chronic pain. • 1.1.3: It must be recognised that not all causes of pain can be diagnosed and a 'label' provided for the patient. • 1.1.4: is overly negative. It is very important to give patients realistic hope that things can improve, and it	Thank you for your comment. The recommendations have been edited to address some of the important issues raised by stakeholders. Highlighting that a cause for the pain may not be identified has been included. A sentence has been added to the recommendation (previously numbered 1.1.4, now 1.1.11) to highlight that quality of life can

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				is felt that the wording of this statement does not convey this. It is our view that the wording currently does not strike the right balance. • Within the assessment there needs to be social assessment as well as biological and psychological. Intensive work with people to change other areas of their lives, to enable them to live more fulfilled lives, improve wellbeing, general health, will positively influence the pain experience. • There needs to be specific guidance on enabling patients to self-manage and take control of their own pathways, especially in CPP, avoiding the use of short-term therapies which may be disenabling by creating patient reliance and delaying acceptance of chronic pain being a long-term condition. • The language is noted to be all about managing, coping, doing things to people with pain. thereby positioning the person living with pain in a passive role. The guidance needs to emphasize the role of people with pain in managing their condition. (MS)	improve even if pain remains unchanged. Social factors have been included as something that should be considered in the recommendation. The recommendations now include specific mention of providing information on self-management. The amendments aim to highlight the shared approach to the assessment and people playing an active role in their pain management.
NHS England and NHS Improvement	Guideline	005	017	Section 1.2 (Managing all types of chronic pain, page 5, line 17)	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled;

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				• It would provide clarity if the committee stated that the recommendations in this document cannot be transferred into the wider scope of pain conditions due to specific causes. • There is an unrealistic expectation that non-specialists will be able to navigate through an increasing numbers of condition specific Guidance documents. Better signposting and definition clarity within the document would prevent this occurring. • It is noted there is no statement on the education of patients and clinicians with regards understanding of the reasoning behind treatments being offered or not, and their role in the overall patient centred management life plans. • It is noted there is no reference to gender differences and its biological and psychological impact on pain management and treatment. • The document needs to emphasise that patients should not be denied trials of reasonable treatments. In return, Clinicians have an obligation to monitor and discontinue ineffective treatments. (MS)	definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. Recommendations have now been added about developing a shared care and support plan. These include recommending that there should be an informed discussion of the risks,

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					benefits and evidence for all of the available treatment options. The committee agreed there was no evidence in the guideline to make different considerations in the recommendations based on gender.
NHS England and NHS Improvement	guideline	006	001-003	Section 1.2.1 (Page 6 Lines 1 – 3 Topic: Evidence for PMP therapy) • The specialised pain CRG is fully supportive of further research into Pain Management Programmes (PMP). However, we are concerned that the lack of further detail may impact the long-term commissioning of these programs. The Pain CRG is of the opinion that a statement to consider PMP in selected groups is required whilst further research is pursued. • The rationale for the statement on PMP's does not sit with the definition 'any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two'. When reviewing the literature assessment concerns are raised by: o Some of the reasons for excluding studies weren't completely clear e.g. Cochrane review excluded	Thank you for your comment. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain.

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				because they were mind-body interventions such as cognitive behaviour therapy, biofeedback, mindfulness meditation, movement and relaxation therapies, which did not meet the protocol definition of a pain management programme for this review – yet many of those included seemed to have these components too. o Population varied widely some specific, some general – e.g. fibro, knee, widespread pain, injuredworkers, osteo & rheumatoid arthritis, back pain, chronic non-cancer pain o Some seemed to not be a group (e.g.Laforest 2008 – "weekly 1 hr individual home visits over 6 weeks", McBeth2012 delivered telephone CBT alongside monthly exercise session). o Input ranged from 6hrs to 160hrs. Some 'programmes' lasted a year. • NICE requires a randomised controlled trial study design as proof of treatment efficacy. Very little PMP evidence is in this format. Most evidence is in the form of outcome studies, and not admissible to NICE. • We welcome the suggestion for more PMP research if that results in increased research funding for UK PMPs. We are aware that some tertiary care pain units are well placed to deliver PMP research These centres have established a PMP Registry to collect outcomes for all participants.	The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome, so they did not include a recommendation for this population. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where

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				• We note that a key NICE recommendation for the treatment of persistent low back pain or sciatica in 2016 (NG59) was 'to consider a combined physical and psychological programme, incorporating a cognitive behavioural approach (preferably in a group context that takes into account a person's specific needs and capabilities) …when they have significant psychosocial obstacles to recovery …and when previous (NICE recommended) treatments have not been effective'. This is essentially a PMP, but witha different name, and we are surprised that NICE do not recommend this in the current guidance since many chronic pain patients in the UK are patients with low back pain. (MS)	appropriate for the type of chronic pain being treated. The definition used for pain management programmes has been included in the recommendation for chronic primary pain for clarity as to what evidence was reviewed within this guideline. The studies included in the relevant Cochrane reviews were reviewed when completing this review, and have been double checked again following stakeholder consultation. Any studies that met the protocol criteria for pain management programmes in this review had been included. The guideline includes a separate review for psychological therapies, however the population of interest for that review is only chronic primary pain. Any studies included in these reviews that were relevant to the psychological therapies review

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					had been included there. However a number were not relevant to include due to being chronic pain populations other than chronic primary pain. Where there was doubt over inclusion of any particular study, this was discussed with the committee. Detail was included in the excluded studies table to specify when the committee agreed that the exclusion reason was due to there being an insufficient element of either component. The committee highlighted the variability across studies in a number of factors including (but not limited to) the duration, setting, and composition of the programme. This is considered in the committee's interpretation of the evidence and detailed in the discussion of the evidence in this chapter. The most appropriate study to inform the review question is determined

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					with the committee when setting the review protocol. In the case of this review it was agreed that RCT evidence, as the highest quality evidence, was required. The committee were aware of the recommendation included in NG59 for low back pain and sciatica. Whilst the committee agree that types of chronic pain can coexist, they agreed that there wasn't evidence in this guideline to inform a recommendation for all types of chronic pain. For chronic primary pain the evidence reviewed did not demonstrate a benefit and so the committee agreed not to recommend pain management programmes. For other types of chronic pain the recommendation advises that pain management options in other NICE guidelines should be followed.
NHS England and NHS Improvement	Guideline	006	005	Section 1.2.2 (page 6, line 5 social intervention) • The committee were aware of evidence for social interventions in conditions other than chronic pain, but	Thank you for your comment.

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				they agreed that this evidence could not be extrapolated as the issues faced by people with chronic pain are likely to be different from those populations. The specialised pain CRG applauds the committee for admission that evidence in other patient groups cannot be extrapolated to chronic pain populations. • Please note previous comments on social interventions and long-term pain management. (MS)	
NHS England and NHS Improvement	Guideline	006	007-008	Section 1.3 (Page 6 Lines 7 to 8 Topic: Chronic pain and chronic primary pain section 1.2 transition to section 1.3) • The guidance is now no longer related to Chronic pain, but chronic primary pain (CPP) only. The CRG would welcome clarification that this change of emphasis does NOT relate to all chronic pain patients to avoid confusion within clinicians, commissioners and patients. • The term chronic primary pain is NOT in general use and is only just beginning to be adopted by a few specialist clinicians. The CRG are concerned that the unfamiliarity of this term will cause misinterpretation of the remit of the guidance. • We recommend that NICE clarifies the training requirements for diagnosticians responsible for differentiating between chronic primary and chronic secondary pain. The CRG believes the draft should recommend improved access to secondary care to rule	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline,

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				out secondary causes of chronic pain before 'labelling' a patient with chronic primary pain. • We note that some chronic primary pains have specific treatments such as CRPS, where multidisciplinary input to improve pain and function is a standard of care identified in published guidelines (RCP CRPS Guidelines). Additionally, previous NICE recommendations for CRPS included spinal cord stimulator treatment. Similar issues are noted in facet joint radiofrequency denervation for chronic low back pain and cluster headache. • We note that in the literature searches NICE have applied a different definition from the ICD-11 definition, therefore we believe that the evidence cannot be applied to ICD-11 chronic primary pain. The NICE definition for the literature search is - "People, aged 16 years and over, with chronic primary pain (whose pain management is not addressed by existing NICE guidance). This includes chronic widespread pain, complex regional pain syndrome, chronic visceral pain, chronic orofacial pain and chronic primary musculoskeletal pain other than orofacial pain." This does not include distress or disability which is part of the ICD-11 definition and has excluded studies where patients from a related "secondary pain" group will have been included. • The above may explain why the search recovered only a few studies, of generally low quality , on the basis of which, the conclusion is then drawn , that most	and a visual summary has been added clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider this evidence could be considered for all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity

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				treatments should not be offered on the NHS. The CRG believe that widening the remit of the search would better serve the chronic pain population and provide a better evidence base for the guideline. (MS)	was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). Additional recommendations have been added to the assessment section, including when to consider a diagnosis of chronic primary pain. The sentence you highlight is not the term that was used in the searches to cover chronic primary pain. The searches were broad and inclusive to include all conditions that were included under the ICD-11 umbrella term of chronic primary pain at the

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					time of development of the guideline. Full details of the search strategies are available in appendix B of each evidence review chapter.
NHS England and NHS Improvement	Guideline	006	011, 015	Section 1.3.1 and 1.3.2. Topic: group exercise therapy for CPP (chronic primary pain); (lines 11 and 15, page 6) • We agree that group exercise therapy is helpful in chronic primary pain, as well as in chronic secondary pain. We note the current difficulties in delivering group therapies. • It is our experience that certain conditions benefit from syndrome specific individual physiotherapy treatment such as CRPS, and chronic pelvic pain. • The CRG note that in the large proportion of chronic pain patients who have already been through musculoskeletal pathways but have then been referred onto pain services there may be a place for short term medication use to allow the introduction of exercise therapies.. • Delivery of, capacity and willingness to engage in activity class work (Medically and non-medically delivered) will be heavily influenced by the peri-post	Thank you for your comment. The committee agreed that the type of exercise may depend on the type of pain, but also that people are more likely to continue with exercise if the programme offered suits their lifestyle and physical ability and addresses their individual health needs. They agreed that the choice of programme as well as the content should take into account people's abilities and preferences. This might include providing individual exercise advice for different members of a group. This was highlighted in the recommendation and in more detail in the rationale underpinning the recommendation. The committee agree that there is no evidence that the interventions

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				COVID era. Remote and online resources will require development and this will influence cost –effectiveness evaluation. • It is noted most of the exercise studiesare about FM- only 1 or 2 studies includes men. Ethnicity of participants is mainly not reported, there is a distinct gap in the literature. Trials do not routinely include elderly population in exercise for chronic pain which is the majority of the population in many hospitals. This narrow remit of the evidence should limit its extrapolation to all types of chronic pain and for all genders and ages. • A further concern raised is that most of the FM studies either exclude people with significant psychiatric problems, suicidal ideation. This is not reflective of the population seen in pain clinics in secondary / tertiary care. Could the guidelines include a caveat that the exercise recommendations have excluded people with significant mental health presentation? • The Chartered Society of Physiotherapy (CSP) stopped using the word exercise a few years ago. The word itself can increase pain in some people. CSP recommends talking about increasing activity levels. (MS)	recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.

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					The committee note that clinical trials and controlled studies frequently exclude people with comorbidities. All of the reviews can be impacted by these limitations. The committee highlight in the recommendations in the assessment section 1.1 that there should be a holistic assessment and also that people's preferences and priorities for managing multiple conditions should be taken into account when developing a care and support plan. The committee acknowledge that the evidence informing the exercise review was largely from populations with fibromyalgia or chronic neck pain. The committee considered that response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions. However it was again considered that the most appropriate type of exercise may depend on the type of pain condition and it should

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					therefore be tailored to individual needs and preferences. Details about the settings and where available the ethnicities of the participants, are given in the evidence tables in appendix D for all included studies. The applicability and generalisability of the evidence was considered by the committee in their discussion of the evidence. The committee agreed that the term 'exercise' should be retained in the recommendation as 'physical activity' has a different meaning and could be interpreted differently to what the evidence had identified benefits for.
NHS England and NHS Improvement	Guideline	007	002,005	Section 1.3.3 and 1.3.4 (Psychological therapy for chronic primary pain; lines 2 and 5 page 7) • The intention of this aspect of the review was to identify the evidence for independent psychological therapies, to inform services as to which are effective for the assessment and management of all chronic pain. • There are some methodological questions which challenge the conclusions reached by the GDG. The criteria applied in the initial searches has led to the	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific

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				exclusion of some higher quality trials (e.g. Smeets et al 2006, a large trial demostarting cost effectiveness).1 This may be because of a misinterpretation of the intervention or because the focus was on more 'specific' conditions, such as low back pain or neck pain. Apart from the risks associated with a dualistic approach, there is a wider problem of definition, in that clearly defining or diagnosing these conditions, where pain is attributed to specific anatomical structures, in order to distinguish them from CWP or CPP, is extremely problematic, (Brinjikji et al 2014)2 as is the agreement on what constitutes 'Fibromyalgia', on which the conclusions of this review were largely based. • The review also focused on content of the intervention, (ACT or CBT), rather than the skills or background of those delivering the programme. which can significantly impact outcomes (Pincus and McCracken, 2013).3 • Thus, the basis for the conclusions reached by the GDG that both ACT and CBT are comparable and cost effective, are therefore questionable. • The GDG also acknowledged a problem with assessing the efficacy of independent psychological approaches to chronic pain, which is that in much of the published research, as is the case in clinical practice, elements of psychological therapies are typically combined e.g. CBT + relaxation + pain education.	intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The review objective, as stated in the protocol, was to determine the effectiveness of the included psychological therapies for chronic primary pain. In the interpretation of the evidence the committee noted that the experience of the person delivering the intervention can have an impact on the effectiveness of the intervention. This is detailed in the

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				• This combined approach would typically take the form of a Pain Management Programme (PMP). PMPs have justifiably only received a research recommendation in the guideline, as the evidence for such combined approaches was deemed unclear by the GDG. How much input is required, such as the length of the intervention or the number of sessions or which components work best for whom, is not clear and requires further research. 1. Smeets_R, Vlaeyen_JWS, Hidding_A, Kester_ADM, Van Der Heijden_G, Van Geel_ACM, et al. Active rehabilitation for chronic low back pain: cognitive-behavioral, physical, or both? First direct post-treatment results from a randomized controlled trial. BMC Musculoskeletal Disorders 2006;7:1-16. 2. Brinjikji W, Luetmer PH, Comstock B, Bresnahan BW, Chen LE, Deyo RS, Halabi S, Turner JA, Avins AL, James K, Wald JT, Kallmes DF and Jarvik JG Systematic Literature Review of Imaging Features of Spinal Degeneration in Asymptomatic Populations Am. J. Neuroradiol. 2015 Apr;36(4):811-6. 3. Pincus T,& McCracken, L. (2013). Psychological factors and treatment opportunities in low back pain. Best practice & Research. Clinical Rheumatology. Vol 27 (5) 625-35.	committee's discussion of the evidence in Evidence review F. The guideline recommendations assume that the healthcare professionals delivering the interventions are appropriately trained to do so. This has been added to the recommendation for ACT / CBT for clarity. The committee agree that there is sufficient evidence of benefit to recommend that their use can be considered, although not enough for a stronger recommendation to offer these to all people with chronic primary pain. The committee do acknowledge that it is true that some studies were excluded due to focussing on combined therapies, but there was also evidence available to inform

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				(MS)	effectiveness of the interventions individually for chronic primary pain. The evidence for pain management programmes with combined therapies was reviewed separately within the guideline. In consideration of stakeholder comments, the evidence in that review has been reanalysed to separate the chronic primary pain population, to be consistent with other reviews within the guideline. The committee agree that for this population most of the evidence did not show an improvement in quality of life and there was no evidence of benefit for pain, physical function or psychological distress. They therefore did not include a recommendation on the topic.
NHS England and NHS Improvement	Guideline	007	007	Section 1.3.5 (Acupuncture for chronic primary pain, line 7, page 7) • On review of the committee rationale there has been a significant application of research and financial indicators to provide a treatment the committee agrees would only deliver short term benefit. The CRG are	Thank you for your comment. The committee agreed that there was variance in type and intensity of interventions included, as well as country that the studies were

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				concerned that the cost implication of the a consistent delivery of 3 monthly acupuncture for all patients with chronic primary pain would be considerable. • Clinical risk is low however there appears to be little recognition that Acupuncture is a passive treatment which often engenders dependency (and challenges service sustainability). There is however recognition that the modality is labour intensive. This therefore appears to conclude with a series of clinical caveats (no more than 5 hours input, B7 delivery (or less), community-based provision, ongoing repetition not to be picked up by NHS services). This approach is at odds with previous NICE recommendations on Acupuncture. • Earlier this year an extensive review of acupuncture systematic reviews found evidence that was conflicting and inconclusive. The CRG are therefore surprised that acupuncture has been recommended as a treatment for chronic pain conditions. o Paley, C.A.; Johnson, M.I. Acupuncture for the Relief of Chronic Pain: A Synthesis of Systematic Reviews. Medicina 2020, 56, 6 • We note that NICE have not recommended acupuncture in the past (CG59 and NG59). What new evidence supports the recommendation of acupuncture for this group?	conducted in. This is also true of the evidence informing the other non-pharmacological interventions recommended in the guideline. The committee were not aware of significant risk of dependency to acupuncture, but do acknowledge that it is largely a passive treatment. That does not however detract from the benefits observed in the review. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation

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					topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The evidence base is therefore more specific than that covered in Paley et al. which was for all types of chronic pain. The committee were aware of the recommendation and evidence review underpinning the recommendation in the current NICE low back pain guideline (NG59). However, the review for this guideline excluded evidence in people with low back pain (as stated above) and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica and was supported by a large evidence base. Consistent benefits were observed for quality of life, and

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					pain compared to sham as well as usual care as well as some benefits in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The committee acknowledge that there can be overlap in conditions. Clinical judgement should be used to determine the appropriate treatment option relevant to the type of pain being treated and the relevant NICE guideline.
NHS England and NHS Improvement	Guideline	008	001	Section 1.3.6 (Electrical physical modalities for chronic primary pain, line 1, page 8) • We agree there is currently little justification for Ultrasound with persistent pain problems • With regards TENS we accept that the evidence base is contradictory and there is little agreement about stimulation parameters, time periods of treatment and indeed optimal pad placement however the evidence base is no more, no less than the vagueness around Acupuncture care which is treated entirely differently in this document.	Thank you for your comment. The evidence base for acupuncture informing the recommendation was considerably greater than that for TENS. Only 2 relevant studies were identified for TENS and no difference was observed between sham or usual care for the majority of outcomes. For acupuncture a total of 32 studies were included and consistent benefits were seen for health related quality of life

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				TENS is a non-dependency treatment in which the patient is operator. The patient is given an active management role in their own self-management strategy. Risks are negligible. Costs are minimal. (MS)	and pain when compared to sham or usual care. The committee do acknowledge there was variation among the interventions included within the review and include this in their discussion of the evidence in the review chapter (Evidence report G). They agreed that this was reflected in current practice, which showed a similarly wide variation in terms of type of acupuncture, length of sessions and duration of treatment programme. The evidence base was agreed great enough to inform a recommendation to consider acupuncture, rather than a stronger recommendation to offer acupuncture to all people with chronic primary pain.
NHS England and NHS Improvement	Guideline	008	008	Section 1.3.7 (Manual therapy for chronic primary pain, line 8, page 8) • The CRG believe that manual therapy may have a role as an adjunct to facilitating movement patterns via a short term, low risk, localised "tissue effect" there can be value, often to simply demonstrate the integrity of underperforming /	Thank you for your comment. This review was for the effectiveness of manual therapies for chronic primary pain as a standalone intervention.

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				problematic tissues and that range of movement can be obtained and functionally utilised. We acknowledge that manual therapy has no place as an isolated, repeat treatment. (MS)	
NHS England and NHS Improvement	Guideline	008	014	Section 1.3.8 – 1.3.14 Pharmacological management of CPP The specialised pain CRG applauds the recommendation that any medication cessation should be a shared decision with the patient. (MS) • We would advise that at the time of individual assessment medicine efficacy should be part of the overall review and cessation of non-beneficial medicines occur. All medication which is commenced by a clinician must be reviewed regularly by that clinician for significant side effects or lack of effect. • There is a known cohort of patients with CPP who respond to one or more of the medications not recommended allowing them to lead a full and relatively normal lifestyle. There needs to be a statement with regards ongoing management of this group of patients.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee also cross refer in this guideline to the NICE guidelines on

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				We recommend a proper structure for deprescribing and support groups led by trained professionals. Community and secondary care pharmacists are, in our opinion, best placed to lead this with pain specialist supervision. This support structure needs to be costed within the guidance. (MS)	medicines optimisation and medicines adherence where the importance of medicines review is highlighted as well as detailing what should be included with a review. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible. The cost of implementing the recommendations is considered within the resource impact assessment produced by NICE alongside the guideline.
NHS England and NHS Improvement	Guideline	011	004	Recommendations for Research • It is noted there are multiple recommendationsfor research priorities and the specialised pain CRG welcomes funding and support to allow further investigation into a	Thank you for your comment.

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				multidimensional and complicated speciality. (MS)	
NHS England and NHS Improvement	Guideline	007	011-013	There are significant concerns regarding the restrictions placed on acupuncture in the delivery of Chronic primary pain, acupuncture should only be delivered by an appropriately trained clinician, who will be responsible for the clinical reasoning associated with it. Detailing the grade of staff who should deliver this, excludes use by advanced and consultant AHP practitioners who may be best placed to provide such intervention in the patients care pathway. Similarly detailing a maximum time for intervention is reducing the ability of these highly trained clinicians to utilise clinical reasoning . (SC)	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.
NHS England and NHS Improvement	Guideline	008	001	Electrical physical modalities- whilst we agree with the limited evidence base for Ultrasound and Interferential therapy in the cohort, the use of TENS can provide significant long term pain relief when used as part of a patient led management plan, reducing the need for stronger analgesia. Clinicians should be allowed to utilise clinical reasoning to determine its effect and any recommendations in terms of long term use. (SC)	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long

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					term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
NHS England andNHS Improvement		010	001 & 003	This is sensible advice and already followed by GPs during regular medication reviews (AMH)	Thank you for your comment. The committee agree that these recommendations reflect what should be considered best practice, but evidence demonstrated shortcomings in some people's experience and therefore it was agreed important to include in the guideline.
NHSE and improvement	Guideline			I fully welcome this key guideline. Management of primary chronic pain is a key focus of our strategy and this will be very useful to inform. Accepting the broad scope, It does reflect that there is a significant challenge with regard to chronic pain across MSK. It is embedded in	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance

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				a personalised approach focusing on active self-management strategies which is great. A few comments • The definition is of chronic primary pain is key, as such aligned with other relevant NICE guidance (LBP/Sciatica, Rheumatoid arthritis, Spondyloarthrtis) we need to insure patients with symptoms for 3 or more months attributable to a specific diagnosis are not wrongly bracketed with chronic pain. I appreciate that the wording is designed to minimise this risk, and the definition on page 10 helps enable this, but wonder whether this can be more front and centre • We acknowledge pain may not get better and the need for a care plan. Suggest we suggest a "long term care plan" (1.1.5) – this may help shift models of service delivery • Re exercise, I understand the term mind-body exercise, but don't think it is commonly used, and the document may benefit from a definition • It is great that we are not advocating passive intervention. We need to encourage patients to actively self-manage and avoid over reliance on passive interventions which are of limited value and indeed can prove iatrogenic. As such I am concerned about the advocacy of acupuncture in isolation as a passive intervention. The use of acupuncture has to be	where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, this also includes clarifying the exclusion of other causes of pain. A recommendation has also been added for when to consider a diagnosis of chronic primary pain. The committee agree that long term management is likely to be required. Acknowledgement of this has been added to 1.1.11. The examples of types of exercise have now been removed from the

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				embedded in the right exercise / psychology based intervention and I think we should emphasise this.	exercise recommendation as this covers all types of exercise considered in the review. The evidence reviewed in the guideline was for acupuncture as a standalone intervention, therefore the committee cannot comment on its use as an adjunct. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is

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					written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.
GP reference panel	Guideline	General	General	The guideline is clear and easy to follow, and lends itself for use as a quick-access resource.	Thank you for your comment.
GP reference panel	Guideline	General	General	Whilst the forum welcomes the emphasis on drug avoidance most respondents expressed concerns about implementation. Both primary and secondary care clinicians find it difficult to access exercise, psychological, and social interventions. We have highlighted specific issues in later sections.	Thank you for your comment. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
GP reference panel	Guideline	General	General	Even experts have difficulty in deciding when pain can be properly identified as neuropathic, chronic primary, or chronic secondary in a clinical environment, especially	Healthcare professionals in primary care should feel confident to be able

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				where co-morbidities of painful conditions are present. It will be tempting for doctors and patients to have pain relabelled or attributed to co-morbidities so as to justify using drugs especially as other resources may not be available. This would, therefore, merely shift the problem.	to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered
GP reference panel	Guideline	General	General	Please replace 'chronic pain' with 'persistent' pain. Most patients consider chronic to mean 'awful'. This can drive a negative spiral of helplessness and dysfunctional core beliefs, which is difficult to reverse.	Thank you for your comment. During the scope consultation for this guideline a specific question was asked of stakeholders regarding whether the term persistent or chronic should be used. The majority of stakeholders said that chronic pain should be used for consistency with ICD-11 terminology.
GP reference panel	Guideline	001	General	In the opening box please provide greater clarity on the focus of the guideline: primary persistent pain (even though it is explained at the end of the document). Then please state what this term means: the brief mention that primary pain is in ICD-11 is not helpful, especially as the code itself is complex and disputed.	Thank you for your comment. The text on the overview page has been edited following stakeholder comments. The context section has also been reworded to include more detail on the population and definitions used

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					and this has been placed before the recommendations to aid clarity.
GP reference panel	Guideline	001	General	Please clarify whether fibromyalgia is included (this is not referenced in the introduction or in section 1.3.2). Some later forum comments assume that fibromyalgic pain is covered by this guideline.	Thank you for your comment. Fibromyalgia has been included as an example of chronic primary pain in the context of the guideline to clarify that it is included.
GP reference panel	Guideline	001	General	The neuropathic pain guideline is referenced in 1.3.2 but not in the Introduction.	Thank you for your comment. Neuropathic pain CG173, has been added to the introduction.
GP reference panel	Guideline	005 - 010	017 - 010	Please consider the resources produced by NHS Sheffield on persistent pain.	Thank you for your comment. The committee are aware of the resources highlighted.
GP reference panel	Guideline	006	010-017	We welcome the greater emphasis on exercise. Overuse of drugs has detracted from the things that do work, namely exercise.	Thank you for your comment.
GP reference panel	Guideline	006	011-014	We welcome this statement but the guideline should recognise the problems arising from current poor access and under-resource. Until provision catches up, please identify resources for home-based exercise programmes.	Thank you for your comment. We hope that by recommending that group exercise should be offered to people with chronic primary pain that provision will be increased and allow better signposting to existing provision. Evidence reviewed demonstrated the most benefits for supervised exercise programmes and

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					therefore the recommendation has been made specific for that rather than home-based as recommendations should encourage best care.
GP reference panel	Guideline	007	012	Are recommendations possible for clinicians over Band7?	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.
GP reference panel	Guideline	008-010	013-005	Currently, in order to reduce polypharmacy, some recommendations advise a step and reduce approach to prescribing in chronic pain i.e. double dose x 3 rounds and if no response wean off before starting an alternative.	Thank you for your comment. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in

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					development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline.
GP reference panel	Guideline	008 - 009	014-002	Please comment on: 1) whether anti-depressants have an optimum duration of treatment. 2) whether anti-depressants are equally effective (unlike in the management of neuropathic pain).	Thank you for your comment. The committee agreed that there was not enough evidence to determine whether one antidepressant was more effective than another. The recommend that the choice of which one should be based on a fully informed discussion with the person with chronic primary pain, taking into account the risks and benefits. This is stated in the rationale for the recommendation and further detail is given in the committee's discussion of the evidence in evidence report J. The evidence did not inform the optimum duration of treatment. The

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					committee considered this should be informed by regular review of medicines as recommended in the NICE guidelines for Medicines optimisation and Medicines adherence.
GP reference panel	Guideline	009	010-204	Whilst we welcome the non-tablet features of this guideline how can we manage those patients (perhaps a minority?) who truly and clearly benefit? This section leaves very little, if any, choice of analgesics for primary care clinicians. As the provision of alternative management strategies is unsatisfactory, will patients seek treatments (including opioids and gabapentinoids) fromsources such as the internet?	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services

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					across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
GP reference panel	Guideline	009	015 - 017	Assuming this guideline includes fibromyalgia) There is strong evidence (albeit short term only) for the use of pregabalin in moderate/severe fibromyalgia (the results are similar to duloxetine) Ref: Derry S et al Pregabalin for pain in fibromyalgia in adults, Cochrane systematic review 2016	Thank you for your comment. When setting the protocol, the committee agreed that studies with an enriched enrolment design would be excluded from the review, due to the potential to over-estimate of an interventions effect and lack of generalisability to a wider population. We believe this is appropriate and a robust methodological decision for a guideline evidence review that is intended to inform population based recommendations for the NHS. The

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					conclusion of our review of gabapentinoids therefore differs from that of this Cochrane review which included such studies.
GP reference panel	Guideline	010	001-002	Please advise on current drug combinations e.g. many patients are on both tramadol and amitryptylline, which is associated with increased side-effects?	Thank you for your comment. The review protocol did not include combinations of the medicines. However the committee agree that the only group of medicines that can be recommended for chronic primary pain is antidepressants and that the others should not be offered, even in combination with antidepressants.
GP reference panel	Guideline	010	003-007	Please make recommendations on effective interventions to achieve the aims in this section and/or co-ordinate publication with that of guidance on safe prescribing and withdrawal of medicines.	Thank you for your comment. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible.

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GP reference panel	Guideline	010	003-007	Please consider making interim recommendations e.g. drug prescribing contracts, urine drug testing, a national database of patients on controlled drugs to check for double prescriptions given elsewhere	Thank you for your comment. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on this topic whilst recommending here that people should be encouraged and supported to reduce or stop where possible.
GP reference panel	Guideline	011	005	We need more research on antidepressants in chronic pain- low dose? best antidepressant? duration?	Thank you for your comment. Although the evidence wasn't able to inform the details on best antidepressant, the committee did not agree this was a priority area for further research. They considered this should be based on the person's additional symptoms and the side effect profiles of these drugs. The suggested doses have been given in the rationale accompanying the recommendation. The committee considered that the duration should be informed by review of the efficacy of the medicine.

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GP reference panel	Guideline	011	005	One respondent's patients are predominantly of Pakistani heritage. They report that older women in particular have a very high incidence of chronic pain without a clinical explanation. Their beliefs and expectations can be different from those of other groups. Cultural and language factors mean that IAPT and some of the other psychological services are inaccessible and may not be appropriate. There is a knowledge gap here.	Thank you for your comment. The committee agree that these are important factors to consider and have added a recommendation in the assessment section to acknowledge that socioeconomic, cultural and ethnic background, and faith group might influence people's symptoms, understanding and choice of management.
GP reference panel	Guideline	General	General	Please acknowledge in the guideline that the majorityof the management of people with primary persistent pain falls on primary care. The access to pain clinics across the country is woeful, and the focus is often on pharmacological interventions. The change in emphasis to alternative treatment modalities and medication withdrawal will further increase the burden on primary care workload and resources (and mental health teams).	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
NIHR ARC	Guideline	15	23	*No evidence was identified.* We wish to highlight two research studies relevant to the guidelines as evidence on social interventions. The first was conducted by NIHR ARC West. This study evaluated a co-produced social intervention, that aimed to maintain the therapeutic impact of UK NHS group pain management programmes (PMPs) after their completion. A protocol was implemented to encourage patients to continue to meet in their established PMP group for patient led peer support (without clinical input) after conventional PMPs finished. The peer support groups aimed to consolidate self-management, and advance recovery of social life. Semi-structured interviews were carried out with 38 patients who had been offered an opportunity to take part in continued peer support, and 7 clinical staff to understand patients and clinician experiences and impacts of peer support groups following on from PMPs. Friendship bonds and a mutual understanding of effective ways of coping with pain encouraged participants to maintain their momentum. Moving on from professional involvement these meetings enabled people to develop a greater sense of agency. Seeing peers successfully cope	Thank you for your comment. The references provided have been checked. Neither study included a comparator arm and therefore these do not meet the criteria of the review protocol as effectiveness cannot be reliably determined by a single arm study to inform national guideline recommendations.

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				could further raise people's achievements and understanding of what was possible when living with pain. However, continuing meetings were not right for all. Reasons for not attending included lack of connection with peers. Co-produced peer support groups after PMPs can be a low-cost, effective social intervention. Groups can provide emotional, practical and social benefits, with improved self-management skills, stronger social connections and some reduced use of health services. Resources for clinicians and patients to support the development of peer support groups after PMPs based on study findings have been produced and are available at https://arc-w.nihr.ac.uk/pain-peer-support.Findings have been submitted for publication and are currently under peer review. A randomised controlled trial to test this type of social intervention is required and we welcome the NICE guideline recommendations for more research to understand the clinical and cost effectiveness of social interventions aimed at improving the quality of life of people aged 16 years and over with chronic pain. Another study on a different chronic pain social intervention was conducted at the NIHR Health Protection Research Unit in Behavioural Science and Evaluation and NIHR ARC West. It found that a	

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				pioneering pilot service set up in South Gloucestershire to review patients' use of prescription opioid painkillers for long-term pain helped many users reduce their use and improve their quality of life. The South Gloucestershire opioid and pain review service aimed to support long term users of opioid painkillers manage their pain in a GP setting and where possible, reduce their opioid use. The service ran for 24 months in two local GP practices. Dedicated project workers provided each patient with an individually tailored pain-management plan which included setting daily goals, developing a relaxation strategy, introducing exercise and improving sleep. They reviewed the types and amounts of opioid that the patient was taking, and provided support, if appropriate, to help them reduce their dose. A mixed methods studyevaluating the service found that 35 per cent of patients who used the service reduced their opioid dose while a further nine per cent stopped taking opioids altogether. On average, service users improved on all health, well-being and quality of life outcome scales, but with no change in their pain relief scores. Interviewswith patients and service providers found that patients welcomed having time to discuss their pain, its management and related psychological issues. They also wanted a long-term approach, as long-term pain is a complex issue which takes time to address. They felt benefits of the service included improved wellbeing such	

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				as greater confidence and self-esteem, being able to use pain management strategies, changes in their use of medication and reductions in their dose. Two papers have been published from this study Lauren J Scott, Joanna M Kesten, Kevin Bache, Matthew Hickman, Rona Campbell, Anthony E Pickering, Sabi Redwood and Kyla Thomas. Evaluation of a primary care-based opioid and pain review service: a mixed-methods evaluation in two GP practices in England. British Journal of General Practice 2020; 70 (691): e111-e119. DOI: https://doi.org/10.3399/bjgp19X707237 Joanna M Kesten, Kyla Thomas, Lauren J Scott, Kevin Bache, Matthew Hickman, Rona Campbell, Anthony E Pickering and Sabi Redwood. Acceptability of a primary care-based opioid and pain review service: a mixed-methods evaluation in England. British Journal of General Practice 2020; 70 (691): e120-e129. DOI: https://doi.org/10.3399/bjgp19X706097 A randomised controlled trial to test this type of care pathway is warranted, therefore we support the NICE guideline recommendations for more research to understand the clinical and cost effectiveness of social interventions aimed at improving the quality of life of people aged 16 years and over with chronic pain.	

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Norfolk & Norwich University Hospital NHS Trust	Guideline	001	007	The implication of the document is that all pain with a biomedical cause is covered by specific NICE guidance for the list: headache, low back pain and sciatica, rheumatoid arthritis, osteoarthritis, spondyloarthritis, neuropathic pain, endometriosis, neuropathic pain and irritable bowel syndrome. We would dispute that this is the case. For example, it is not clear how cervical pain, particularly radicular pain can be encompassed by this document where interventional treatment may be appropriate. This and many other skeletal pain syndromes would not be covered by Nicholas et al's (PAIN 160 (2019) section 4.2.5) description of ***primary***musculoskeletal pain. It must be acknowledged that NICE considers lumbar pain and sciatica as a secondary pain rather than chronic primary low back or limb pain.	Thank you for your comment. The committee agree that existing NICE guidance does not cover all pain conditions. Clinical judgement has to be used to supplement guidance where it is not available. Radicular pain is however covered by the NICE guideline for low back pain and sciatica, NG59.
Norfolk & Norwich University Hospital NHS Trust	Guideline	001	General	Chronic primary pain is a new concept (Nicholas et al PAIN 160 (2019) 28–37) and will be unknown to much of primary care and most non pain-specialists, including, we fear, commissioning groups. The NICE draft as it currently stands is a series of valid recommendations for the management of chronic primary pain - I.e. pain for which there is no clear underlying biomedical mechanistic explanation and for which pharmacological or interventional treatments are likely to be of harm rather than benefit.	Thank you for your comment. We agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate so that it is correctly interpreted. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well

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					as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Norfolk & Norwich University Hospital NHS Trust	Guideline	001	General	The attempt to create a guideline for the management of adult chronic pain is laudable; however, we have significant concerns regarding the document that is, particularly to the non-specialist, confusing in its terminology and layout.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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					included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Norfolk & Norwich University Hospital NHS Trust	Guideline	005	017	Further to the above, a very large proportion of patients have mixed diagnoses - a classical rheumatological referral to a pain management service might read: *this patient with longstanding rheumatoid arthritis has now developed fibromyalgia*.....ie we have the development of widespread pain in the context of pre-existing pain that might lead to a biomedical explicable central sensitisation alongside associated psychological distress. Such patients would be mechanistically and therapeutically different to a patient with a primary widespread pain condition associated with coexistent or pre-existing psycho-social stress.	Thank you for your comment. The committee acknowledge that chronic primary pain and chronic secondary pain can coexist, and that this is important to highlight. A recommendation has been added to the assessment section to highlight this, and recommendations to highlight that each type of pain should be treated according to the relevant guidance.
Norfolk & Norwich University Hospital NHS Trust	Guideline	011	028	We have major concern that complex regional pain syndrome is included within the remit of this document. It is acknowledged in Nicholas et al's review (and indeed by WHO ICD-11) that CRPS also falls within diseases of the autonomic nervous system. Whilst acknowledging that CRPS is resistant to many biomedical treatments, it is a mechanistically disparate condition for which a minority require intervention including neuromodulation. It is not	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this

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				clear how CRPS could therefore be accomodated within bot this guideline and that of neuropathic pain?	category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to where CRPS should be categorised, but it is the committee's view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there is no reason not to consider this with other types of chronic primary pain.
Norfolk & Norwich University Hospital NHS Trust	Guideline	General	General	We support a guideline that minimises the risk of over medicalisation and over-prescription for biomedically unexplained primary pain. However, the document as is, creates an alarming potential to deny access to medical, interventional and multidisciplinary treatments where a valid and mechanistically justifiable therapeutic strategy exists.	Thank you for your comment. As stated in the response to your comment above, the committee agreed that in the majority of cases the conditions that fall under the ICD-11 umbrella shared similarities to enable evidence to apply across the range of conditions. Where evidence, or expert opinion suggested different considerations were required, recommendations were tailored accordingly. For example, research

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					recommendations for gabapentinoids and local anaesthetics for CRPS.
NuroKor BioElectronics	Guideline	022	001-010	We are concerned that not offering transcutaneous electrical nerve stimulation (TENS) as a treatment option would reduce the analgesic interventions repertoire, with a potentially negative impact on patients' health and wellbeing, and also increasing the cost of chronic pain management. Herein is provided scientific evidence to support this view. Chronic pain can result from various types of injuries and diseases, but sometimes its origin is unknown. Despite the significant investments, the treatment of patients with chronic pain is often difficult and challenging (Weisberg & Clavel, 1999). Chronic pain affects patients physically and emotionally, and creates psychological and social problems that are difficult and frustrating for patients and physicians (Thomas, 2003). A systematic review and meta-analysis revealed that chronic pain affects between one-third and one-half of the population of the UK, corresponding to just under 28 million adults (Fayaz et al., 2016). This figure is likely to increase further in line with an ageing population. However, at least 40% of chronic pain patients treated in a routine practice setting do not achieve adequate pain relief (Leverence et al., 2011), which suggests that chronic pain management presents a challenge to many physicians (Sinatra, 2006). This leads to considerable frustration and dissatisfaction	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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				with the management of chronic pain (Dobscha et al., 2008; Johnson et al., 2013; Upshur et al., 2006; Wenghofer et al. 2011; Wolfert et al., 2010). However, effective chronic pain management is of primary concern to the patient and also of importance to the physician, because it has detrimental effects on health and wellbeing, daily activities and quality of life of patients (Abu-Saad Huijer, 2010; Bair et al., 2003, Banks & Kerns, 1996; Bookwala et al., 2003; Breivik et al., 2008; Kenefick, 2004). The aetiology of chronic pain is very complex and a single treatment to resolve the different types of chronic pain is currently unavailable. Furthermore, there is considerable variation in patient responses to analgesia, both in terms of efficacy and side effects (Moore et al., 2010). Chronic pain is most likely to respond to a comprehensive, integrated multidisciplinary treatment that includes various therapeutic components (Gatchel & Okifuji, 2006; Stanton-Hicks et al., 2002). Antidepressants are often prescribed to treat chronic pain, but these drugs are associated with a number of side effects (Ferguson, 2001). Tricyclic antidepressants (TCAs) generally are not well tolerated, while the analgesic effects of selective serotonin reuptake inhibitors (SSRIs) are limited and inconsistent (Dharmshaktu et al., 2012). Patients often discontinue this type of medication because the side effects occur early, while the analgesia may take several	The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended. All references provided have been checked for relevance to the review

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				weeks to occur (Park & Moon, 2010). In addition to being associated with various side effects with limited analgesic efficacy, antidepressants are also expensive (Agency for healthcare research and quality, 2007; Regional drug and therapeutics centre, 2020), increasing considerably the cost of chronic pain treatments. Therefore, it is essential to decrease the use of these medications for managing chronic pain, in order to reduce their adverse effects and decrease the cost of treatments. Taking into account this evidence, it is important to reconsider other interventions, such as TENS, which could be included in the treatments options for chronic pain management. The evidence regarding TENS effectiveness for pain management is conflicting, and requires not only description but also critique. Systematic reviews usually examine data from large numbers of studies. Reeve and colleagues (1996), conducteda systematic review and reported mixed results, with some studies showing that TENS is effective in relieving pain, and other studies suggesting that this technique is no more effective than placebo. The authors concluded that it is difficult to determine the effectiveness of this technique due to the lack of good quality trials. Even though many trials are designed with high standards, recent evidence suggests that stimulation parameters and protocols need to be considered in an assessment of TENS efficacy. In any type of intervention, including TENS, the efficacy is	protocol. The majority are not specific to chronic primary pain, with the exception of Chiu et al. which does not meet the guideline review protocol due to being a combination of TENS and exercise. Sharma et al. was not a randomised study, and therefore also did not meet the protocol criteria for inclusion.

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				dependent on treatment variables optimisation. TENS can only be efficacious when administered correctly and efficiently, applying appropriate stimulation parameters and protocols. Suboptimal selection of parameters and protocols, can result in TENS efficacy being compromised. This helps explain the mixed findings of TENS application for pain management. For instance, the stimulation intensity (amplitude) utilised is critical with TENS application. The findings from several studies, revealed that TENS administration at the strongest intensity titrated to subjects' tolerance, produces hypoalgesia, whereas lower intensities are ineffective (Aarskog et al., 2007; Chesterton et al., 2002; Chesterton et al., 2003; Claydon et al., 2008; Cowan et al., 2009; Pantaleao et al., 2011; Moran et al., 2011; Rakel et al., 2010). This because higher pulse amplitudes activate greater numbers of sensory afferents and deeper tissue afferents, resulting in greater analgesia (Radhakrishnan & Sluka, 2005). Thus, the stimulation intensity is an important factor that influences TENS efficacy in alleviating pain. Moreover, it should be noted that the stimulation intensity must be of sufficient strength in order to produce ananalgesic response (Bjordal et al., 2003; Moran et al., 2011; Rakel & Frantz, 2003; Rakel et al., 2010). Other stimulation parameters can affect TENS effectiveness, and discussing each of them is beyond the scope of these comments.	

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				Research has revealed that depending on the stimulation parameters settings, TENS application can mediate analgesia through segmental, extrasegmental and peripheral mechanisms (Chung et al., 1984a, b; Duranti et al., 1988; Garrison and Foreman, 1996; Ignelzi & Nyquist, 1976; Le bars et al., 1979; Sjolund, 1985; Sjolund, et al., 1977; Wagman, 1969; Woolf et al., 1988; Woolf et al., 1980). TENS represents an efficacious tool that can be utilised as a stand-alone treatment, and also can be incorporated into multidisciplinary interventions, comprising different analgesic and therapeutic components. A double blind, controlled study, conducted by Melzak and colleagues (1983), showed that TENS is significantly more effective in relieving chronic low back pain than sham TENS. Similarly, Cheing and associate (1999) found that TENS treatment produces a significant improvement in acute and chronic pain intensity, compared to placebo. The results from many other studies suggest that TENS administration can help improve different types of pain, including complex regional pain syndrome (Anundkumar & Manivasagm, 2004; Bilgili et al., 2016; Pandita & Arfath, 2013; Spacek et al., 1998); chronic pain following a peripheral nerve injury (Bohm, 1978); severe pain due to rheumatoid arthritis (Mannheimer & Carlsson, 1979; Mannheimer et al., 1978); pain due to peripheral nerve injury, phantom limb pain, shoulder-arm pain and low-back pain (Melzak, 1975). Some studies examined long-term usage of TENS	

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				application in individuals with chronic pain through a retrospective interview (Chabal et al., 1998; Fishbain et al., 1996). The findings from these studies revealed that patients who use TENS long-term (six months or longer) have significant decreases in pain during activities, augmented activity levels, and reduced use of pharmacological analgesics and healthcare services. A rigorous meta-analysis, carried out by Johnson and Martinson (2007), included data from 27 randomized trials on patients with chronic (three months or longer) musculoskeletal pain. The authors reported that TENS had a favourable pooled effect that was greater than placebo. Ghoname et al. (1999) observed that TENS application in chronic low back pain patients, produced significant decreases in the severity of pain, increases in physical activity, improvements in the quality of sleep, and decreases in oral analgesic requirements. A randomized, controlled clinical trial, conducted by Chiu and co-workers (2005), evaluated the effect of TENS and standard exercise in chronic neck pain patients. The results showed that after a six-week treatment, patients in the TENS and exercise groups had a better and clinically relevant improvement in pain, disability and isometric neck muscle strength, compared to control. All the improvements in the intervention groups were maintained at the six-month follow-up. Sharma and	

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				colleagues (2017) assessed the effectiveness and safety of TENS in idiopathic chronic pelvic pain. The authors reported a significant improvement in pain scores in the TENS group, compared with the control group, and some of the patients were completely pain free following TENS therapy. In a double blind, placebo controlled randomized study, TENS was applied to patients with chronic back pain either alone or in combination with neuromuscular electrical stimulation (NMES). TENS or NMES applied alone mediated a greater pain reduction and pain relief compared to placebo, and the two techniques combined produced a greater analgesic effect (Moore & Shurman, 1997). TENS is viewed by many clinicians as an effective therapeutic tool for treating chronic pain conditions, and a wide range of surveys provide evidence to support this belief (Abelson et al., 1983; Johnson et al., 1991; Verdouw et al. 1995). Thus, the results from all these studies provide evidence suggesting that TENS therapy can improve different types of pain, including chronic pain. Moreover, TENS is very versatile and can be administered in combination with pain relief medications, as there are no drug interactions. Numerous studies have demonstrated that TENS administered in combination with various types of painkillers drugs increases the analgesic effect, decreases the medications dosage requirements and reduces their side effects (Ahamed,	

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				2010, cara et al., 2011; Chandra et al., 2010; Da Siva et al., 2015; DeSantana et al., 2008; et al., 2005; Erdogan Hamza et al., 1999; Jimoh et al., 2014; Mahure et al., 2017). In addition to being efficacious and versatile, TENS has many other advantages, as it is non-invasive, non-toxic, non-addictive, almost side effects free, and there is no potential for toxicity or overdose (Electrotherapy Standards Committee, 2011; Sharma et al., 2017). Also, TENS is cost effective, especially in the long-term, and can be applied within healthcare infrastructure and/or self-administered by the patients at home (Bates and Nathan, 1980; Chabal et al., 1998; Grower et al., 2018; Pivec et al., 2013). In conclusion, optimising the variables of any treatment is vital, as it influences the effectiveness. Analogously, the optimal selection of TENS stimulation parameters and protocols is critical in order to produce an analgesic response. We suggest that such factors are not always optimised when designing clinical trials for TENS, and this could contribute to the confusion in the literature on TENS efficacy. However, there is evidence to suggest that optimal TENS application can improve different types of pain, including chronic pain. Considering the efficacy, versatility and the many advantages of TENS, we suggest that this technique should be offered as a treatment option for chronic pain	

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				management. The use of TENS would broaden the treatments repertoire, helping improve clinical outcomes and patients' quality of life, and would offer significant potential savings to the struggling healthcare systems. References Aarskog R, Johnson MI, Demmink JH et al. (2007) Is mechanical pain threshold after transcutaneous electrical nerve stimulation (TENS) increased locally and unilaterally? A randomized placebo-controlled trial in healthy subjects. Physiother. Res. Int. 12, 251–263 Abelson K, Langley GB, Vlieg M, et al. (1983) Transcutaneous electrical nerve stimulation in rheumatoid arthritis. NZ Med J 96:156-158 Abu-Saad Huijer H. (2010) Chronic pain: a review. Leb J Med, 58: 21–7 Ahamed MT. Effect of Transcutaneous Electrical Nerve Stimulation on Postoperative Pain after Inguinal Hernia Repair: A Randomized Placebo-Controlled Trial. (2010) Turk J Phys Med Rehab; 56:170-6 Anundkumar S, and Manivasagm M. (2014) Multimodal physical therapy management of a 48-year-old female with post-stroke complex regional pain syndrome.	

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				Weisberg MB, Clavel AL. (1999) Why is chronic pain so difficult to treat? Psychological considerations from simple to complex care;106(6):141-2, 145-8, 157-60; passim. doi: 10.3810/pgm.1999.11.771 Wenghofer EF, Wilson L, Kahan M, et al. (2011) Survey of Ontario primary care physicians' experiences with opioid prescribing. Can Fam Physician;57(3):324–332 Wolfert MZ, Gilson AM, Dahl JL, et al. (2010) Opioid analgesics for pain control: Wisconsin physicians' knowledge, beliefs, attitudes, and prescribing practices. Pain Med;11(3):425–434 Woolf, C, Thompson, S, King, A (1988) Prolonged primary afferent induced alterations in dorsal horn neurones, an intracellular analysis in vivo and in vitro. Journal of Physiology 83: 255–266 Woolf, CJ, Mitchell, D, Barrett, GD (1980) Antinociceptive effect of peripheral segmental electrical stimulation in the rat. Pain 8: 237–252	
NuroKor BioElectronics	Evidence review	046	017	When looking at the conclusions drawn from TENS, it strikes me that the volume/breath of evidence is low. The range of frequencies, pulse settings and wave characteristics used in the studies is therefore very limited. In addition the range of clinical applications	Thank you for your comment. The committee agree that the evidence base for chronic primary pain, which was the focus of this review, was very limited. When setting the review

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				assessed are extremely low and limited. In order to accurately draw conclusions about the application of Bioelectrical therapy transcutaneously to deliver analgesia, we would expect to see a much broader literature search looking at specific variables on the technology side as they apply to specific conditions and even specific individuals. Our research indicates that, whilst there are generalisable trends, the efficacy of bioelectronic applications relate to a number of factors, which should all be optimised per individual's case.	protocol the committee prioritise interventions to consider within the guideline scope. The review protocol focussed on the effectiveness of all types of TENS pooled, rather than the different parameters.
Oxford University Hospitals	Guideline	006	010	In terms of **managing chronic primary pain**we agree with the proposal for exercise	Thank you for your comment.
Oxford University Hospitals	Guideline	007	001	In terms of **managing chronic primary pain**we agree with the proposal for psychological therapy.	Thank you for your comment. It is correct that this section is for chronic primary pain.
Oxford University Hospitals	Guideline	008	014-015	CPP is defined as 'chronic pain in one or more anatomical regions that is characterised by **significant emotional distress**(anxiety, anger/frustration or depressed mood) or **functional disability**. Thus, recommending antidepressants does have some merit and evidence, yet because NICE have not defined CPP this recommendation at 1.3.8, the role of antidepressants has the potential to be misread as a recommended treatment for all chronic pain.	Thank you for your comment. Antidepressants are recommended for their effects on symptoms of chronic primary pain and benefits observed on patient reported outcomes related to this. A recommendation has been added to highlight this is not for depression but because they may help with quality of life, pain, sleep and psychological distress. The committee agree that it is important this

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					guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Oxford University Hospitals	Guideline	009	0015	It is our understanding that pregabalin is licensed for the treatment of generalised anxiety disorder so there is a conflict here between what CPP is and what treatment is recommended.	Thank you for your comment. Although chronic primary pain is associated with significant emotional distress, including anxiety, it is not the same as a diagnosis of generalised anxiety disorder. The committee therefore do not agree there is a

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					conflict in this regard. They acknowledge that chronic primary pain may coexist with other conditions. Clinical judgement should be used to determine the appropriate treatment option relevant to the condition being treated according to the relevant NICE guideline.
Oxford University Hospitals	Guideline	011	006	Under *Recommendations for research* the guidance flips between recommendation for research in 'chronic pain' and 'chronic primary pain'. Another area that needs editorial clarity. This again happens under the section of *'Other recommendations for research'*	Thank you for your comment. Both have these sections have been reorder for clarity.
Oxford University Hospitals	Guideline	014	019-024	The document recommends having longer consultations or that additional follow up may be needed to discuss self-management and treatment options. This is something that we as clinicians have been lobbying for years. We fully support this paragraph. Commissioners and NHS Trusts management need to acknowledge this if this guidance is approved.	Thank you for your comment. The committee highlighted this as something that may be required to change in practice for these recommendations to be fully implemented.
Oxford University Hospitals	Guideline	019	020	Offering a passive treatment such as acupuncture but not offering a patient directed treatment such as TENS doesn't make sense. Manual therapy is passive	Thank you for your comment. The committee agreed there was a large body of evidence of benefit for acupuncture across a range of

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				treatment and is also not supported for CPP but acupuncture is.	outcomes, and it was demonstrated to be cost effective by de novo economic analysis. For both TENS and manual therapy the committee agreed the evidence base was too limited for a recommendation. The evidence for manual therapy was more promising than that for TENS and so in that case the committee included a research recommendation to inform future updates of the guideline.
Oxford University Hospitals	Guideline	6 & 10	8 & 14	The guidance goes into 'Managing chronic primary pain at section 1.3 (page 6), yet the definition of chronic primary pain appears on page 10. An emphasis needs to be made that NICE must **provide clarity that chronic pain and chronic primary pain are not the same thing**. The guidance as it stands at the moment is open to misinterpretation, particularly by commissioners who know very little about managing patients with chronic pain conditions.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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					included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Oxford University Hospitals	Guideline	General	General	The draft is difficult to understand. The draft is titled '**Chronic pain**in over 16s…' the guidance says it should be used alongside other guidance but then it goes on to talk extensively about **chronic primary pain**.	The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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					clarifying what populations are covered by each recommendation.
Oxford University Hospitals	Guideline & Evidence review G	007	007	We do not agree that acupuncture should be offered for CPP. There is a very limited evidence base for acupuncture and we suspect this intervention is promoted by an enthusiast on the committee. We question if the 27 studies quoted are for CPP. We question how NICE as an organisation committed to evidence based medicine quote 27 articles (generally with small sample size and a wide heterogeneity of the study populations) that only show short term (3 months) benefit for an intervention in a chronic condition. The document states that 'The model showed that acupuncture was likely to be cost effective.' We question this assessment. Acupuncture was stopped in secondary care because it led to unmanageable waiting lists. We cannot see primary care taking on a treatment that only provides short term relief for a chronic condition even with the caveats listed on page 20	Thank you for your comment. NICE declaration of interest policies were adhered to throughout guideline development. The committee member with a conflict relating to acupuncture withdrew from all discussions in decision making on this topic, as detailed in the declaration of interest register. All 27 studies met the inclusion criteria for chronic primary pain specified for the review. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care. Benefits were also observed in function and psychological distress. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive

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					evidence than other interventions reviewed in the guideline. De novo cost effectiveness modelling was undertaken in line with NICE methodological guidance based on clinical evidence identified in the systematic review. Full details are available in the modelling report.
Pain Concern	Guideline	General	General	We are deeply concerned by this guidance, by the use of a barely out of the blocks definition of chronic primary pain on which evidence has not been developed with its use as yet. The conflation of all types of chronic pain together with this new definition, the lukewarm support for pain management programmes, the lack of balance on pharmacological advice, the poor statement on acupuncture and the confusion with self-management has caused members deep concern. In what is a difficult and complex area overall we feel there is too much reliance on papers and not enough interpretation by experts We feel this statement from one of our members sums it up : "*Surely the best thing to be done is to fully inform chronic pain sufferers of all the risks any medication comes*	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in

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				with and let the patient decide what is best for them. The health professionals say they 'must do no harm' yet by the current blanket policies they harm the patients more in allowing the intractable pain to take over the sufferers'lives causing them so much despair that suicide seems the only option of escape."	the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews,

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					types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). Recommendations were made in accordance with Developing NICE guidelines: The manual as well as the methods chapter for this guideline. The committee agree they reflect best practice and recommend the treatments that demonstrate benefit for people with chronic primary pain.
Pain Concern	Guideline	General	General	The Guidance is better separated into two documents - Chronic Pain and Chronic Primary pain (or chronic primary pain removed due to the lack of research directly	Thank you for your comment. The guidance needs to reflect the areas

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				appertaining to it). Otherwise commissioners and managers will conflate two which is too risky. "*Without the strong and systematic underlying knowledge base, Chronic Pain: assessment and management as a document, will only serve to confuse and distress the medical community at large causing more, not fewer, problems than are presently plaguing people suffering with chronic pain, and those that care for them."*	that were agreed to be covered as set out in the scope. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation.
Pain Concern	Guideline	014	010	*"The committee seems not to have taken account of the complexity of education and self-management for chronic pain. Getting people to adopt, and adhere to, self-management techniques (and the cognitive and behavioural changes these require) is quite difficult enough without withdrawal of appropriate pain medications which can support the patient through these changes. "*	Thank you for your comment. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain,

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					and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits. They agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.

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Pain Concern	Guideline	004	General	In assessment of chronic pain we welcome the approach - emphasising the biopsychosocial approach. However, no tools provided to support this. Such tools are available and we would recommend an evaluation of these. Without such tools we are concerned that clinicians will be unable to carry out a structured assessment. Most assessment is in primary care where use of templates is the norm. The Chronic Pain Navigator Tool produced by Pain Concern was designed to meet this need and to be used by both patients and clinicians https://painconcern.org.uk/navigator-tool/	Thank you for your comment. Tools for assessment were not raised as priority areas to include within the guideline during scoping or when setting the protocols and therefore recommendations cannot be made.
Pain Concern	Guideline	005	018 - 020	Our greatest concern is that Physicians have enough issues with diagnosis and this guideline will confuse them further. Patients have picked up on this and feel this will worsen this and their future care The lack of definitions, and the lack of clarity surrounding the different types of chronic pain is deeply concerning. When the consultation documents were published many patients assumed that chronic pain encompassed all chronic pain, which is what the title of the draft document implies. However, the draft guidance itself appears to be aimed primarily at chronic primary pain. Conflating Chronic Primary Pain and Chronic Secondary Pain in this way will only serve to confuse patients and their busy clinicians. Detail from ICD - 11 as to how to make the diagnosis isn't included and in fact there is no research to support how to do this as yet	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in

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				We have included some quotes from our members: *"There should be more emphasis on the definition of both pain generally and the different classifications of chronic pain as set out by ICD-11. These definitions are new and many people, clinicians and patients alike, are confused or naive about these new definitions."* *"..Already taken many years to get a diagnosis in the experience of patients – lots of labels but no diagnosis – now separation of chronic pain into a heterogenous group of disorders has helped diagnosis. This (guideline) is a backwards step."*	the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. A recommendation has also been included for when to consider a diagnosis of chronic primary pain.
Pain Concern	Guideline	006	001 - 006	Pain Management Programmes (PMP): PMP is a multidisciplinary solution . PMP applies to all pains PMP's are based on specific psychological treatment to achieve behaviour change in the areas where chronic pain management is thought to be effective.eg most (85%) are based on these Cognitive Behaviour Therapy or /Acceptance and Commitment Therapy .The nature of a PMP is to learn effective self-management of pain, of which the implementation into daily life takes considerable time. Although it is not a 'quick fix' solution, it does provide the permanence of many significant long-term benefits and improvement. We wondered if the 8	Thank you for your comment. The review included 26 studies, as detailed in evidence review C. The 8 studies referred to in the rationale were the only ones that demonstrated a benefit in quality of life. The committee's opinion was that it was important and appropriate to review psychological therapies as a standalone intervention as well as when included as part of a pain

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				studies selected to represent the PMP were adequately reflective of the success of this long-term process. As 85% of PMPs that are delivered in the UK follow either a CBT or and ACT approach, and therefore would be considered as psychological therapy, that the studies considered in this section do not represent the clinical reality of the UK situation. This is potentially harmful for the provision of pain management programmes as the guidance might lead to these services being de-commissioned. This also reflects the definitional confusion in the document, which specifies in some detail what might comprise a pain management programme, but is satisfied with psychological therapies defining themselves by the labels the authors have chosen. Examination of some of these studies of psychological therapy suggest that they would meet the definition of a pain management programme.Definitions of what is a PMP and what is psychological therapy need to be clearer. We are also concerned that the guidance does not reflect the lived patient experience for example: *'there were no benefits observed in terms of physical function and psychological distress. Where benefits were observed, they were only small' to be greatly uncharacteristic of my own, and numerous other graduates experience*	management programme. This was in part because the two reviews were in different sections of the guideline scope; the pain management review covered all types of chronic pain, whereas the guideline was also covering specific pharmacological and non-pharmacological interventions for chronic primary pain only. It was agreed important to include psychological therapies within these interventions. The definition of pain management programme agreed by the committee for the review protocol was 'any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two'. This was deliberately not too specific to exclude too many studies, but the committee agreed there

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				We are concerned that this guidance also does not really shed light on how this will be applied to all chronic pain - a number of patients have come back to say they have found PMP very helpful as below: "*although the benefits of Pain Management Programmes on pain may be hard to quantify for cost-effective purposes and duration, it doesn't mean that they are not a) cost-effective in the long-term, b) sustainable, orc) the most effective treatment of Chronic Primary Pain available to date. "* .	needed to be a physical component as well as psychological. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of

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					life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may

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					be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline.
Pain Concern	Guideline	006 - 007	010 - 017	Managing chronic primary pain : Patients agree exercise is helpful but often through working with someone who understand pain physiology (sensitised nervous system) and in the context of pacing - this is often applied thoughtlessly so context is important ….we would suggest that patients are given the tools to manage flare ups first before contemplating exercise. A physiotherapist who has had training in delivering physiotherapy using psychological principles may be a good suggestion. There is some evidence to support this both from the Clinical and Patient perspectives	Thank you for your comment. The committee agree there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. They also agree that it is important that assessment and care and support plan development includes considering flare up of pain, and have now added a recommendation in section 1.1 to address this.
Pain Concern	Guideline	007	001 - 006	**Psychological therapies relaxation therapy, mindfulness and psychotherapy**: This isn't something you dish out like a pill – it has to be placed in context of the pain Context is missing from the RCT's . CBT/ACT as applied and developed for chronic pain is missing	Thank you for your comment. The searches and sifts of the literature were not restricted to the term 'chronic primary pain'. They were broad and inclusive to include all conditions that were included under

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				Again this may be because the diagnosis is too new - there may be enough research out there for all chronic pain and this is what needs including. *", I feel it to be somewhat short-sighted to not recognise the connection between pain and distress, and consequently thebenefit which relaxation therapy, mindfulness and psychotherapy provides."*	the ICD-11 umbrella term of chronic primary pain at the time of development of the guideline. Full details of the search strategies are available in appendix B of each evidence review chapter.
Pain Concern	Guideline	018	025	**Hypnosis, pain education and sleep hygiene for chronic primary pain:** What is meant by pain education ? It is unclear. We feel that a primary care doctor is unlikely to know what is understood by this . It is concerning that only one study is cited on mindfulness despite the wealth of evidence to supports its use in chronic pain. This is because the guideline group focussed on chronic primary pain, however this diagnosis is too early in its life cycle to consider grouping treatments into it. Sleep hygiene – the one study included showed an effect the group threw the work out. This yet again demonstrates how psychological interventions can in no way ever match up to other trials. *""Pain education, incorporating aspects of sleep hygiene has been an invaluable tool of my successful pain management and has allowed me to self-manage my condition, without having to regularly visit my GP."*	Thank you for your comment. The protocol included any study definition of pain education. The specific details of the interventions are given in the evidence tables and in the summary of included studies in evidence review F. The committee have expanded on the discussion of this in the discussion of evidence in the evidence review for clarity. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. The conditions that were included under the ICD-11 classification of chronic primary pain at the time of guideline

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					development were included within the review population, with the exception of those already covered by existing NICE guidelines. The searches and sifts of the evidence were therefore broad and inclusive of any studies that may fall under the umbrella term of chronic primary pain, rather than limiting to studies that used this specific term. The evidence for sleep hygiene was carefully considered by the group. This was from 1 small study and although the committee noted it reported promising results it was insufficient to inform a recommendation for its use on the NHS. The committee agreed further research was required. Another study demonstrated that sleep hygiene was less effective that CBT for insomnia however. As a research recommendation was included for CBT for insomnia, the committee considered this would include elements of sleep hygiene and a separate research recommendation

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					wasn't required. This is explained briefly in the rationale in the guideline, and in more detail in the committee's discussion of the evidence in chapter F.
Pain Concern	Guideline	007	007 - 015	**Acupuncture** :Due to short lived benefits this needs to be conducted in the context of sensitised nervous system and biopsychosocial approach. It is unlikely that a junior physiotherapist would have this level of knowledge and skills and so it may not be cost effective in the real world. A short course only and restricted , in the context of many years lived with pain is not how acupuncture should be approached with this group. Separation is needed between cost effectiveness and effectiveness to explain decision making to the taxpayer.	Thank you for your comment. The guideline recommendations assume that all people delivering the interventions recommended should be appropriately trained to do so. This has been added to the recommendation for clarity. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the

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					treatment options should be discussed at all stages of care.
Pain Concern	Guideline	008 - 010	030 - 010	**Pharmacological management for chronic primary pain** There is a risk of throwing baby out with bathwater – as guidance can be applied thoughtlessly to all types of chronic pain rather than chronic primary pain It is unclear what search strategy was used. What did the search cover ? We have significant concerns that to thoughtlessly withdraw drugs could cause huge drops in function and distress .A large group RCT should be supplemented by n of 1 studies - as this reflects clinical practice Also it might be useful to review See Andrew Moore on only small numbers in each group actually benefit Moore A, Derry S, Eccleston C, Kalso E. Expect analgesic failure; pursue analgesic success. Bmj. 2013 May 3;346:f2690.Comments in drugs section are made as if mechanisms fully understood which is not the case *"Overall I would say that I am not a fan of using medication, following early attempts from primary care services (prior to my being accepted to the Glasgow Pain Management Programme) to manage my pain with opioids and various others, which I found to be detrimental to my overall health, pain and mobility. However I do recognise the benefits of medication when used moderately, carefully and in combination with other strategies and techniques.*	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.

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				Medication alone will have some impact on pain, but not as much as the incorporation of other tools. " The part of the guidelines which is of most concern to chronic pain sufferers is the assertion that chronic pain patients not be given analgesia to help them.*"I think most people with chronic pain will agree that the side effects of drugs used are horrendous. My concern here is that removing drugs without adequate support during withdrawal is not that helpful. The report mentions that work needs to be done in developing this support. I think that should be in place before just stopping the drugs. My experience when I did decide to reduce drug intake was that I got no advice on how to do it and what to expect from my GP. The pharmacist was my chief source of help. So some thought needs to be put into what is needed here."* *"The only medication fully recommended by NICE are antidepressants. Yet they also come withserious side effects in the shape of "serotonin syndrome" and cognitive impairment."*	The methods followed in the development of the guideline are consistent with those detailed in Developing NICE Guidelines: The Manual, and the Methods chapter for the guideline. The search strategies for each review question are detailed in appendix B of the relevant chapters. The protocols for each review (in appendix A) detail the study design that is appropriate to answer each review question. For intervention reviews, the best quality evidence widely recognised in evidence based medicine is RCTs or high quality systematic reviews of RCTs. When setting the protocol for this review it was agreed that the best quality evidence should be used to inform recommendations on this topic. N of 1 trials or case studies were agreed as not sufficient quality to include. The committee discussed that the limitations of such evidence include that they are not controlled and have

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					no comparator, therefore are particularly at risk of being impacted by the high placebo response rate observed in pain studies and cannot inform on true effectiveness of an intervention. This evidence is therefore not generalisable to a wider population. The committee agree that mechanisms are not fully understood. They do however agree that the conditions that fall under the umbrella term of chronic primary pain are likely to share similar features such that there is no reason recommendations cannot be made across this group of painful conditions, unless evidence suggests otherwise. The committee agree that supporting people withdrawing from ineffective and/or harmful medicines can be difficult and further support may be required. They highlight the upcoming NICE guideline on safe prescribing and withdrawal management. The

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					committee do not agree that it is appropriate to continue people on such medicines until there is further support. Healthcare professionals are already having to support people through stopping or reducing medicines, and should do so where it is known that risks outweigh the benefits. The committee agree that the side effects of antidepressants should be considered when making a decision to use these medicines. The recommendation states that this decision should be made after a full discussion of the benefits and harms.
Pain Concern	Guideline	024	017 - 025	**Opioids for chronic primary pain** Generally we are supportive - See Opioids aware guidance and NICE KTT 21 - much of what is here is already contained within these documents. This will be a small group of patients – guidance is to withdraw carefully – what tools and resources (including workforce) will be made available for general practitioners to achieve this? What incentives will there	Thank you for your comment. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. This guideline highlights areas where resources should be focussed and those interventions that

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				be for PCN's to do this? Some areas have pharmacists - could a recommendation be made for PCN's to provide this level of support? It is unclear from the guidance when to refer for an expert opinion on this	should not be recommended, saving resource in other areas. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible. The committee did not review the evidence for when to refer, however it is the committee's opinion that chronic primary pain can be management in primary care as well as secondary care. Clinical judgement should be required if referral for a specialist assessment is thought necessary.

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Pain Concern	Guideline	025	010 - 025	**Anti-epileptics for chronic primary pain**: this is at odds with the Cochrane review on Fibromyalgia and doesn't match the patient experience in some instances. *"I have discovered that discontinuing the use of gabapentinoids has resulted in the reduction of my physical function, mobility and quality of life. "* Again responder analysis needs to be considered when interpreting trial results. Moore A, Derry S, Eccleston C,Kalso E. Expect analgesic failure; pursue analgesic success. Bmj. 2013 May 3;346:f2690.	Thank you for your comment. The committee were aware of the relevant Cochrane reviews and their conclusions. They were fully considered when undertaking this review and all of their included studies were checked for relevance for inclusion in this guideline review. A key difference was the inclusion of studies with an enriched enrolment design / placebo run in phase. When setting the review protocol for the pharmacological review included in this NICE guideline the committee agreed these should be excluded, the reasons are set out below. Placebo run in studies: While this can be a useful methodology employed in a proof of concept study, it does not provide a generalizable estimate of the efficacy of the medicine in the general

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					population. There are two main concerns: 1, such trial designs will likely increase the observed magnitude of effect of the medicine compared to the placebo group as placebo responders are removed. Whilst the placebo response in pain is known to be high, this is reflective of how the general population are likely to respond, and so excluding these gives a biased estimate of effectiveness gained from these trails compared to those without a placebo run in phase. 2 – the side effect profile of many of these medicines (including pregabalin) are notable. Having a placebo run in phase can effectively unblind study participants as they are able to notice the difference between tablets received. This again biases the results of the study, generally in favour of the active intervention when in a clinical trial setting. Enriched enrolment design:

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					The committee considered that including enriched enrolment design studies would not provide the committee with an overview of the effect of pharmacological interventions for people with chronic primary pain and would not support their decision making for this population as a whole. By including studies that only recruit known responders there are difficulties with interpreting the data for a patient population, particularly for people that have not been prescribed the drug of interest previously. By the nature of these studies people that don't respond (but are diagnosed with chronic primary pain) are not included. The effect of this is to likely increase the observed magnitude of effect of the medicine in a population when it is known not to be effective for some people. It does not provide a generalizable estimate of the efficacy of the medicine in the general population. In addition, the concerns re the side effect profile stated above

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					(in our discussion about placebo run in studies) also apply here. Responder criteria for pain were discussed and included for pain, however this was agreed only to be used when continuous data were not reported by the study for that outcome. This has been clarified in the methods chapter. Number of responders was very rarely reported in studies, with the exception of the pharmacological studies where it was more commonly reported. It would therefore not have been possible to apply consistent thresholds across reviews for different interventions had this been used as a basis of determining clinical importance.
Pain Concern	Guideline	026	012 - 019	**Withdrawing medicines/How the recommendations might affect practice** There should be greater emphasis in the guidance on the harm that can occur	Thank you for your comment. The committee agree that people should be supported to withdraw from these medicines if a shared decision has

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				The guidance needs a lot more on tools to support the clinician and patient in doing this **"**"*withdrawal of medicines should be reviewed exclusively on a case-to-case basis, with focus on the needs of the patient outweighing the cost effectiveness of the action. I feel that more research should be obtained before blindly concluding that withdrawing medication, such as anti-depressants, will 'have wider benefits both to an individual and to society by, for example, enabling people to return to the workforce'"*	been made to do so. The recommendation has been reworded to state that people should be encouraged and supported to stop or reduce where possible. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible.
Pain Concern	Guideline	010	010 - 013	3.13.13 Shared Decision Making people have the right to be involved in discussions and make informed decisions about their care. *"Any chronic pain sufferer will tell you that this just does not happen inthe real world. They just get told their drugs are going to be stopped."*	Thank you for your comment. The committee agree that evidence reviewed in the guideline on communication between people with chronic pain and healthcare professionals supported you concern that although some of these points appear to be best practice, there are shortcomings in people's experience

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					of consultations with healthcare professionals. The committee therefore agreed it was important that the recommendations on assessment and development of a shared care and support plan are central to this guideline. These recommendations reinforce the need for shared decisions. This is again reflected in the section on pharmacological management particularly in the recommendation for the review of people who are already receiving these medicines. This highlights considerations both for those who aren't receiving benefit and also those who are and report low harms again restating the importance of a shared decision.
Pain Concern	Guideline	General	General	*"On the one hand NICE say analgesia isn't allowed – only self-management is, but there is no evidence it actually works. The 28 page guidelines just confirm the complete disarray and understanding of chronic pain conditions."*	Thank you for your comment. The committee recommend those treatments for chronic primary pain where there is evidence of benefit; exercise, CBT or ACT, acupuncture or

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					antidepressants for their effects on the symptoms of chronic primary pain.
Pain Concern	Guideline	022	001 - 018	1.3.16 Electrical Physical Modalities TENS is a good example of a tool in a Flare-Up Plan. The big difference between it and the other modalities mentioned is that it is an active strategy as part of self management whereas the others are passive techniques needing to be delivered by an HCP.	Thank you for your comment. The committee agree that there is no evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up.
Pain Concern	Guideline	Gene ral	General	COVID: " *Overall I think the guidelines are very sensible and should improve matters. I am concerned with the lack of resources that are likely to be available and the document makes really passing reference to this saying as I read it that it will take*	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions

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				more! If Chronic pain is as widespread as even the pooled mean then it is going to require A LOT. In the middle (or the beginning) of a pandemic which is increasing the size of waiting lists daily I fear the resources will not be there. Pain management NEEDS face to face contact I think to work most effectively (although I could be wrong). Now that most of the consultations we have are by telephone how will this affect effective treatment for pain? Perhaps NICE needs a wee appendix to tell us what it thinks?"	as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be

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					recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Pain Psychology in London	Equality Impact assessment	002	003.4	As stated elsewhere in the guidance, about half of people with chronic pain have depression. Depression can include lack of motivation. Low motivation can make it very difficult for people to access many interventions. Furthermore, people experiencing depression may be accessing psychological therapy or other support within a mental health service. Under these circumstances, some people will struggle to engage with another type of psychological therapy at the same time. As such, it may be helpful to suggest how there can be a compromise e.g. pain psychology may be more focussed or sessions less frequent, to ensure patients are not overwhelmed. Secondly, depression will impact on how people engage with appointments more generally; they will be more likely to struggle to attend appointments and more likely to not attend. As such, services can liaise with mental health services in thinking about how to improve accessibility, co-produce their Access Policy with local service users, & clearly communicate, this Access Policy at all stages of care, including before the person attends their first appointment by having this on the service website. Improved accessibility may include text reminders, making it easier for patients to contact services to change	Thank you for your comment. The committee agree this is an important consideration, and should be something that is considered within the person-centred assessment of the person. The recommendations include highlighting the need to discuss how the person's pain impacts on their physical and psychological wellbeing and vice versa (amongst other factors). The committee agree that a care and support plan should be developed with the person, based on their priorities, abilities and goals.

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				their appointment times or to choose a more convenient time initially, and clarity/boundaries around how many appointments can be missed before the person is discharged. There should also be inter-agency working to make decisions about how to address engagement difficulties.	
Pain Psychology in London	Equality Impact assessment	003	003.6	There should be consideration of social differences (gender, race, religion, class, ethnicity, sexuality) and how these impact on engagement with interventions. Some interventions may be less accessible to people due to those social differences. For example, metaphors and examples used to help patients relate to information given are often framed from a locally dominant social perspective (i.e. white, middle class, heterosexual). This can impact on engagement, therapeutic relationships and social dynamics, especially in group settings. This article demonstrates that a PMP can be effectively adapted for the Turkish community: Perry, Gardener, Oliver, Taz, Ozenc (2019). Exploring the cultural flexibility of the ACT model as an effective therapeutic group intervention for Turkish speaking communities in East London. The Cognitive Behaviour Therapist, Vol 12, e2, 1-25. Currently many services are investing into online interventions. These improve accessibility for some, but	Thank you for your comment. The committee agree these factors need to be considered in the assessment of people with chronic pain and included a recommendation highlighting this: 1.1.7 Be sensitive to the person's socioeconomic, cultural and ethnic background, and faith group, and think about how these might influence their symptoms, understanding and choice of management.

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				exclude others, such as those without broadband, the right equipment, a private space at home, and confidence with using technology.	
Pain Psychology in London	Guideline	004	018	The use of the word "acceptance" can be unhelpful, due to its ambiguity. There's lots of literature around patients and staff having different definitions for this, and so patients can often either find this word dismissive, or assume we mean "stop trying to do things you used to do". This tends to change as patients progress through using pain services. It's helpful to unpack this word and use more patient-focussed language, perhaps by consulting a service user involvement group.	Thank you for your comment. On consideration of stakeholder comments the committee agree that the word 'acceptance' should not be included in the recommendation and have now removed it.
Pain Psychology in London	Guideline	005	004	"their family or carers" – many people will be estranged from family due to the toll of chronic pain on relationships. Reinforcing in staff minds that those closest to the patient is usually family can influence the language staff use to assess and support patients with chronic pain, thereby potentially missing and invalidating other significant relationships. Whilst some patients have carers, this is a loaded term in relation to power; some people with chronic pain will call those who help them "carers" but not all, and again, it can be disempowering to people with pain to infuse language with power when it's not strictly necessary. It may be	Thank you for your comment. The committee acknowledged and considered this when forming the recommendations and included all of the term 'family, carers and significant others' to encapsulate different circumstances as appropriate to the person.

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				more respectful here simply to use "significant others" or "personal networks"	
Pain Psychology in London	Guideline	006	002	This could have a big impact on commissioners' and patients' impression of PMPs and how valid/ effective they believe them to be. The language used will be misleading to those who don't understand that building an evidence base is a very complex matter; that will include most patients. Alternative language could be more constructive and informative here.	Thank you for your comment. The committee agreed that the evidence reviewed did not inform a recommendation for or against the use of pain management programmes. The guideline definition of a pain management programme has been included in the 'terms used in this guideline' section for clarity. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for

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					this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline.
Pain Psychology in London	Guideline	010	002	Staff should be directed to do more than "explain the risks" of continuing. I'm sure that it's hard to capture the complexity of what effective pain management support looks like in practice, but the current phrasing implies that medication support is a separate topic to other aspects of pain management. We know in practice that patients need more than an explanation of risks to support them in even considering reducing medications.	Thank you for your comment. This recommendation has been reworded to include different considerations, and in those reporting little benefit or significant harms, to support them to reduce and stop where possible as well as explaining the lack of evidence for their effectiveness and the risks of continuing. The committee agree that additional support may be required and highlight the recommendations on stopping or reducing

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					antidepressants in the NICE guideline on depression in adults as well as the upcoming guideline on medicines associated with dependence or withdrawal symptoms.
Pain Psychology in London	Guideline	014	014	It could be helpful to be more specific about what's meant by "all stages of care" e.g. this starts with the GP, and when people have acute pain. If patients receive advice about how they should manage pain when it's acute, many will assume this continues to be correct no matter how long they have the pain for.	Thank you for your comment. Management of acute pain is outside the scope of this guideline. The committee agree it is appropriate to leave this statement as 'all stages of care'.
Pain UK	Guideline	001	007	50.81% reduction in quality of life with the pain regime they are currently on, so our concerns are the reducing or restricting pain medication will only make this statistic raise.	Thank you for your comment. We note your concern, however the evidence reviewed suggests that many of the pain medications do not have a beneficial effect for most people and other management options would better improve their quality of life.
Pain UK	Guideline	004	015	We found that pain effects almost 30% of peoples work life 100% of the time. We are concerned that with the guideline recommendation to reduce the amount of people on pain medication that this will in turn raise the percentage of people that have their work life effected by pain.	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where

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					there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain, including improving their ability to engage in activities of daily living, such as work where that is relevant.
Pain UK	Guideline	004	015	We found that almost 46% off the people owe surveyed said that Pain effects their lifestyle 100% of the time, if removing medication from these people, we are concerned that this figure will rise.	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain, including improving their ability to engage in activities of daily living.
Pain UK	Guideline	004	015	We found that almost 48% of the people we surveyed said that pain effects their sleep 100% of the time. We are concerned that removing medication from these people will raise this figure	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of

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					benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain. Sleep was included as an outcome in the reviews of interventions for chronic pain. There was evidence to suggest that acupuncture and psychological therapies improved sleep.
Pain UK	Guideline	004	016	We are concerned about the reduction of pain medication as we have found that from the 124 people we surveyed over 50% have said that their pain effects their physical ability every day. This is a concerning statistic in its self. With a reduction in the prescription of pain medication this figure can only rise.	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic

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					primary pain, including improving their ability to engage in activities of daily living. Physical function was included as an outcome in reviews of interventions for chronic pain. There was some evidence to suggest exercise and psychological therapies led to improvements in physical function.
Pain UK	Guideline	004	016	Nearly 40% of the 124 people we surveyed have said that they are effected Psychologically by pain. We are concerned that this figure will rise and will therefore have a knock on effect to the currently struggling mental health services if GP's are to reduce the amount of pain medication prescribed.	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain, including improving their ability to engage in activities of daily living. Psychological distress was included as an outcome in reviews of interventions for chronic pain. There

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					was some evidence to suggest acupuncture and psychological therapies led to improvements in psychological distress.
Pain UK	Guideline	004	017	We have found that from the 124 people we surveyed that almost 40% scored 10 out of 10, that pain effects their personal relationships. Our concern is that this figure will rise if pain medication prescriptions are reduced.	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain.
Pain UK	Guideline	004	017	Over 28% of people we surveyed have said that pain effects their social life, with a 10 out of 10 on the survey. Social interaction is we feel important and the reduction of pain m medication can only raise this figure.	Thank you for your comment. The committee agreed that there was no evidence that these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of

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					chronic primary pain and better outcomes for people with chronic primary pain.
Pain UK	Guideline	006	002	We asked our 124 responders on a scale of 1 - 10 did you benefit from the pain management course - Our results show that almost half of the people we surveyed found this corse beneficial. Our concern is that this is only a small survey and that more data needs to be collected on a larger scale, to confirm or refute the usefulness to those that live with chronic pain or chronic primary pain.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of

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					life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.
Pain UK	Recommendations	004	011	We surveyed 124 people, and have evidence to support the fact that patients do not feel believed regarding chronic pain	Thank you for your comment. This was a theme that also came from the qualitative review undertaken and we agree it was important to highlight in the recommendations.
Patient Led Engagement for Access	Evidence Review J	040	012	The cost of unlicensed cannabis-based medicines has significantly reduced. Patients are now reporting costs through the private sector between £30-600 per month for unlicensed cannabis-based medicines, depending on product and quantity prescribed. A significant proportion of costs associated with cannabis-based medicines is resulting from importation, licensing and transportation. The costs of cannabis-based medicines could be significantly reduced further if bureaucratic barriers were	Thank you for your comment. During the development of this guideline the NICE guideline for cannabis based medicinal products was commissioned and published. This guideline covers the use of these for a range of conditions and therefore it was agreed appropriate to cross refer to this for

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				removed. These costs are significantly lower than those associated with nabilone.	all guidance and considerations for cannabis based medicinal products.
Patient Led Engagement for Access	Evidence review J	064	044	Cannabis has a large number of active compounds, including cannabinoids, terpenes and flavonoids. Limiting further research to cannabidiol excludes understanding of the potential of these compounds and their synergy. There are currently no active NIHR studies being undertaken into chronic pain and cannabis based medicinal products, therefore funding should be made available to undertake research into safety and efficacy of a range of cannabis based medicinal products, with varying cannabinoid contents. Patient involvement is key to ensuring research undertaken accounts for lived experience and meets the needs of patients.	Thank you for your comment. Oral cannabinoids (nabilone, nabiximols oromucosal spray) were included within the protocol for the review of pharmacological interventions for chronic primary pain, and the committee agreed there was insufficient evidence for a recommendation, but that further research was important. During the development of this guideline the NICE guideline for cannabis based medicinal products was commissioned and published. This guideline covers the use of these for a range of conditions and therefore it was agreed appropriate to cross refer to this for all guidance and considerations for cannabis based medicinal products.
Patient Led Engagement for Access	Guideline	005	009	Patients discussing cannabis-based medicines with their clinician have often reported incidents of stigmatisation and inappropriate comments. Clinicians often do not have the training to understand the complexities of medicinal cannabis, including regarding consumption methods,	Thank you for your comment. The guideline does not recommend the use of cannabis based medicinal products for chronic primary pain,

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				benefits, risks and side effects. As an increasingly explored treatment option for chronic pain patients, it is essential that clinicians receive education into the endocannabinoid system and medical cannabis in order to support their patients.	however the committee did agree that there was a need for further research. The guideline cross refers to the NICE guideline on cannabis-based medicinal products where further research is recommended.
Patient Led Engagement for Access	Guideline	024	010	We are concerned that this recommendation does not address the fact that an estimated 174049 - 305497 chronic pain patients (95% CI) are consuming illegal cannabis to manage their condition. Cannabis obtained illegally causes significant risk to the patient from consuming unregulated products and the harms of criminalisation. Cannabis obtained from the black market is often highly concentrated in THC, which can cause further harm when misused. In the interim of further research into the safety and efficacy of medicinal cannabis being undertaken, observational studies should monitor outcomes of patients prescribed unlicensed cannabis based medicines. With no risk of fatal overdose and incidences of serious side effects significantly reduced following careful screening and prescribing by clinicians, cannabis based medicines are a safer option than many currently prescribed medications. Facilitating observational studies is both a harm reduction measure and necessary for research purposes. According to the NHS Five Year Forward Plan (2014), 'NHS England already has a £15m a year programme, administered by NICE, now called	Thank you for your comment. Oral cannabinoids (nabilone, nabiximols oromucosal spray) were included within the protocol for the review of pharmacological interventions for chronic primary pain, and the committee agreed there was insufficient evidence for a recommendation, but that further research was important. During the development of this guideline the NICE guideline for cannabis based medicinal products was commissioned and published. This guideline covers the use of these for a range of conditions and therefore it was agreed appropriate to cross refer to this for all guidance and considerations for cannabis based medicinal products.

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				"commissioning through evaluation" which examines real world clinical evidence in the absence of full trial data. A managed access programme could utilise the Innovative Medicines Fund for England.	
Patient Pain Support Group	Guidance	016	006-013	In our view, there are a number of factors that are likely to give rise to inconsistent results in the effectiveness of PMPs. One reason for their apparent lack of efficacy in some cases could be that the benefits of attending a PMP, in our collective experience, can often be delayed, as the information can take a while to be assimilated. As one member of our patient pain support group (PPSG) described, "I enjoyed my PMP but at the time I didn't think I had learnt much. But what I realise now is that they are embedded in my behaviour now so I must have learnt, just didn't realise it at the time." This member now acknowledges that two years on, it has been techniques that they learnt at the PMP thathave enabled them to return to full-time work. PMPs provide patients with the necessary tools to improve their self-management, enabling them to become much more active and live more fulfilling lives despite their pain. We believe it would be a mistake to evaluate the cost effectiveness of PMPs solely on the basis of the duration of the programme itself, as the longer-term benefits need to be considered. This includes peer support amongst those who have forged connections through doing a	Thank you for your comment. The committee agree there may be factors that impact on the results of the evidence review. They discuss their interpretation of the evidence in section 1.7 of evidence review C. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may

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				PMP, which has provided incalculable benefits to members of our PPSG. Instead, we would advocate assessment of PMPs on a broader set of measures such as a patient's return to valued activities and reported experiences of patients, not just of pain levels, but also of improvement in quality-of-life. Group size can make a big difference to patient experience, with patients reporting group sizes between 3 and 20. A group size of 6 to 8 seems to be about right to foster camaraderie and peer support amongst fellow chronic pain patients. For many of us, this peer support was a major benefit of attending the PMP, as it was the first time that many of us had contacted others experiencing chronic pain, who could truly empathise and understand one another. Even though PMPs can be quite different from one another, simply having attended a PMP creates a bond between people. It is our experience that PMPs instil a certain attitude of self-management, which is more proactive, enabling patients to thrive rather than simply survive. Many of us have made life-long friends through attending a PMP, and continue to provide ongoing patient-led peer support via our PPSG on a twice weekly basis. Our opinion is that PMPs without peer support (i.e. online, self-directed) can be useful but not as effective as face-to-face or group PMPs, as we have found the peer support component to be essential. This	be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline. The cost effectiveness evaluation was a published study. We did not do any de novo modelling due to the absence of sufficient evidence of clinical effectiveness to recommend pain management programmes. Peer led pain management programmes were considered within the review, but there was insufficient evidence on these. The evidence for peer support groups was not specifically reviewed within the guideline however.

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				might be something to consider in light of the current coronavirus pandemic.	
Patient Pain Support Group	Guideline	General	General	At present, it can be very challenging as a patient with both primary and secondary chronic pain to get these conditions dealt with separately from one another, as secondary pain is often attributed to an existing primary chronic pain diagnosis. We welcome the distinction between primary and secondary pain, but did not feel the guidelines always made clear what kind of pain (primary, secondary or both) was being referred to. Furthermore, it was not clear to us how this guidance would apply to patients who are suffering with both primary and secondary types of chronic pain, a category that many of our members find themselves in.	Thank you for your comment. In consideration of stakeholder comments further clarification has been added to the guideline regarding the populations. This includes a visual summary clarifying what populations are covered by each recommendation. The assessment recommendations have also been amended to include consideration of other causes of the pain and when to consider a diagnosis of chronic primary pain as well as highlighting that chronic primary pain and chronic secondary pain can coexist.
Patient Pain Support Group	Guidance	General	General	We are concerned that, overall, these recommendations allow little room for nuance, or for guidance to be adapted for individual circumstances. This is a particular concern when chronic primary pain is having a significant impact on a patient's mental health, as these factors can often feed into one another. In general, we would like to see a more holistic approach that can be tailored to the needs of the individual, and felt this was often lacking in the recommendations.	Thank you for your comment. The committee agree that there should be an individualised approach. This is detailed in the assessment recommendations and also detailed in recommendations (for example the exercise recommendation specifically states it should be tailored to individual needs).

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Patient Pain Support Group	Guidance	004	006-007	We welcome the focus on knowing the patient as an individual and enabling them to actively participate in their care. This struck us as a particularly important point to emphasise at the start of the guidance, and felt this made a positive start to the report.	Thank you for your comment.
Patient Pain Support Group	Guidance	005	007	We were pleased to see mention of developing a care plan alongside input from the patient. The majority of respondents (75%) to our patient pain support group members' survey said that they had not received a care plan of any kind, while a quarter said that they had only received a partial care plan. We believe that developing a formal care plan is a crucial part of enabling patients to self-manage their own conditions as far as possible. However, we are concerned that the guidance fails to acknowledge the importance of maintaining regular contact between clinicians and patients to facilitate long-term self-management of chronic pain. Once a care-plan has been established together with a patient, this needs to be regularly reviewed by both patients and clinicians to maintain effective management strategies and ensure that patients are not left feeling abandoned once a care plan has been established.	Thank you for your comment. The recommendations include one to say that treatment options should be discussed when first developing the care plan and at all stages of care. Frequency of review was not considered within the guideline and so specific recommendations about regular reviews cannot be made.
Patient Pain Support Group	Guidance	005	015-016	Our group was particularly pleased to see the recommendation that clinicians should be sensitive to the risk of invalidating the experience of pain when communicating negative test results, as this is something	Thank you for your comment.

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				that many of our members have had negative experiences of in the past.	
Patient Pain Support Group	Guidance	006	002-004	Our patient pain support group (PPSG), brings together members with a range of chronic pain conditions at many different stages of life: the one thing we all have in common is that at some point we have all attended, and derived a great deal of benefit from, a Pain Management Programme (PMP). The majority of these have been NHS programmes in the London borough of Camden. In our collective experience, PMPs can often be difficult to access, and patients may be offered many alternative treatments, including surgery, before being offered a PMP. We would strongly support increased provision of PMPs, at an earlier stage of treatment, and hope that the research recommendation provided by these guidelines is recognition of the promise these treatments have to offer, and an attempt to optimise and standardise the features of a PMP rather than to pause provision of PMPs while further research is carried out. We acknowledge that there needs to be consistency between programs so that there is a sense of fairness amongst chronic pain patients that they are all receiving the same, excellent experience. These days patient can find out quickly about the experience of others through social media. As one of our members said, "Please do not abandon these groups. By all means do more research	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for

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				into them and check which groups work well, which groups are actually successful and roll them out to more hospitals, because one of the problems is that they are not really available or accessible to a lot of people." We hope that in time as more PMPs are organised, GP surgeries could also begin to host PMPs, improving communication between primary and secondary care pathways.	other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with

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					chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline.
Patient Pain Support Group	Guidance	006	006-007	Our patient pain support group, a patient-led self-help support group for those living with a range of chronic pain conditions in the London Borough of Camden, is currently available on social prescription, and we would strongly support similar support groups becoming more widely available across the country. We would also like to see gentle movement programmes, such as yoga therapy, available more widely on social prescription. The majority of our members have found yoga therapy to be effective, but for many, the cost of regular yoga therapy would be prohibitive were it not for the generous subsidies that are locally available. Members report that they find participating in our support group to be hugely beneficial, helping them with their self-management of chronic pain. The patient-led peer support we have provided has been particularly valuable during lockdown, as we were able to adapt quickly to meeting online within just a few weeks, while many other pain management services were put on hold.	Thank you for your comment. The evidence for support groups was not specifically reviewed within the guideline. There was also no evidence for social interventions specifically for chronic pain so the committee have recommended further research. Yoga was included within the exercise review and is recommended within that recommendation for people with chronic primary pain. Peer led pain management programmes were included within the review, but there was insufficient evidence to recommend these.

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				We note that peer support is not specifically mentioned in these guidelines, although members of our support group report it being vital element in their self-management of chronic pain. We imagine that, since our PPSG was founded two and a half years ago, the peer support we have provided to one another has greatly reduced use of clinician time and repeated healthcare visits, by helping patients maintain coping strategies or providing reassurance, encouragement and empathy when someone is going through a pain-related crisis, such as an acute flare-up, or having had a fall, for example. Being able to speak to someone who has had a similar experience is very helpful, and is in our opinion key to coping with chronic pain in the long-term.	
Patient Pain Support Group	Guidance	006	011-014	Many members of our patient pain support group find the concept of exercise quite intimidating, having had negative experiences in the past, and so we have found the term 'movement' to be more helpful. Movement can be effective in helping to reduce musculoskeletal pain, reduce anxiety and improve mood, but members suffering with nerve pain have generally seen little benefit from exercise. Furthermore, many support group members report difficulties in finding classes that are appropriate to their needs, especially as many have certain specific issues that can be aggravated by general exercise without the proper guidance and support. We would like to see supervised group movement programmes that are tailored specifically to those living	Thank you for your comment. The evidence reviewed in the guideline demonstrated effectiveness of supervised group exercise programmes. The committee agreed that this term should be retained as other suggested terms had broader meanings and could lead to misinterpretation of the recommendations. The committee agreed that the type of exercise may depend on the type of pain, but also that people are more likely to

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				with chronic pain, and that are sensitive to the limitations of patients living with chronic pain. We are concerned that, unless movement classes are tailored in this way, pain patients could be put off trying exercise again in the future, if they become demotivated by differences from their peers in their needs and abilities. If put together in the right way, small group movement classes could have the additional benefit of connecting patients dealing with similar issues, and fostering a sense of camaraderie and peer support amongst the group. In effect, exercise is the only treatment that is given a firm recommendation by these guidelines, in light of currently available evidence. We are concerned that this guidance doesn't take account of the fact that it's often the use of other pain management techniques, especially analgesic drugs, that enable people with chronic pain to take any exercise at all. However, we welcome recognition of the benefit that combined mind-body exercise programmes such as gently yoga-type movement therapy can have in managing chronic primary pain.	continue with exercise if the programme offered suits their lifestyle and physical ability and addresses their individual health needs. They agreed that the choice of programme as well as the content should take into account people's abilities and preferences. This might include providing individual exercise advice for different members of a group. This was highlighted in the recommendation and in more detail in the rationale underpinning the recommendation.
Patient Pain Support Group	Guidance	006	015-017	We are concerned that many existing exercise programmes, such as those subsidised by local councils or available on social prescription are often too short, and leave their patients on their own to cope at the end, making it hardfor patients to motivate themselves and maintain good habits. We would emphasise the value of	Thank you for your comment. The committee hope that by recommending that group exercise should be offered to people with chronic primary pain that provision will be increased and allow better

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				patient-led peer support in maintaining motivation once a formal programme has ended, and would recommend that resources are made freely available to patients to help them maintain their home practice in the longer-term.	signposting to existing provision. The committee have included a recommendation to encourage people to continue with their physical activity, acknowledging the longer term benefits of doing so.
Patient Pain Support Group	Guidance	007	002-004	We welcome the recommendation for clinicians to consider psychological therapy, especially mindfulness and acceptance-based therapy. Many members of our patient pain support group reported that they find this an effective method of managing chronic pain when used in combination with other strategies. These psychological treatments can often help manage difficult emotions such as anxiety or low mood associated with living with chronic pain, as well as improving mood and reducing stress. Compassion-focussed therapy can also be very useful in our collective experience, as this can help patients to apply pacing strategies and not push themselves too hard, too quickly. These psychological therapies often seem to work best in conjunction with other pain management techniques, especially programmes of physical exercise, helping participants overcome anxiety around exercise, and encouraging them to be more accepting of sensations that show up in the body during movement. One PPSG member said, 'my mindfulness practice has been at the centre of my treatment and my ability to live well".	Thank you for your comment. The guideline recommends considering ACT or CBT for chronic primary pain. For mindfulness, the committee agreed the effects looked promising, but further research was required before a recommendation could be made. They therefore made a research recommendation to inform future updates of the guideline. This evidence review was for these interventions as stand-alone therapies rather than combinations of treatments.

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				Mindfulness practices have the advantage that, once learnt, they can be accessed instantly and are therefore much quicker to work than medication.	
Patient Pain Support Group	Guidance	007	008-015	Some patients have reported that, while they have previouslyhad access to acupuncture on the NHS, this has since been withdrawn. Acupuncture can be extremely effective for many patients in treating chronic pain, and some report that, for them, it is the only thing that really works. We therefore welcome the recommendation for acupuncture to be once again considered for use in chronic pain on the NHS. Despite this, we are concerned that five hours is insufficient time to benefit from acupuncture, in the experience of many of our members. It takes time for the body to get used to acupuncture, and many people experience side effects andinitial worsening of pain in the initial weeks of treatment. Additionally, we welcome the recommendation for further research into the use of long-term acupuncture treatment for chronic pain, and hope that this guidance will establish a precedent for the wider acceptance of acupuncture as a viable treatment for chronic pain.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Patient Pain Support Group	Guidance	008	002-006	A number of members of our patient pain support group have found electrical therapy, particularly use of a TENS machine, to be an effective method of alternative pain relief, with one member reporting; "this was the thing	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies

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				that got me off codeine, paracetamol and NSAIDs". We feel the guidelines do not consider the possible short-term benefits that TENS machines can offer when used in combination with other management techniques, especially as side-effects are minimal, and easily reversed by discontinuing use. We are concerned that these recommendations may prevent clinicians from recommending that patients can purchase a TENS machine themselves (as many of our members have done), even where this treatment is not available freely on the NHS. The cost of a TENS machine is low (an initial outlay of perhaps £20 plus approximately £5 a year for replacement electrode pads and batteries depending on frequency of use – with costs often covered by the individual) and our collective experience is that it can be a very effective intervention,whenused under the correct guidance during acute flare-ups. However, there needs to be instruction and direction available to patients, especially those purchasing their own machine, as patients are often advised to simply find the right settings by trial and error, leading to many patients losing patience and ceasing usage.	were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended. The committee consider that as there is sufficient evidence of benefit people also should not be encouraged to buy these machines themselves for chronic primary pain but should

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					instead be directed towards management options that have demonstrable evidence of benefit.
Patient Pain Support Group	Guidance	008	009-011	Whilst we were pleased to note that manual therapy shows promise in the management of chronic pain and has therefore been recommended for further research, we are concerned that in the meantime many patients will have difficulty accessing this treatment. Many of members of our patient pain support group have, at times, found manual therapy to be the only effective therapy in managing acute flare-ups of pain, especially in releasing tight muscles such as in the neck or the jaw, which are frequent problem areas in chronic primary pain. Although the benefits of manual therapy such as osteopathy or sports massage are only temporary, many in our group have found it particularly effective in combination with exercise, as manual therapy often enables patients to achieve a better range of mobility, or to keep up with a program of rehabilitative physiotherapy.	Thank you for your comment. The committee agreed the evidence reviewed within this guideline was insufficient to recommend for manual therapies for chronic primary pain at present. They recommend further research is required to inform future updates of the guideline.
Patient Pain Support Group	Guidance	008	014-015	Many members of our patient pain support group report positive experiences in using antidepressants in combination with other treatments to manage chronic pain. However, there can often be a stigma attached to antidepressants, which deters pain patients from taking them. We feel that better patient education, explaining that the low doses prescribed for treating pain are not utilised for treating depression, would be beneficial.	Thank you for your comment. The committee agree that there needs to be a move away from the stigma attached to the use of antidepressants. A recommendation has been added to highlight this is not recommended for depression but

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					because they may help with quality of life, pain, sleep and psychological distress. The rationale accompanying the recommendation details the outcomes that benefit was seen in to highlight that this is not for depression, your comments will also be considered by NICE where relevant support activity is being planned.
Patient Pain Support Group	Guidance	009	010-024	As a group of patients suffering from a range of chronic pain conditions, the patient pain support group is extremely concerned by the recommendation to clinicians not to offer any pharmacological treatments, by any route. We are particularly worried that members of our patient pain support group will experience difficulties in accessing their current pharmacological treatments, or that they will be advised against using these medications altogether in light of the draft guidance. We recognise the possible risks of using these medications constantly in the long term, but many members felt these pharmacological treatments have been critical in alleviating extreme pain in the short-term, when nothing else was working. A number of members described that they simply do not know how they would have got through these short-term flare-ups of extreme, unbearable pain. One of our members described these	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is

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				recommendations as "like they're pulling up the drawbridge and saying you are on your own". Painkillers can be literally lifesaving, and we are concerned that without access to analgesics of any kind, many chronic primary pain sufferers will be driven to take their own lives. In light of this, we believe that the guidance ought to take account of the short-term benefit that these medications can provide in treating extreme flare-ups where other non-pharmaceutical pain management methods are unable to provide an acceptable level of relief. Many chronic pain conditions are characterised by these periodic flare-ups in symptoms, yet there appears to be little flexibility in these recommendations for short term use of these medications by patients with chronic primary pain.	recommended that a shared plan to continue safely can be agreed. The evidence reviewed and the committee's consensus opinion was that these are not beneficial for the majority of people with chronic primary pain. The committee agree that there is no evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up.

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					It is also important to note these recommendations are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Patient Pain Support Group	Guidance	009	013	Whilst we acknowledge the severe side effects that can be caused by long-term systemic use of non-steroidal anti-inflammatory drugs, these can be an extremely effective way to manage short-term pain flare-ups, especially musculoskeletal pain. One member of our	Thank you for your comment. This recommendation is for the chronic primary pain population only, rather than all types of pain. Chronic pain

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				patient pain support group said that if drugs such as these were to be withdrawn, they would frequently end up in A&E, as the pain is simply unbearable without use of NSAIDs. External application of these drugs by pain-relieving gels could provide an effective way to locally target the delivery of these drug whilst minimising unwanted side effects. As these gels are widely available without prescription, they could prove cost-effective when used in a time-limited way.	already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. Thank you for your comment. There was some, albeit limited, evidence available for the use of NSAIDs for chronic primary pain. This evidence demonstrated no difference between NSAIDs and placebo for quality of life, pain or psychological distress and

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					worse outcomes for function. This is detailed in the rationale accompanying the recommendation. The committee agreed this was consistent with their experience of the use of NSAIDs for chronic primary pain, and taken with the knowledge of potential harms, agreed it was appropriate to recommend against its use. The committee agree that there is no evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including

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					considering investigation of new symptoms and any factors contributing to the flare-up.
Patient Pain Support Group	Guidance	009	015-017	A number of members of our patient pain support group have described gabapentin as critical in alleviating extreme pain, in the short-term, when nothing else was working. Whilst we acknowledge the severe side effects that can be caused by long-term gabapentin use, one member said they were unsure how they would have coped had this not been available when their pain was "completely out of control". Despite the side effects of these drugs, many patients feel that gabapentinoids remain a vital option as a last resort for getting their pain back to a manageable level. Again, we feel the guidance needs to distinguish between short-term and long-term use of these drugs when managing chronic pain, as our collective experience suggests that time-limited use of gabapentin can be helpful in managing acute but prolonged flare-ups.	Thank you for your comment. This recommendation is for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation

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					between the recommendations for different topics. The committee agreed that the evidence reviewed in this guideline was not supportive of a recommendation for gabapentinoids for chronic primary pain. There was not good evidence of effectiveness, but there was evidence of harm. The committee agreed that there is no evidence that they are more effective for short terms use. They agreed it is appropriate to recommend against gabapentinoids for chronic primary pain.
Patient Pain Support Group	Guidance	009	021	We acknowledge that long-term constant paracetamol use is likely to offer little tangible benefit, but feel this guidance does not take account of the short-term benefit that simple analgesics such as these can offer in managing acute flare-ups of chronic primary pain. Time-limited use of paracetamol, which is readily available at low cost without a prescription and with few side-effects, would appear to make sense. If non-prescription drugs such as these are to be withdrawn, what are the implications of patientsbeing able to simply self-medicate	Thank you for your comment. The committee agree that there is no evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these

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				using drugs bought in a pharmacy or supermarket, when few other pain-relief options are available? We would argue that this could lead to a lack of trust between patients and clinicians, with patients not feeling they could be honest when reporting their use of non-prescription medication.	interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up (for example, stressful life events).
Patient Pain Support Group	Guidance	010	003-007	Many members of our patient pain support group expressed particular concern regarding the potential problems associated with withdrawing medications such as opioids, antidepressants and particularly gabapentinoids. If a collective decision is made to stop these drugs, it is critical that patients are provided with sufficient support during this period of withdrawal. Some members of our group described their symptoms getting much worse when these medications taken regularly are suddenly withdrawn, as well as feeling like clinicians were no longer engaged in managing their condition or taking their pain seriously when these treatments were withdrawn.	Thank you for your comment. The committee agree that people should be supported to withdraw from these medicines if a shared decision has been made to do so. The recommendation has been reworded to state that people should be encouraged and supported to stop or reduce where possible.
Patient Pain Support Group	Guidance	010	008-010	We strongly support the existing recommendations for research into use of cannabinoid dugs in treating fibromyalgia and treatment-resistant neuropathic pain. We follow developments in certain US states of the	Thank you for your comment. The committee agree that further research is required and cross refer to the NICE guideline on Cannabis based medicinal

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				increased legalisation of cannabinoid drugs with interest, and acknowledge that with the proper regulation, these drugs have the potential for great benefit in the management of chronic pain. Some treatments such as CBD oil are becoming easier to access through health shops and some pharmacies, but members of our patient pain support group expressed concerns about lack of guidance, high costs of these treatments, and lack of assurance about effectiveness and quality of CBD oils. However, some patients described CBD oil as highly effective in managing their pain when used occasionally, and reported experiencing very few side effects when compared to traditional pain-relief drugs.	products (NG144) where this research recommendation is included.
Patient Pain Support Group	Guidance	016	014-016	We asked members of our patient pain support group what, in their mind, had contributed most significantly to a successful PMP. Patients valued learning about and understanding their pain better; being in a small group size; having a good spirit within the group; provision of useful, gentle exercises to help strengthen muscles and improve mobility; learning valuable pacing skills; and gaining an introduction to mindfulness and acceptance & commitment-based strategies of pain management. Regular follow-up is also really important, to ensure that good habits are maintained and to reinforce techniques that have been made, for example through attendance of a maintenance programme.	Thank you for your comment. The committee agreed that the evidence reviewed within the guideline was not sufficient to make a recommendation for or against pain management programmes. Peer led pain management programmes were considered within the review, but there was insufficient evidence on these. The evidence for peer support groups was not specifically reviewed within the guideline however.

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				However, one common factor that was repeatedly mentioned when describing a successful PMP was the importance of excellent physiotherapists and psychologists, who had a very good way of communicating the value of acceptance-based pain management without dismissing patients' experiences. Many of us felt like it was the first time our pain had truly been taken seriously. One member described their involvement in the Camden Pain Service PMP as a "lifesaver". Another said they didn't think they would have managed without it; "my recent life is divided into the time before and after doing the PMP." A third member described how their PMP attendance had enabled them to come off strong medication which wasn't really working for them. Another member said "the pain management programme is one of the things that has transformed the way I manage my pain myself. Peer support… was a huge part of that."	
Patient Pain Support Group	Guidance	General	General	Overall, we are concerned that this guidance appears only to address the effectiveness of continuous use of these interventions in the long-term management of chronic primary pain. When used for the short-term management of acute pain, we believe many of the interventions considered (for example pharmacological interventions or electrical therapies) may prove to be both clinically and cost-effective. Chronic primary pain conditions are often characterised by such periodic flare-	Thank you for your comment. The committee do not agree that there is evidence that the interventions recommended against for chronic primary pain, are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer

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				ups of symptoms, yet there is little in these guidelines to reflect this.	term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including highlighting the need to investigate new symptoms and any factors contributing to the flare-up (for example, stressful life events).
Patient Pain Support Group	Guidance	General	General	This document describes itself as "guidance for healthcare professionals; commissioners and providers of service; and people with chronic pain, their families and their carers". However, as members of a patient pain support group, we feel that the guidance is written in a form that is in accessible to general members of the public, let alone to those patients who may have particular difficulties in assimilating complex information due to the brain fog often associated with chronic primary pain. When finalised, we would welcome the information being made available in a range of more accessible formats, for example video and/or audio guides for patients on how these recommendations might affect them and their treatment options.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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				Furthermore, members of our group who did feel able to engage with the content of this document were extremely concerned at the lack of options made available to patients with chronic primary pain, despite the guidancehighlighting the importance of patient choice and involvement at all levels of the assessment and treatment process. A number of members were quite distressed upon reading this guidance, and left feeling completely at a loss as to how they would cope if their treatments were to be withdrawn according to the recommendations set out here.	included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The guideline webpage will also include Information for the public about the guideline. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not

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					beneficial in the management of chronic primary pain.
Paul Clarke (Staffordshire) Community Interest Company	Equality Impact Assessment	003, 4	General	It could make it more difficult if clarity is not given to exclude people with Sickle Cell Disorders to access current services particularly during acute crisis and entering through A/E. There already exist barriers and challenges for medical professionals to not stigmatise or judge the sickle cell crisis as the person being a drug addict and the stereotypes that follow these negative opinions. Including not giving pain medication in thirty minutes of arrival or not giving sufficient dose that the patient needs.	Thank you for your comment. This guideline does not cover the management of sickle cell disorders. Additional clarity on the populations covered and the definition of chronic primary pain has been added to the overview page, context, and in a visual summary that will accompany the guideline.
Paul Clarke (Staffordshire) Community Interest Company	Equality Impact Assessment	003. 2	General	As above Concerns that this document could be used to override the current NICE Guidance of the Management of Sickle Cell Disease, which as a chapter that specifically covers Chronic and Acute Pain. What we don't want is Sickle Cell Warriors turning up in A/E and been refused Pain Analgesia because they are referring to this new draft guidance. Research and patient experience evidences that current practice is still problematic in terms of accessing pain medication which precipitates or can trigger further complications for example Chest Syndrome. Need to be clear that this document does not relate to individuals with Sickle Cell Disorders.	Thank you for your comment. This guideline does not cover the management of sickle cell disorders. Additional clarity on the populations covered and the definition of chronic primary pain has been added to the overview page, context, and in a visual summary that will accompany the guideline.
Paul Clarke (Staffordshire) Community	Equality Impact	003. 5	General	Adverse impact for Sickle Cell Warriors if they are not excluded from this document and reference directed to	Thank you for your comment. This guideline does not cover the management of sickle cell disorders.

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Interest Company	Assessment			the Management of People with Sickle Cell Disease. (Pain Chapter) Need some reference to how to manage people with learning disabilities who potentially can be taking long term pain medication and psychological impact of discontinuing their use.	Additional clarity on the populations covered and the definition of chronic primary pain has been added to the overview page, context, and in a visual summary that will accompany the guideline. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is

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					recommended that a shared plan to continue safely can be agreed. Learning difficulties was included as a consideration within the equalities impact assessment form. The committee agreed that the recommendations equally apply and separate recommendations were not required.
Paul Clarke (Staffordshire) Community Interest Company	Equality Impact Assessment	003.6	General	Make reference to excluding people with Sickle Cell Disorders from this document and reference the NICE Guidance for Management of Sickle Cell Disease. Consideration for management of people with learning disabilities and their understanding of discontinuing analgesia when taking tablets has become a habit or ritual. Ensure as much consultation and Patient Involvement is given at the commencement of all changes.	Thank you for your comment. This guideline does not cover the management of sickle cell disorders. Additional clarity on the populations covered and the definition of chronic primary pain has been added to the overview page, context, and in a visual summary that will accompany the guideline. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include

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					considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. Learning difficulties was included as a consideration within the equalities impact assessment form. The committee agreed that the recommendations equally apply and separate recommendations were not required.

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Paul Clarke (Staffordshire) Community Interest Company	Equality Impact Assessment	3.1	General	Reference should have been made to Individuals with Sickle Cell Disorders who should be exempt from this document due to their chronic pain being caused by underlying issues for instance Vascular Necrosis of the joints (hips, shoulder etc) Unsure if due consideration has been given to individuals with Learning Disability who may have been on long term analgesia and the impact of discontinuing to their mental health and wellbeing.	Thank you for your comment. This guideline does not cover the management of sickle cell disorders. Additional clarity on the populations covered and the definition of chronic primary pain has been added to the overview page, context, and in a visual summary that will accompany the guideline. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving little benefit or significant harms the guideline now states that

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					they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. Learning difficulties was included as a consideration within the equalities impact assessment form. The committee agreed that the recommendations equally apply and separate recommendations were not required.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	006	001	Disappointed no recommendation for further research of Oxygen Therapy as an option to control or alleviate pain.	Thank you for your comment. Research recommendations can only be made for interventions that have been included within one of the guideline review questions. Oxygen therapy was not an intervention that was raised during scoping nor protocol setting as a priority area for consider for chronic primary pain.
Paul Clarke (Staffordshire) Community	Guideline for Chronic Pain	006	005	Social Interventions recommendation for research should also look at the impact of Diversional Therapy.	Thank you for your comment. The specific interventions to be covered

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Interest Company					within the social interventions research recommendation have not been defined as the committee agreed this could be determined when the research is commissioned.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	008	004	TENS several people have commented that they find this machine particularly helpful, whether this is psychologically or not comments shared includes '…it helps to clear my head…find it relaxing… I guess the question is do we not offer TENS at all or leave it for individual preferences.	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the

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					committee agreed that without any evidence of benefit this should not be recommended.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	008	008	General suggestion Massage Therapy should be included in the further research.	Thank you for your comment. Massage therapy is included as one of the interventions in the research recommendation protocol which is in appendix J of evidence review I.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	008	014	General comment not sure this is the best approach substituting analgesia for antidepressants.	Thank you for your comment. The committee agreed that from the review of the evidence the only medicines that demonstrated benefit for chronic primary pain were the antidepressants. For other medicines it was agreed that there was either evidence they were not effective or the harms outweighed the benefits and they should not be recommended for chronic primary pain.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	010	011	Terms used in this guideline could be earlier in the document so people understand from the offset what is chronic pain.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of

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					the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	010	8: 1.3.14	Consideration must include the use of CBD Oil for pain management.	Thank you for your comment. This guideline cross refers to the NICE guideline on Cannabis based medicinal products (NG144) where CBD is considered within the research recommendations.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	017	012	Is there room for discussion with Local Authority and free vouchers for less frequently used times. Tend to find that this is not just a health issue but social care issue as well. Need collaboration and joint working as many people will not be in positions to continue an exercise programme	Thank you for your comment. We acknowledge that continuing a formal supervised exercise programmes may come at a cost that some people cannot afford. This was not the

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				and it has to be a life style change not just a one off session.	intention of the recommendation and this has been reworded to encourage ongoing physical activity. This is known to have longer term health benefits, but does not have to be activity that requires a gym membership or financial outgoings. We have clarified this where the statement is made.
Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	General	General	Extremely useful document and can be agreed in principle providing a clear guidance is given not to include people with Sickle Cell Disorders in this document. (NICE Guidance of Management of Sickle Cell Disease, chapter on managing acute and chronic pain) If Sickle cell Disorders is not excluded potential for increase in bed days and complications from the Sickle Crisis leading to harm and suffering for the sickle cell warriors. Challenges and impact to Safety, issue for Practitioners and Primary Health Care staff and increase risk of violence and abuse. Trying to explain to people who are not benefiting from the analgesia that although it is clearly not working to eliminate all the pain, the drug is now going to be stopped altogether may not be welcomed positively.	Thank you for your comment. The recommendations for management are for chronic primary pain only and so exclude the management of pain due to Sickle Cell Disorders.

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Paul Clarke (Staffordshire) Community Interest Company	Guideline for Chronic Pain	General	General	Key facts and figures cant disagree with the principles and the cost to the NHS need more encouragement for different mindset and thinking. Spiritual healing and complimentary medicine must also be explored. Counterproductive to swap one drug for another (analgesia to antidepressants). Definitely support change of lifestyle through increase in exercise and increase in fluid water intake.	Thank you for your comment. The guideline reviews only considered those identified in the scope as key areas to consider. Spiritual healing and complimentary medicine were not included. The committee agreed that antidepressants were the only medicine where consistent benefits were observed for chronic primary pain that were sufficient to inform the recommendation. The committee agree that exercise should be offered to all people with chronic primary pain.
Pelvic Pain Support Network	General	General	General	Regarding the impact of Covid 19, face to face appointments are less likely to take place. Research studies have not been able to recruit patients in person. Manual therapies are increasingly difficult to access.	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing

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					where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
Pelvic Pain Support Network	General	General	General	Concern that qualitative evidence has not been given the same weight as some other NICE guidelines eg Endometriosis	Thank you for your comment. The qualitative evidence reviewed in this guideline underpins the recommendations in the assessment section of the guideline which the committee agree are critical to chronic pain management. We therefore do not agree that this evidence has been given any less weight than in other guidelines.
Pelvic Pain Support Network	Guideline	006	001-004	This states that there is inconsistent evidence for pain management programmes, however the NICE Endometriosis guideline recommends pelvic pain management programmes for those with Chronic Pelvic Pain. This is inconsistent. Bearing in mind that it takes an average of 7 years to get a diagnosis of endometriosis are you going to prevent patients with chronic primary pelvic pain access to such a programme ?	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be

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					undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.

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Pelvic Pain Support Network	Guideline	007	002 1.3.3	ACT/CBT Not aware of any evidence for chronic pelvic pain. Recognition that there is a heavy psychological burden as a **consequence of chronic pelvic pain. See review "First Do No Harm" IMMDS**	Thank you for your comment. No evidence for ACT or CBT in people with chronic pelvic pain was identified that was relevant to the review protocol. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant for all types of chronic primary pain unless evidence suggests otherwise.
Pelvic Pain Support Network	Guideline	009	004-005	Anti depressants also have side effects. Rarely discussed with patients and off label use rarely mentioned	Thank you for your comment. We have stated in the recommendation that these should be considered after a discussion of the benefits and risks. The guideline also states that this use is off license.
Pelvic Pain Support Network	Guideline	009	010-024	Great concern about a proposed ban on pain medications that give many patients hope enabling them to function. The guideline emphasizes putting the patient at the centre of their care and the importance of fostering a supportive relationship between patient and healthcare professional. Withdrawal of these would be devastating	Thank you for your comment. The committee agree people should be able to make informed decisions on which treatment to use, but that this should be based on those treatments

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				for many of those who get some relief from these medications having tried the recommended medications and non medical options without success. What works for one patient won't for another.The approach needs to be personalized.The approach recommended in this guideline contradicts the emphasis on " Putting patients at the centre of their care ". The charity has considerable anecdotal evidence of many patients who sought help elsewhere in Europe from an interdisciplinary pelvic pain team where they were able to access a combination of medical and non medical treatments including some of the medications on this " non recommended" list which gave some relief, sufficient to enable them to cope and in many cases to continue working. We regard the restrictive approach described in this guideline whereby patients with severe pelvic pain, unable to function in any capacity, had tried the recommended medications without success and were not allowed access to the "non recommended" medications as unacceptable and fear this would do far more harm than good.	demonstrated to be effective for chronic primary pain. The assessment recommendations in section 1.1 of the guideline have been reworded to strengthen the emphasis of fostering a collaborative and supportive relationship between the healthcare professional and person with pain to facilitate good management and effective shared decision making. The recommendations also state that a shared care and support plan should be developed, including having an informed discussion about the benefits and harms of all treatment options, and all stages of care. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are

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					receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
Pelvic Pain Support Network	Guideline	011	012-014	The paper included in your evidence review did not show adherence/benefit of mindfulness for chronic pelvic pain	Thank you for your comment. The research recommendation for mindfulness is for all types of chronic primary pain and therefore might be able to inform future guidance on the topic, including people with chronic pelvic pain.
Pelvic Pain Support Network	Guideline	012	003-007	Manual therapies are generally only available on a private basis and research studies/trials are not funded	Thank you for your comment. All NICE research recommendations are reviewed by the NIHR and help inform their future funding streams. Highlighting areas where research is required also helps inform other research funders of priority areas.
Pelvic Pain Support Network	Guideline	014	022-024	Agree with this wholeheartedly	Thank you for your comment.
Pelvic Pain Support Network	Guideline	018	003-005	Not aware of any studies for chronic pelvic pain	Thank you for your comment. No evidence for CBT in people with chronic pelvic pain was identified that was relevant to the review protocol.

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					The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant for all types of chronic primary pain unless evidence suggests otherwise.
Pelvic Pain Support Network	Guideline	019	020-025	Nothing for chronic pelvic pain even short term	Thank you for your comment. There were two studies included in the review with populations of prostatitis / chronic pelvic pain. These contributed to meta-analysis of outcomes where benefit was observed for a number of outcomes. There was no evidence in the review to indicate a difference in effect according to subtype of chronic pain. Where there was heterogeneity in pooled analysis, subgroup analysis was undertaken by type of chronic primary pain, but this did not explain the heterogeneity. The committee

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					therefore agreed there was no reason that the recommendation should not apply for all types of chronic primary pain.
Pennine Care NHS Foundation Trust	General		**Interdisciplinary**	The assessment and management of pain needs to be interdisciplinary- can the document highlight this. A unidisciplinary approach to managing pain increased the risk of doing things badly (as we don't know what we don't know) e.g a CBT therapist missing red flag signs, an anaesthetist missing opioid misuse, a physio missing PTSD	Thank you for your comment. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The committee agree that a joined up approach between healthcare professionals is important.

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Pennine Care NHS Foundation Trust	General comment		**Self help resources**	Should there be something about helpful self help resources…eg 'pain toolkit' www.paintoolkit.org…..youtubevideo 'understanding pain in less than 5 mins' . again anecdotal evidence suggests many people suffering with pain find these of interest/ support….could this be a recommendation for research…as well as peer lead/ patient led/ co-led self help groups/ movements?	Thank you for your comment. The committee agree self-management is an important aspect. Peer led pain management programmes were considered within the review, but there was insufficient evidence on these to inform a recommendation. The evidence for the pain toolkit and peer support groups was not specifically reviewed within the guideline however.
Pennine Care NHS Foundation Trust	General comment		**Training / competencies**	In order to improve care…the stated ambition of the guidance, we need to improve the skills of health and social care professionals in assessing and managing chronic pain. This is barely touched on in many curricula. We should be ambitious and advise that core competencies in the assessment and management of pain are developed and imbedded in all health care training programmes, with supervision for this work a core part of the framework. Safe prescribing needs to be a key component for prescribers.	Thank you for your comment. It is beyond the remit of the guideline to recommend what should be included in healthcare professional's curricula.
Pennine Care NHS Foundation Trust	Guideline	001	007	In terms of the reasons why the guideline should be developed I'd suggest including something like ' to promote a holistic bio-psychosocial approach to the assessment and management of chronic pain'……'using evidenced based approaches where available'. How it reads currently suggests the care plan should be based on	Thank you for your comment. The overview page has been reworded and focuses on what the guideline covers.

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				what the sufferer wants, but we know that sometimes this can end up with unhelpful approaches such as ++ opioids/ epidurals which may inadvertently make a situation worse. Perhaps we need to add something about reducing unhelpful approaches and iatrogenic harm as an important factor in the path to improving people's lives/ ability to cope with pain. These factors play a huge part in the patients I see in a specialist pain clinic setting (especially multiples medications/ investigations/ operations/ unco-ordinated and confusing health care/ advice to rest/ not work etc)	
Pennine Care NHS Foundation Trust	Guideline	004	2 **Bio-psychosocial assessment**	I think the assessment section is quite weak. A full bio-psychosocial assessment is absolutely key to effective and helpful interventions. I'd suggest the section is organised along these lines and includes (not exclusively): a) in the 'bio' bit 1) ensuring all appropriate physical examination and investigations have been done to exclude other treatable causes of pain/ red flags (*this is because patients can develop serious disease that may get obscured/ missed because of the 'chronic pain ' diagnosis*)	Thank you for your comment. The committee have edited the assessment recommendations in consideration of stakeholder comments and added some additional recommendations to cover most of these aspects. Specific recommendations for investigations for treatable causes of pain have not been made as these are covered in relevant condition specific NICE

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				2) full review of medication to address polypharmacy, inappropriate medication and unhelpful use or prescribing (*this is because a lot of people get prescribed lots of meds/ opioids and some take what is prescribed in a way that is not recommended)* 3) physical activity levels *(as so many people with pain are deconditioned)* 4) sleep 5) weight and diet b) in the psycho bit 1) current and past mental health 2) current and past suicidal thoughts/ plans *(as these are v common and pain/ physical health problems are common in those who sadly die by suicide. Also the most common prescribed medication implicated in completed suicide are opioids)* c) in the social bit 1) housing/ heating/ finances 2) support/ social contacts 3) meaningful/ pleasurable activities and interests 4) cultural context 5) use of illicit medication/ excess alcohol/ cigarettes	guidelines which will be linked to from the guideline. A recommendation has been added to state that a diagnosis of chronic primary pain should be considered when there is no clear underlying cause or the pain or its impact are out of proportion to any observable injury or disease. The context section also highlights that the decisions about the search for any injury or disease that may be causing the pain, and about whether the pain or its impact are out of proportion to any identified injury or disease, are matters for clinical judgement in discussion with the patient. The guideline also cross refers to the NICE guidelines on medicines adherence and medicines optimisation (CG76 and NG5) which include recommendations about medicine reviews.

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Pennine Care NHS Foundation Trust	Guideline	008	013	Should there be a comment on capsaicin cream? Licenced for post herpetic pain/ neuropathic pain/ diabetic neuropathy and osteoarthritis of the knee….and used sometimes outside these conditions for chronic primary pain with some anecdotal benefit?	Thank you for your comment. Capsaicin cream was not prioritised as a medicine to include when agreeing the protocol for this review as the committee did not consider that it was widely used for chronic primary pain.
Physiotherapy Pain Association	Guideline	018	025 - 030	***Hypnosis, pain education and sleep hygiene for chronic primary pain*** *Limited evidence showed little benefit of hypnosis and no clinically important effect of pain education, but no evidence of harm. The committee noted that education should be part of good clinical practice and is not specific to chronic primary pain. This is already addressed by the NICE guideline on patient experience in adult NHS* We strongly disagree with the above statement about pain education and are deeply concerned by the methods used to reach these conclusions. We believe this to be a misrepresentation of the evidence regarding pain education for chronic pain management.	Thank you for your comment. This statement has been reworded to clarify that the committee consider education should be part of good clinical practice, and that providing information on pain is included in the recommendations for developing a care and support plan. Further detail on the committee's discussion on pain education has been added to the discussion of the evidence in Evidence review F.
Physiotherapy Pain Association	Evidence review F	119	017	The conclusions regarding pain education are only based upon 2 studies. This is a gross misrepresentation of the evidence that currently exists for pain education for chronic pain management.	Thank you for your comment. This was the only evidence available for chronic primary pain.

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					The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Physiotherapy Pain Association	Evidence review F	006	Table 1	*TABLE 1: People, aged 16 years and over, with chronic primary pain (whose pain management is not addressed by existing NICE guidance) (chronic widespread pain, complex regional pain syndrome, chronic visceral pain, chronic*	Thank you for your comment. Your understanding of the populations excluded is correct. This was agreed and defined during the scoping phase

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				orofacial pain, chronic primary musculoskeletal pain other than orofacial) The above statement regarding participants within the PICO table implies that studies including chronic pain conditions such as back pain and knee osteoarthritis have been excluded, as NICE guidelines regarding these conditions exist. If this is the case this is a serious limitation and partly explains why there are only two studies on pain education included in the review. If such studies have been excluded the title of the guidelines is completely misleading and should be changed to emphasise that it is not for people with chronic pain but rather chronic pain not including back pain and osteoarthritic pain etc. Alternatively, the process needs to be rerun to include **all**participants with chronic pain as the title implies. A number of important pain education RCTs for people with chronic pain have not been identified in the review such as *Moseley GL, Nicholas MK, Hodges PW: A randomized controlled trial of intensive neurophysiology education in chronic low back pain. Clin J Pain 20:324-330, 2004*. This may be because the guidelines have chosen to exclude studies on chronic low back pain, but we do not know for certain as it is not in the excluded studies tables. Not including studies like this will be a key reason	for this document and was stated in the scope when it was published in 2018. For the reviews of specific interventions for chronic primary pain, populations already covered by existing NICE guideline were excluded as recommendations already exist for these topics. In response to stakeholder comments received, the title has been changed to more clearly reflect the populations covered and further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. Studies which can be excluded from the first sift of title and abstract alone are not detailed in the excluded studies table, only those for which the full text is ordered and assessed for

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				why the pain education section includes so few studies, and thus why the recommendation is misleading.	inclusion will be included in this list. Therefore any studies which detailed in their abstract that they were clearly for pain education for other types of chronic pain, would have been excluded at an earlier stage.
Physiotherapy Pain Association	Evidence review F	452	Excluded studies table	Van Ittersum MW, Wilgen CP, Schans CP, Lambrecht L, Groothoff JW, Nijs J: Written pain neuroscience education in fibromyalgia: A multicenter randomized controlled trial. Pain Pract 14:689-700, 2014 Van Oosterwijck J, Meeus M, Paul L, De Schryver M, Pascal A, Lambrecht L, Nijs J: Pain physiology education improves health status and endogenous pain inhibition in-fibromyalgia: A double-blind randomized controlled trial. Clin J Pain 29:873-882, 2013 Both of these pain education studies have been excluded (see excluded studies table). The reasons given was "inappropriate comparisons". However, both these studies have been meticulously well controlled. In addition, both are on Fibromyalgia so they should not have been excluded based upon the participants section of the PICO table as currently written (See point 3). We cannot identify any reason why these studies have not been included – please could the committee explain why they have been excluded. This is not an exhaustive list of studies that should have been included but clearly	Thank you for your comment. Both of these studies compare 2 different types of psychological therapies to each other; Van Ittersum compares pain education to relaxation, an van Oosterwijck compares Pain physiology education to pacing self-management education. This was not a comparison that was relevant for this review protocol, therefore they ae appropriately excluded from the guideline review. All references provided by stakeholders have been checked for inclusion and no additional studies have been identified for pain education that meet the review protocol.

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				illustrates the point that important pain education studies that fully fit the inclusion criteria, appear to have been missed incorrectly.	
Physiotherapy Pain Association	Evidence review F	446	Excluded studies table	Malfliet A, Kregel J, Meeus M, Roussel N, Danneels L, Cagnie B, Dolphens M, Nijs J: Blended-learning pain neuroscience education for people with chronic spinal pain: Randomized controlled multicenter trial. Phys Ther 98:357-368, 2018 Gallagher L, McAuley J, Moseley GL: A randomized controlled trial of using a book of metaphors to reconceptualize pain and decrease catastrophizing in people with chronic pain. Clin J Pain 29:20-25, 2013 The two above studies on pain education have been excluded. Malfliet et al was excluded because it was "not the correct population" and Gallagher et al. was excluded because "incorrect interventions, unclear population" Again, both of these studies included, at least in part people with back pain, so it may not have fitted with the exact PICO statement. However, this process of selection would appear to have led to many important RCTs investigating pain education to be excluded, and the misleading conclusions that have been drawn.	Thank you for your comment. These studies were appropriately excluded according to the review protocol. Malfliet includes a mixed population of chronic low back pain, failed back surgery syndrome (performed more than 3 years ago, anatomically successful operation without symptom disappearance), chronic whiplash associated disorders, and chronic nontraumatic neck pain. The breakdown of types of pain in the included participants is roughly 50/50 neck pain and low back pain. Our protocol criteria for inclusion of types of pain other than chronic primary pain was a maximum of 20% therefore this could not be included to inform recommendations on chronic primary pain, excluding conditions covered in existing NICE guidelines.

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					Gallagher et al. was also appropriately excluded. The study population was 'people with pain that had been sufficient to disrupt their activities of daily living for more than the previous 3 months'. This cannot be categorised as chronic primary pain, which is the population of interest for this review protocol. Furthermore the interventions are a pain education booklet about metaphors and stories to help understand the biology of pain compared to a booklet with advice about managing pain. Therefore 2 different education booklets, which was not a comparison of interest as specified in this review protocol.
Physiotherapy Pain Association	Evidence review F	128	009 - 014	*The committee considered the evidence to be insufficient to support a recommendation for or against pain education.Therefore no recommendation was made*. In light of the above statement why do the guidelines state - "*no clinically important effect of pain education*". Surely, at best the guidelines should have stated no recommendation can be drawn.	Thank you for your comment. The statement about there being no clinically important effect relates directly to the evidence reviewed where no clinically important difference was observed when pain education was compared to usual

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				The committee also noted that education should be part of good clinical practice and is not specific to chronic primary pain, which is addressed by the NICE patient experience guideline (CG138) and therefore no research recommendation was made. This statement appears to miss the point of good pain education. It is more than the simple provision of information, such as a description of how much exercise a person should be getting. Rather it is a process that aims to facilitate conceptual change about the meaning/cause of pain that would aid to remove barriers to exercise such as fear avoidance beliefs. If the NICE guideline committee feel "the evidence to be insufficient to support a recommendation" then surely there is a need for more research into pain education.	care. It was also noted this was low to very low quality evidence from one small study. The statement in the rationale about pain education has been reworded to clarify that the committee consider education should be part of good clinical practice, and that providing information on pain is included in the recommendations for developing a care and support plan. Further detail on the committee's discussion on pain education has been added to the discussion of the evidence in Evidence review F. The committee discussed that education about the science of pain may be a useful enabler to people with chronic primary pain being able to effectively cope with and manage their pain, but may not be expected to improve patient reported outcomes as a standalone intervention. They therefore agreed it was more appropriate to include as

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					part of the care and support plan considerations rather than suggest further research specifically for its effects on management of chronic primary pain. This is detailed in the committee's discussion of the evidence in Evidence review F.
Physiotherapy Pain Association	Guideline	018	003 - 011	***CBT for chronic primary pain 3*** *Most of the evidence showed that CBT for pain improved quality of life for people with chronic primary pain. A consistent benefit was not demonstrated in other outcomes, but the committee considered that the evidence may have underestimated the benefits because the studies varied in terms of the level of training of the therapists and the way the therapy was delivered. There was no strong evidence of harm. Two economic evaluations also showed CBT to be cost effective. The committee agreed that the evidence was not of high quality so they decided to recommend that CBT (for pain) is considered.* Was the same consideration given to other forms of intervention? Pain education for example will have been delivered by individuals of varying levels of training. A recent mixed methods systematic review of education has identified that the quality of training of the individual is important when delivered pain education to patients. (*Watson JA, Ryan CG, Cooper L, Ellington D, Whittle R, Lavender M et al. Pain neuroscience education for adults*	Thank you for your comment. The comment in the discussion of CBT specifically relates to the committee's discussion about the limitations of some of the studies and the variability in the methods of delivering CBT, including internet delivered programmes which may have underestimated the effects of CBT delivered face to face. The committee discuss limitations and applicability of the interventions in all of the reviews and discuss the potential effects it may have had on the results, where relevant. There was very limited evidence for pain education. The committee's discussion is included in Evidence review F.

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				with chronic musculoskeletal pain: A mixed-methods systematic review and meta-analysis. The Journal of Pain. 2019; 44 20(10):1140 e1-1140 e22). Contemporary pain education isrelatively newand the same argument could be made, it would seem important to apply the same principles.	
Physiotherapy Pain Association	Guideline	018	025 - 030	***Hypnosis, pain education and sleep hygiene for chronic primary pain*** *Limited evidence showed little benefit of hypnosis and no clinically important effect of pain education, but no evidence of harm. The committee noted that education should be part of good clinical practice and is not specific to chronic primary pain. This is already addressed by the NICE guideline on patient experience in adult NHS* These guidelines appear to have made no distinction between the different types of education that exist. Much like there are many different types of psychologically informed approaches such as CBT and ACT, there are many different types/approaches to pain education. Contemporary pain education usually referred to as "pain science education" is rooted in the biopsychosocial model and attempts to reduce pain related fear and anxiety through conceptual change around pain. This contrasts markedly with the more traditional and largely now out of date educational	Thank you for your comment. The statement in the rationale about pain education has been reworded to clarify that the committee consider education should be part of good clinical practice, and that providing information on pain is included in the recommendations for developing a care and support plan. Further detail on the committee's discussion on pain education has been added to the discussion of the evidence in Evidence review F. The committee discussed that education about the science of pain may be a useful enabler to people with chronic primary pain being able to effectively cope with and manage their pain, but may not be expected to improve patient reported

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				approach rooted in the biomedical model which focuses on biomechanics and ergonomics. In comparisons of these two educational approaches it has been shown that biopsychosocial education can have a positive effect while biomedical education can have a negative effect (*Moseley GL, Nicholas MK, Hodges PW: A randomized controlled trial of intensive neurophysiology education in chronic low back pain. Clin J Pain 20:324-330, 2004).* There is robust evidence that pain science education rooted in the biopsychosocial model can bring about significant improvements pain related fear and anxiety (*Watson JA, Ryan CG, Cooper L, Ellington D, Whittle R, Lavender M et al. Pain neuroscience education for adults with chronic musculoskeletal pain: A mixed-methods systematic review and meta-analysis. The Journal of Pain. 2019; 44 20(10):1140 e1-1140 e22*). Of the two pain education studies included in this review (Soares et al. 2002 [ref 500]; Amer-Cuenca et al. 2019 [ref 11]) only one investigated contemporary pain science education rooted in the biopsychosocial model as the intervention (Amer-Cuenca et al. 2019). The other included study (Soares 2002) was not pain science education [pain scienceeducation only emerged as an intervention around this time and does not appear to have informed the work of Soares et al. in an way) and included components such as ergonomics – which	outcomes as a standalone intervention. They therefore agreed it was more appropriate to include as part of the care and support plan considerations rather than suggest further research specifically for its effects on management of chronic primary pain. This is detailed in the committee's discussion of the evidence in Evidence review F.

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				suggest it may have had a biomechanical approach. Such biomedical model education can have a negative impact on outcomes. By not considering the philosophically different types of pain education in isolation, these guidelines have not given equal treatment to education as they have to other interventions (e.g. ACT and CBT).	
Physiotherapy Pain Association	Guideline	018	025 - 030	***Hypnosis, pain education and sleep hygiene for chronic primary pain*** *Limited evidence showed little benefit of hypnosis and no clinically important effect of pain education, but no evidence of harm. The committee noted that education should be part of good clinical practice and is not specific to chronic primary pain. This is already addressed by the NICE guideline on patient experience in adult NHS* These guideline statements are out of step with recent systematic reviews published in the field of pain education for chronic pain. Examples of conclusions from these reviews are pasted below. We find it concerning that there is such a discrepancy between the NICE guideline review and current pain education reviews within the peer-reviewed literature:	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic.

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				"Education, as part of multi-disciplinary programs, is likely to improve self-management and self-efficacy in people with chronic pain of any aetiology." (Joypaul et al 2019) *"The results of this systematic review support the conclusion that utilizing pain education strategies in conjunction with interventions provided by physical therapists demonstrates a moderate to large effect sizes on pain and disability constructs but lack pooled statistical significance" (Marris et al 2019)* *This review presents moderate evidence that the addition of [pain science education] to usual physiotherapy intervention in patients with CLBP improves disability in the short term. (Wood & Hendrick, 2019)* *There was moderate evidence supporting the hypothesis that [pain science education] has a small to moderate effect on pain and low evidence of a small to moderate effect on disability immediately after the intervention. [Pain science education] has a small to moderate effect on pain and disability at 3 months follow-up in patients with CLBP. (Tegner et al. 2018)* *Current evidence supports the use of [pain science education] for chronic MSK disorders in reducing pain and improving patient knowledge of pain, improving function and lowering disability, reducing psychosocial factors, enhancing*	The references you provide all relate to chronic pain more broadly or types of chronic pain that were excluded from the scope of these reviews (for example low back pain). All of the reference lists of these reviews have been checked for any relevant studies, however no new studies were identified.

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				movement, and minimizing healthcare utilization. (Louw et al. 2016) The treatment effect of [pain science education] for kinesiophobia was clinically relevant in the short term (−13.55/100; 95% CI, −25.89 to −1.21) and for pain catastrophizing in the medium term (−5.26/52; 95% CI, −10.59 to .08). (Watson et al. 2019) REFERENCES Joypaul S, Kelly F, McMillan SS, King MA (2019) Multi-disciplinary interventions for chronic pain involving education: A systematic review. PLoS ONE 14(10): e0223306. https://doi.org/10.1371/journal.pone.0223306 Louw, A., Zimney, K., Puentedura, E.J. and Diener, I., 2016. The efficacy of pain neuroscience education on musculoskeletal pain: a systematic review of the literature. *Physiotherapy theory and practice*, *32*(5), pp.332-355. Marris, D., Theophanous, K., Cabezon, P., Dunlap, Z. and Donaldson, M., 2019. The impact of combining pain education strategies with physical therapy interventions for patients with chronic pain: a systematic review and meta-analysis of randomized controlled trials. *Physiotherapy Theory and Practice*, pp.1-12.	

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				Tegner, H., Frederiksen, P., Esbensen, B.A. and Juhl, C., 2018. Neurophysiological pain education for patients with chronic low back pain. *The Clinical journal of pain*, *34*(8), pp.778-786. *Watson JA, Ryan CG, Cooper L, Ellington D, Whittle R, Lavender M et al. Pain neuroscience education for adults with chronic musculoskeletal pain: A mixed-methods systematic review and meta-analysis. The Journal of Pain. 2019; 44 20(10):1140 e1-1140 e22.* Wood, L. and Hendrick, P.A., 2019. A systematic review and meta-analysis of pain neuroscience education for chronic low back pain: Short-and long-term outcomes of pain and disability. *European Journal of Pain*, *23*(2), pp.234-249.	
Physiotherapy Pain Association	Guideline	018	025 - 030	***Hypnosis, pain education and sleep hygiene for chronic primary pain*** *Limited evidence showed little benefit of hypnosis and no clinically important effect of pain education, but no evidence of harm. The committee noted that education should be part of good clinical practice and is not specific to chronic primary pain. This is already addressed by the NICE guideline on patient experience in adult NHS*	Thank you for your comment. The statement in the rationale about pain education has been reworded to clarify that the committee consider education should be part of good clinical practice, and that providing information on pain is included in the recommendations for developing a

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				Within this statement the committee seem to be equating pain education with good communication skills as set on in the NICE guideline on patient Experience (CG138). While of course good pain education requires good communication skills, so do many other pain based interventions such as CBT and ACT. Why has pain education been singled out in this way?	care and support plan. Further detail on the committee's discussion on pain education has been added to the discussion of the evidence in Evidence review F. The committee discussed that education about the science of pain may be a useful enabler to people with chronic primary pain being able to effectively cope with and manage their pain, but may not be expected to improve patient reported outcomes as a standalone intervention. They therefore agreed it was more appropriate to include as part of the care and support plan considerations rather than suggest further research specifically for its effects on management of chronic primary pain. This is detailed in the committee's discussion of the evidence in Evidence review F.
Physiotherapy Pain Association	Guideline	General	General	The draft guideline suggests that it applies to management for Chronic Primary Pain and the definition of this is specified as per Nicholas et al 2019, however, the inclusion criteria for the study categories e.g. acupuncture, manual therapy do not suggest they are	Thank you for your comment. The ICD-11 brings together different conditions under the heading chronic primary pain. The search terms used to

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				specific enough to meet the criteria for Chronic Primary Pain. An important aspect of the diagnosis includes significant emotional distress and/ or functional disability and this has been overlooked. There is no suggestion in the inclusion criteria that the studies have met this important criterion. This is important clinically because the management for people with pain versus pain with emotional distress/ functional disability is different. The literature shows that people with higher psychosocial need, which this aspect of the chronic primary pain diagnosis contains, benefit from input that meets that need. It is unhelpful and inaccurate to take evidence from a broad chronic pain population (with studies which occasionally exclude people with emotional distress/ functional disability) and suggest it should be applied to narrower criteria. The new category of ICD-11 Chronic Primary Pain will not come into effect until next year and so it is not surprising that studies have not used it for inclusion criteria. The development of this category will be very useful clinically and for research in the future which starts to separate out clinical need in order to tackle the, much called for, research need here. Unfortunately, these guidelines be detrimental to this development if they overlook this important psychological and behavioural aspect of the condition. It may be more reflective of the guidelines to suggest that they are for chronic pain more	identify literature were broad to identify any of the conditions that may fall under this definition. Inclusion criteria was not based on the use of the term 'chronic primary pain'. The details of the populations included within the studies were reviewed, considering whether they were under the umbrella term of chronic primary pain, as listed in ICD-11 at the time of development. Studies in broad chronic pain populations were not included in these evidence reviews. In consideration of the stakeholder comments received the guideline has been renamed and subheadings have been added throughout the guideline to clarify populations covered to avoid any misinterpretation.

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				broadly, but even with this the populations that will benefit from manual therapy versus for example, a pain management programme are quite different and present different clinically	
Physiotherapy Pain Association	Evidence review G: Acupuncture	008 - 017		***Table 2: Summary of studies included in the evidence review*** The studies authored by Molsberger (2010) ref 153 and White (2004) ref 218 are not restricted to pain over 3 months, suggesting over 6 weeks, and 2 months respectively. Some other studies do not have the timescale stated and some have 3 months stated. This is at odds with the timeline of 3 months for a diagnosis of Chronic Primary Pain.	Thank you for your comment. Although both of these studies define their inclusion criteria for chronic pain at a lower criteria than 3 months, the baseline characteristics of each do represent populations consistent with the chronic primary pain definition of greater than 3 months pain. Molsberger et al. states chronic shoulder pain ⩾6 weeks duration, however the duration in disease in the verum acupuncture group was a mean of 10.7 ± 9.7 SD months and 11.6 ± 11.4 months in the sham acupuncture group. White et al. defined their inclusion criteria for chronic pain as >2 months, the average duration of disease (defined as time from onset of symptoms to date of the trial) stated in their baseline characteristics was 4.81 ± 7.03 (mean ± SD) years in the acupuncture group and 7.71 ± 11.39

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					years in the control group. Therefore both of these were considered relevant to the review (and guideline) population. This was checked with all trials when considering inclusion.
Physiotherapy Pain Association	Evidence review G: Acupuncture	General	General	Many of the included studies (e.g. Aranha (2015) ref 6, Casanueva (2014) ref 17, Cho (2014) ref 29), did not appear to have sufficient long term follow up. Clinically, there appears to be potential psychological harm associated with offering acupuncture to patients with chronic primary pain in that they are less likely to engage in longer term management options which would benefit such as Pain Management Programmes. It is more likely that people who would require pain rehabilitation will have Chronic Primary Pain with the emotional distress and functional disability that is part of that condition. This guideline could potentially obstruct optimum management by giving such advice, and as we have outlined, feel it is not possible to claim that the people included in the acupuncture studies have Chronic Primary Pain in the first place.	Thank you for your comment. The committee agree that some of the studies had only a limited follow up, with some (such as Aranha et al.) only recording post treatment results at the end of the intervention period. Casaneuva et al. had a follow up 6 weeks after the end of the intervention as well as post-treatment and Cho has follow up 4 weeks after the post-treatment measurement. There were also studies with longer follow up available of 3, 6 or 12 months which also informed the recommendations. We also developed an original economic model which incorporated the available evidence about what happens after treatment ended. All of these factors were taken

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					into account when making the recommendations.
Physiotherapy Pain Association	Evidence review G: Acupuncture	General	General	Most studies included people with head/neck/arm pain or fibromyalgia/ 'myofascial' pain. I doubt this warrants extension to people with CRPS or low back pain. The category of chronic primary pain suggests that it is more than 'myofascial pain.'	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more

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					easy navigation between the recommendations for different topics. The committee noted that for acupuncture the majority of evidence was based on women with chronic neck pain or fibromyalgia. However, the committee agreed that for interventions such as acupuncture, response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions, even when evidence was available for only one condition. They also noted that the specific type of acupuncture may differ according to type of pain, which would be informed by expertise of the practitioner delivering acupuncture. This is detailed in the rationale for the recommendation and in the discussion of the evidence in evidence review G.
Physiotherapy Pain Association	Evidence review C: pain	015	General	Some of the included literature for PMPs such as the study by Heuts (2005) ref 164 would not be recognised as a pain management programme as defined by The	Thank you for your comment. The committee agreed that the following

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	management programmes			British Pain Society and Faculty of Pain Medicine which recommends that programmes are delivered by a multidisciplinary team for minimum of 36 hours. In clinical practice patients attending secondary and tertiary pain management programme present with higher levels of complexity than those attending community pain rehabilitation or pain management programmes lasting 6 – 18 hours and therefore research linked to stratification would be helpful. We welcome the research recommendation for pain management programmes in order to provide higher quality evidence related to optimum content, cost effectiveness and duration of programmes.	definition would be used to identify studies for inclusion in the pain management programme review in the guideline: any intervention that has 2 or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the 2. This was detailed in the protocol in Appendix A, and in the PICO table, table 1. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research.
Physiotherapy Pain Association	Guideline	006	011	This recommendation is a core offering within a number of NHS Trusts e.g. Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Trust, The Walton Centre NHS Foundation Trust, University College London Hospitals	Thank you for your comment. We will pass this information to our local practice collection team. More

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				NHS Trust with many group programmes now being successfully delivered virtually and would be willing to submit its experiences to the NICE shared learning database. Contact email: ppapro1994@gmail.com	information on local practice can be found here: www.nice.org.uk/sharedlearning
Physiotherapy Pain Association	Guideline	006	012	We are concerned about the unusual use of the classification of 'mind-body' exercise. This is a not a known category of exercise such as cardiovascular, aerobic, anaerobic, strength etc. The ambiguous use of the term will make it difficult for services to implement this unclear recommendation. We would like to point out that all exercise could be described as 'mind-body' as human beings use both to execute movement. To suggest otherwise hails to past times in biomedicine where the mind and body were seen as separate. This so-called dualist perspective has since been superseded by more humanistic language and approaches.	Thank you for your comment. The term 'mind body exercise' was used to encompass exercise interventions such as yoga and tai chi. This is detailed in the protocol in appendix A. The examples of types of exercise used to guide the review have been removed from the recommendation to avoid confusion. The recommendation covers all types of exercise.
Physiotherapy Pain Association	Evidence review E: exercise	010	General	The majority of the evidence involved women with Fibromyalgia. Many studies excluded people with cardiovascular or respiratory disease and / or psychiatric disorder. Few studies included people with severe depression and mental wellbeing was not measured formally. There is literature to suggest that suicide rates are higher in people with chronic pain compared to the general population and that they present with comorbid physical and mental health problems (e.g. Ratcliffe 2008).As such the literature used in the review is not representative of patients seen in secondary and tertiary care pain clinics	Thank you for your comment. The committee note that clinical trials and controlled studies frequently exclude people with comorbidities. All of the reviews can be impacted by these limitations. The committee highlight in the recommendations in the assessment section 1.1 that there should be a holistic assessment and also that people's preferences and priorities for managing multiple

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				where a high proportion of attendees have clinical depression or anxiety. In an analysis of a random sample of 300,000 people registered with a UK GP, the second most common long-term condition was chronic pain and on average these individuals were living with 2 other conditions. Almost all individuals in the study with pain were living with conditions such as cancer, cardiovascular disease, chronic obstructive pulmonary disease and mental health problems, the most common co-morbidity being hypertension and pain. Widespread pain, mental health problems and co-morbidity are recognised as factors resulting in greater healthcare usage and poorer response to treatment.WE welcome the recommendation for exercise, however where physical or mental health co-morbidities are evident, these individuals may be better managed in a multidisciplinary pain clinic setting due to the risks to long -term health of inactivity and / or suicide. Lastly most of the studies did not include details about ethnicity or where details were included the studies mainly involved white females. In a survey conducted in primary care clinics in the United States, in practices with > 30% of patients from minority ethnic groups, patients reported significantly higher limitations due to depression, hypertension and heart disease, whilst physicians reported asignificantly higher proportion of patients presenting with chronic pain or as medically and psychologically complex, compared to practices with a lower percentage of patients from minority ethnic	conditions should be taken into account when developing a care and support plan. The committee acknowledge that the evidence informing the exercise review was largely from populations with fibromyalgia or chronic neck pain. The committee considered that response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions. However it was also considered that the most appropriate type of exercise may depend on the type of pain condition and it should therefore be tailored to individual needs and preferences. This is detailed in the committee's discussion of evidence in the evidence review and has been added to the rationale in the guideline for clarity. Details about the settings and where available the ethnicities of the participants, are given in the evidence tables in appendix D for all included studies.

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				groups. A multidisciplinary approach may better serve these individuals and interventions that overcome systemic difficulties with access to treatment. **References** Jimenez-Rodríguez, I., Garcia-Leiva, J.M., Jimenez-Rodriguez, B.M., Condés-Moreno, E., Rico-Villademoros, F. and Calandre, E.P., 2014. Suicidal ideation and the risk of suicide in patients with fibromyalgia: a comparison with non-pain controls and patients suffering from low-back pain. *Neuropsychiatric disease and treatment*, *10*, p.625 Lichtenstein, A., Tiosano, S. and Amital, H., 2018. The complexities of fibromyalgia and its comorbidities. *Current opinion in rheumatology*, *30*(1), pp.94-100. Ratcliffe GE, Enns MW, Belik S-L, Sareen J. Chronic Pain Conditions and Suicidal Ideation and Suicide Attempts: An Epidemiologic Perspective. The Clinical journal of pain. 2008;24(3). M. Stafford, A. Steventon, R. Thorlby, R. Fisher, C. Turton, and S. Deeny, "Briefing: Understanding the health care needs of people with multiple health conditions," no. November, pp. 1–26, 2018. J. Hartvigsen *et al.*, "What low back pain is and why we need to pay attention," *The Lancet*. 2018.	The applicability and generalisability of the evidence was considered by the committee in their discussion of the evidence.

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				M. Racine, "Chronic pain and suicide risk: A comprehensive review," *Progress in Neuro-Psychopharmacology and Biological Psychiatry*. 2018. A. B. Varkey *et al.*, "Separate and unequal: Clinics where minority and nonminority patients receive primary care," *Arch. Intern. Med.*, 2009. Smith, J.G., Knight, L., Stewart, A., Smith, E.L. and McCracken, L.M., 2016. Clinical effectiveness of a residential pain management programme–comparing a large recent sample with previously published outcome data. *British journal of pain*, *10*(1), pp.46-58. Morley, S., Williams, A. and Hussain, S., 2008. Estimating the clinical effectiveness of cognitivebehavioural therapy in the clinic: evaluation of a CBT informed pain management programme. *PAIN®*, *137*(3), pp.670-680.	
Physiotherapy Pain Association	Guideline	007	008	The quality of much of the evidence was low or very low, given that acupuncture is a passive intervention where benefits were only evident for 3 months, suggests that acupuncture, where offered should be combined with exercise since exercise is recommended and may mitigate for the long term adverse effects of physical inactivity for people with long term pain. Acupuncture will not encourage self-management of pain and may encourage repeated attendance and requests for episodes of treatment. There will also be associated costs of training clinicians. D. Smith, R. Wilkie, O. Uthman, J. L. Jordan, and J. McBeth, "Chronic pain and mortality: A systematic	Thank you for your comment. The evidence reviewed was for acupuncture as a standalone intervention, we cannot comment on its effectiveness combined with other interventions. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence.

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				review," *PLoS ONE*. 2014.	Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive

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					the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Physiotherapy Pain Association	Evidence review E and C	General	General	Mixed methods studies which included public and patient involvement were lacking. The patient voice should be included.	Thank you for your comment. When setting the protocol it was agreed that the best type of evidence for these intervention reviews was RCT evidence. We do agree that the patient voice is very important in informing recommendations. Our committee includes two lay members who were involved in all decision making and particular effort was made to ensure a wide range of patient organisations were included in the stakeholder consultation.
Physiotherapy Pain Association	Guideline	018	007	Recently published evidence demonstrates that there is moderate quality evidence that CBT reduces disability and distress when delivered by trained psychologists.	Thank you for your comment. This review was specifically for chronic primary pain, rather than all types of

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				Psychological therapies for the management of chronic pain (excluding headache) in adults - Williams, AC de C - 2020 | Cochrane Library	chronic pain as in the 2020 Williams et al. Cochrane review. The committee did agree however that there was sufficient evidence to recommend that CBT can be considered for people with chronic primary pain. The guideline recommendations assume that all people delivering the interventions recommended should be appropriately trained to do so. This has been added to the recommendation for clarity.
Primary Care Rheumatology and Musculoskeletal Medicine Society	Guideline	General	General	There is a risk of conflict and confusion between different but related NICE guidance. I understand that the NICE low back pain document https://www.nice.org.uk/guidance/ng59 is being reviewed and is currently out for consultation, but in its current edition endorses the use of NSAID's and advises against acupuncture. If chronic low back pain sits under 'chronic primary pain' (which it does by definition), according to https://www.nice.org.uk/guidance/indevelopment/gid-ng10069/consultation/html-content-2, we should not offer NSAIDs and consider acupuncture.	Thank you for your comment. The committee were aware of the recommendations in the NICE low back pain and sciatica guideline. It was agreed at scoping that chronic pain already covered in existing NICE guidelines would be excluded from the reviews for management in this guideline to avoid populations being covered in two guidelines. The recommendations in NG59 still stand for people with a diagnosis of low back pain. Further clarification has

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					been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Primary Care Rheumatology and Musculoskeletal Medicine Society	Guideline	General	General	What is concernind is acupuncture! This guidelines states 5 hours of acupuncture? This has to be an adjunct of a comprehensive pain management program and not stand alone treatment.	Thank you for your comment. Acupuncture as an adjunct to other treatments was not covered within this review protocol and therefore this recommendation is for acupuncture alone.
Royal College of General Practitioners	Guideline	General	General	This draft NICE guidance, if approved, will have a significant impact upon what GPs are able to offer patients struggling with chronic pain. The increased focus on non-pharmacological approaches to pain management is supported by the evidence and by the Royal College of GPs, but if we are to support these guidelines there needs to be a realistic alternative for primary care to offer patients who are looking for medical help and support. Currently there are insufficient services recommended in this guidance available, and even if they are available there are often long waits to access these therapies and alternative treatments. Despite the	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				evidence, in many cases, even after discussing options using shared decision making, patients prefer and indeed often demand pain medication to be prescribed. To implement this guidance will therefore increase workload in primary care and require longer and more frequent consultations with this large group of patients. The resource implications on primary care therefore needs to be considered. If this guidance is to be realised, it will require significant resource investment in time, personal, public health population education campaigns (promoting the alternative approaches to care) and retraining and education of all health care professionals across primary and secondary care to ensure joined up and consistent practice across all specialists ranging from rheumatology and surgery, through to primary care and psychiatry. There will also need to be a significant expansion of specialist clinics, including but not limited to urgent and routine access to psychological services (to ensure all patients are able to access these services at the appropriate time), exercise programmes, chronic pain and acupuncture. The RCGP requests that consideration be made to ensure that this national investment is put in place and appropriate services and public health campaigns commissioned, to enable patient and clinician's	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.

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				knowledge to be improved and the evidence-based practice tobe realised, before the NICE guidance is finalised and published. It would be demoralising for GPs, pain teams and their patients, if the guidance is confirmed without appropriate patient and clinician education or enough commissioned alternatives in place to roll out the changes.	
Royal College of General Practitioners	Guideline	General	General	It is important to note that it is our opinion that there is extremely limited evidence for the management of pain in either socially excluded populations (e.g. those in secure environments), or those from minority groups. This is extremely important as help-seeking behaviour pertaining to pain is significantly influenced by socio-cultural factors. We would therefore request that the committee consider making amendments to the final guideline to take account of such factors. The strength of socially excluded patient expectation regarding both their entitlement to, and the effectiveness of long term analgesic prescriptions should not be under-estimated. Addressing this will be a significant challenge that will require public health as well as clinical interventions. Such public health interventions will have the potential to explain and "socially market" such reconfigured pathways to patient, thus optimising the chances of patient acceptance over the long term.	Thank you for your comment. Thank you for your comment. The committee agree that these groups are not well represented by the published literature, however the committee agreed that the recommendations should equally apply. The guideline reflects the evidence for best practice. There are areas that may need support and investment, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those

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				For example, a trial of antidepressant is recommended on P8 line 14 to P9 line 2 (recommendation 1.3.8). Prison based clinicians have, for many years, been recommending such options to patients when undertaking tapered reductions of long-term repeat prescriptions for opioids/ gabapentinoids. Such prescribing decisions have often been met with considerable resistance from prisoner patients, often accompanied by threats of violence. Shared decision making is often not possible in these situations. Therefore we would suggest that if this was to be a recommendation to prisoner populations it would need to be accompanied by significant reorganisation of the prison and healthcare regime e.g. integrated rapid access physiotherapy and prison exercise activities to support pain management; "social marketing" of the service change to the prisoner population to manage patient expectations prior to the consultation with the primary care prison prescriber.	interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Royal College of General Practitioners	Guideline	General	General	Management of Pain in Patient with a history of Drug Addiction. Can the committee consider adding a subsection in the final guideline addressing this important topic since many drug users present with symptoms of pain, when in fact their intent is to obtain habit forming analgesia to feed	Thank you for your comment. A bullet has been added to recommendation 1.1.5 to highlight that current or past history of substance misuse is also an aspect that might be included in the

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				their addiction. We would recommend that such a subsection would clearly articulate that some of the guideline recommendations would be difficult to apply to patient populations with a history of addiction.	discussion during the assessment of someone with chronic pain. The committee are aware that while the scenario described in the comment does occur, it is mostly in secure environments. They are also aware of evidence to the contrary demonstrating that people with addictions can be denied medication when they are in pain and agree both aspects need to be considered.
Royal College of General Practitioners	Guideline	004	General	Can the committee consider adding more context to the beginning of the document to set the scene? The draft guideline understandably has been controversial, and we believe that covering the facts that are currently covered at the end of the document in the introduction would help those reviewing it to put the guidance into context. For example, p28, lines 4-6: 'There is no medical intervention, pharmacological or non-pharmacological intervention that is helpful for more than a minority of people with chronic pain, and benefits of treatments are modest in terms of effect size and duration.' SIGN guidance on chronic pain management appeared less controversial to primary care professionals: https://www.sign.ac.uk/assets/sign136.pdf, partly	Thank you for your comment. The context section has been reworded and moved to the beginning of the guideline.

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				because the document clearly set out the limitations of medical interventions at the beginning, thereby setting the scene, ensuring clinicians understood the rationale behind the recommendations made.	
Royal College of General Practitioners	Guideline	004	002	Can the committee consider enhancing the assessment section of the document. In primary care, patients are seen from the initial presentation of acute pain, through the weeks and months it takes to transition into chronic pain. It would be beneficial to explore and explain the interface between acute and chronic pain, as this is essential when deciding when to stop medication that is no longer working and transition the patient into a "chronic pain pathway". Pain does not suddenly become chronic at 3 months despite this being the IASP formal definition. The NICE guidance on low back pain recommends risk scoring e.g. STartBack tool to assess for a risk of chronicity developing at the initial presentation, enabling a focussed approach on those requiring additional support. Can this or something similar be applied to this guideline? Identifying those at risk of chronicity at an early stage may allow patients and clinicians to work through the transition to chronic pain more easily.	Thank you for your comment. The assessment section has been edited and additional recommendations added on consideration of stakeholder comment. Assessment of acute pain is beyond the scope of this guideline and therefore specific reviews on transition or risk stratification were not included. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should

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					be encouraged and supported to reduce or stop where possible.
Royal College of General Practitioners	Guideline	004	018	Can the committee consider adding "where/if appropriate" to the statement "Ask the person about their understanding and acceptance of their condition and that of their family, carers and significant others." For some patients, for example those with co-morbid drug addiction, presenting with pain, relationships with family, carers and significant others is often not supportive, for example: 1. Presenting with symptoms of pain in the absence of significant pathology/disability can afford secondary gain by being attended to by family, carers or significant others 2. Those with addiction problems can present "in proxy" by manipulating family members to present with symptoms of pain to request analgesia 3. Family members or significant others may have caused the pain/persistence of pain due to negative psychological adverse events during childhood (or, on occasions, adulthood)	Thank you for your comment. The committee understand the important issues raised. However they believe it is still important to discuss these with the person being mindful of issues such as these which may arise from these discussions. A bullet has also been added to highlight that current or past history of substance misuse is also an aspect that might be included in these discussions.
Royal College of General Practitioners	Guideline	005	004	Can the committee consider clarifying this statement to confirm that chronic pain is aLong Term Condition and that treatment is not likely to cure the condition, as per comment 4 above? Adding that health care professionals	Thank you for your comment. A sentence has been added to state that quality of life can improve even when pain remains unchanged.

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				will help patients to live with and manage their pain better is the aim, rather than cure. Expectation setting and use of the correct language is essential.	
Royal College of General Practitioners	Guideline	005	007	Can the committee consider developing the template for a care plan for patient with chronic pain?	Thank you for your comment. It is beyond the remit of the committee to develop a care plan template. Your comments will be considered by NICE where relevant support activity is being planned.
Royal College of General Practitioners	Guideline	005	017	Can the committee consider adding a statement that reads: "Management should always start with the treatment of any identified underlying condition, not limited to, but including…" Currently the guidance only refers to those conditions where NICE has issued guidelines. Other conditions such as chronic pancreatitis or abdominal adhesions and myofascial pain can also cause chronic pain and these additional causes must not be forgotten. Including them in the list of types of chronic pain would therefore be helpful to clinicians	Thank you for your comment. The committee acknowledge that NICE guidelines may not cover all causes of chronic pain. In these cases clinical judgement should be used. The guideline recommendation focusses on pointing towards those where guidance is available.
Royal College of General Practitioners	Guideline	006	Chronic primary pain	Can the committee please consider adding a definition of chronic primary pain here rather than later in the document for ease of use? Chronic Pain & Chronic Primary Pain terminology is mixed up by many health care professionals and used almost interchangeably. Clarification is important to enable differentiation. The definition does appear at the end of the document for	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received

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				ease of use it would be helpful for clinicians to include here.	we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Royal College of General Practitioners	Guideline	006	015	Can the committee define what they mean by "exercises"? Does this relate to exercise with sports e.g. the gym, football etc, physiotherapy exercises or simple exercises and stretches often provided by primary care or physiotherapists.	Thank you for your comment. The review considered a range of supervised group exercise. Those considered are detailed in the protocol, and where there was evidence the descriptions are in the summary of included studies in evidence review E. The committee agreed that as the evidence did not demonstrate that one type of exercise was more effective than another, that this would not be specified further but

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					should be tailored according to the needs of the person.
Royal College of General Practitioners	Guideline	006	General	Can the committee consider adding a section on self-management and patient directed care? The use of publications such as 'The Pain Tool Kit', amongst others, has shown benefit and is widely accepted and publicised within the NHS (https://www.paintoolkit.org/)	Thank you for your comment. The committee agree that self-management is an important aspect of chronic pain management. There was no evidence to recommend this as a specific strategy, but the assessment recommendations have been edited to include exploring what self management tools the person has and a specific recommendation about providing advice and information relevant to the person's individual preferences, at all stages of care, to help them make decisions about managing their condition, including self-management.
Royal College of General Practitioners	Guideline	007	001	Psychological Therapies for chronic pain: Many psychology services across the UK have long waiting times and currently do not accept chronic pain referrals as an indication for support. This type of therapy is only available via pain clinics, which often have extremely long waiting times due to underfunding and lack of availability. When patients access help,	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that

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				urgent clinics offering psychological support would also be required, but again currently these are not currently available. In the current climate, a patient presenting for help with chronic pain may wait several months to be seen in an alternative clinic and naturally want something to help in the meantime. With no other options than antidepressants within this guidance, there is a huge risk of many more primary care prescriptions for antidepressants, as a holding measure whilst awaiting ongoing referral.	may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Royal College of General Practitioners	Guideline & Evidence review 7	007	007	There is an extensive review and economic assessment of acupuncture. The review shows very wide estimates for the cost benefit of acupuncture, and the committee's resulting recommendations are consequently and appropriately careful. The committee even considered that the benefits of 'real' over 'sham' acupuncture might have arisen through belief of the therapist, potential unblinding etc. (Evidence review, p44 lines 28-41). Can the committee confirm whether 'dry needling', advised in recommendation1.3.5, is equivalent to 'sham acupuncture'? Unfortunately, the term is not defined in the section on 'Terms used ….' It is essential to define whether sham procedures are supported, and clarity	Thank you for your comment. When setting the protocol the committee agreed that dry needling and acupuncture were appropriate to pool in the analysis as an active intervention. Where heterogeneity was observed, this was explored with subgroup analysis. However this did not explain any heterogeneity observed in the review. The PICO table and full protocol in evidence review G state that dry

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				would be welcomed on this point within the guidance to ensure the correct procedures are commissioned.	needling is included as an intervention, not a sham. The recommendation also specifically states acupuncture or dry needling to reflect the interventions reviewed.
Royal College of General Practitioners	Guideline	024	026	Can the committee consider a review of this statement? We agree with the statement pertaining to benzodiazepines, where there is a clear risk of addiction. However, the lack of evidence for NSAID effectiveness should not be equated with a lack of effectiveness since it does not appear that trials have been undertaken to demonstrate therapeutic effect. There is therefore a lack of evidence rather than an evidence of lack. Can the committee call for further research into the use of NSAIDs and/or other medications to treat "flare-ups" or "acute on chronic pain"? A recommendation to prescribe short term NSAID as "pulse" therapy to manage such flares, often used clinically, would also more appropriately balance the risks of long-term prescribing (e.g. gastrointestinal haemorrhage) with a need for reasonable therapeutic options.	Thank you for your comment. There was some, albeit limited, evidence available for the use of NSAIDs for chronic primary pain. This evidence demonstrated no difference between NSAIDs and placebo for quality of life, pain or psychological distress and worse outcomes for function. This is detailed in the rationale accompanying the recommendation. The committee agreed this was consistent with their experience of the use of NSAIDs for chronic primary pain, and taken with the knowledge of potential harms, agreed it was appropriate to recommend against its use. The committee agree that there is no evidence that the interventions

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					recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up.
Royal College Of Nursing	Guideline	General	General	The Royal College of Nursing (RCN) welcomes the opportunity to review and comment on the draft guidelines for assessment and management of Chronic Pain. The RCN invited members who have expertise and experience of caring for people with pain to review the draft guidelines on its behalf. The comments below reflect the views of our reviewers.	Thank you for your comments.

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Royal College Of Nursing	Guideline	001	General	The guideline is for both a variety of disorders associated with chronic pain and chronic primary pain. We feel that this remit is too broad and that there should be two separate guides. We note that this comment was addressed at the scoping stage, but healthcare professionals (HCP) and patient feedback demonstrates that there is great potential for confusion and concerns about mismanagement due to the current broad remit of the guidelines.	Thank you for your comment. In response to stakeholder comments we have made a number of revisions to the layout and headings in the guideline to clarify the populations covered in each section. The title has been amended to clearly include chronic primary pain. Additional headings and descriptions of included populations have been provided at the beginning of each section, and a visual summary will accompany the guideline demonstrating what populations are covered by each recommendation.
Royal College Of Nursing	Guideline	001	General	We welcome the focus on reduction of distress and improvement of quality of life that is espoused at the outset.	Thank you for your comment.
Royal College Of Nursing	Guideline	001	General	We welcome the fact that the guideline is as much for patients and their families and carers as it is for healthcare professionals and commissioners. However, we do not feel that the language and tone of the document as it stands is suitable for patients and carers. Social media commentary on this document has already demonstrated how anxiety levels have been increased dramatically for patients and carers who believe that this	Thank you for your comment. In response to stakeholder consultation we have reworded sections of this guideline and added additional definitions and headings to improve clarity and help readers. We hope this improves the usability of this guideline. The recommendations in

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				guideline will mean the removal from them of current therapies and interventions.	the first section of the guideline do highlight that people with chronic pain should be central to discussions and decisions about their care and the healthcare professional should foster a supportive collaborative relationship to help best support the person in living with chronic pain.
Royal College Of Nursing	Guideline	1.1.1	6	We welcome the emphasis placed on the patient as an equal partner in shared decision-making about their care.	Thank you for your comment. The committee agree this is central to effective management of chronic pain and chronic primary pain.
Royal College Of Nursing	Guideline	1.1.4	004	It is important to acknowledge that pain may not improve but this discussion must take place while considering the impact of pain on the individual. It must be recognised that pain reduction, and reduction of pain-related distress and disability are separate so that the latter can be achieved without the former.	Thank you for your comment. The committee agree this is important and that all recommendations on assessment need to be considered together, including the recommendation to discuss how pain impacts on people's lives and vice versa. A sentence has also been added to recommendation 1.1.11 to highlight that quality of life can improve even if pain remains unchanged.

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Royal College Of Nursing	Guideline	1.1.5	013	We believe it is important to recognise the social, cultural and faith context of pain for an individual and would welcome the inclusion of the word 'values' in this section.	Thank you for your comment. An additional recommendation has now been included for consideration of these factors in the assessment.
Royal College Of Nursing	Guideline	1.2	018	It is difficult to produce a definitive list of which other guidance should be consulted to support pain management decision-making. It may be unhelpful to provide this list here which suggests that those conditions not included should not be considered	Thank you for your comment. The committee agree a definitive list cannot be provided. A list of the most directly relevant guidelines is provided on the overview page and in the context for the guideline however to assist users.
Royal College Of Nursing	Guideline	1.2.1	002	It is important to note that lack of consistent high-quality evidence does not mean that patients do not benefit in myriad ways from following well-constructed pain management programmes. While we fully support the call for a better evidence base, there is evidence that the current pain management programmes provide benefit. We are concerned that this statement will lead to the withdrawal of pain management programmes by commissioners which (especially considering other guidance in this document), will leave patients without any effective management options. We would welcome the committee's advocacy for programmes to follow best-practice guidance such as that provided by the British Pain Society and the adoption of standard outcome measures to facilitate improved research.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of

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					chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered

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					individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline.
Royal College Of Nursing	Guideline	1.2.2	006	We agree that there is limited evidence for many social interventions, especially in relation to pain conditions and we, therefore, fully support the recommendation for research.	Thank you for your comment.
Royal College Of Nursing	Guideline	1.3.1	011	While we agree that group exercise can be an effective intervention, we believe that there is a need to offer some patients individual sessions instead of, or as a precursor to group activities. Some patients are too	Thank you for your comment. The evidence reviewed was largely for group exercise. This was therefore also what informed the economic model and this is reflected in the

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				embarrassed to attend group sessions, and others may be disruptive to group sessions.	recommendation. The committee agreed there wasn't enough evidence to comment on the clinical or cost-effectiveness of individual exercise although do acknowledge the importance of tailoring this to individual needs or preferences.
Royal College Of Nursing	Guideline	1.3.2	015	We applaud the inclusion of a link to support healthcare professionals to consider carefully how to encourage ongoing physical activity because this is an important but difficult to achieve target. However, we would also encourage the guideline development committee toconsiderthe role of activity generally as well as 'exercise'. The former is often equally challenging and effective for people with significant pain-related disability and has the psychological advantage of having an immediate outcome (achievement of a required task for example).	Thank you for your comment. The committee agreed that this recommendation should be reworded to encourage people to remain physically active as it was agreed this covered a broader range of activities. This recommendation was made to follow on from the recommendation for an exercise programme, and taking the existing NICE guidelines on physical activity into account. The evidence for the role of activity in chronic primary pain more generally was not reviewed within the guideline.
Royal College Of Nursing	Guideline	1.3.3	002	Cognitive Behaviour Therapy (CBT) and Acceptance and Commitment Therapy (ACT) are welcome components of this guideline although we acknowledge that these are often subsumed into pain management programmes of various descriptions. We would welcome direction from	Thank you for your comment. The evidence review was not able to inform the specifics of the intervention to provide more detail.

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				this document to guidelines on best-practice approaches to these therapies as we recognise that there are a plethora of interpretations and not all are equal in terms of potential to benefit the patient. In common with pain management programme we feel that poorly informed healthcare professionals can do more harm than good using these approaches if only in terms of leading the patient to dismiss the therapy.	The guideline recommendations assume that all people delivering the interventions recommended should be appropriately trained to do so. This has been added to the recommendation for clarity. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Royal College Of Nursing	Guideline	1.3.5	008	We are concerned at the recommendation for acupuncture in this document when it has been rejected from other pain related guidelines. We believe that further research is required given that many patients find acupuncture helpful to the extent that they will continue	Thank you for your comment. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and

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				to pay for it after the short course has been completed. We feel that the short course may lead a patient to choose to pay for further acupuncture when it is likely to fail. Many pain patients face financial hardship. We are concerned that the stipulation of the grade of practitioner is unhelpful. This is likely to relate to limiting the cost of this treatment, but it would be better if accompanied by a statement relating the minimum standard of qualification the practitioner is expected to have.	although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform

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					future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation. The evidence review did not inform minimum qualification standards, however all recommendations in this guideline require the healthcare professional delivering them to be appropriately trained. This has been added to the recommendation for clarity.

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Royal College Of Nursing	Guideline	1.3.6	004	Many of us have found TENS to be a low-cost treatment (for example in comparison to a course of acupuncture) that empowers the patient in the control of their pain. Many patients find this a helpful adjunct and we would prefer the guidelines to encourage a trial of TENS supported by appropriate education and follow up.	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
Royal College Of Nursing	Guideline	013	General	We are concerned with this section of the guidelines. Patients are fearful of having medication removed from their multimodal treatment regime even when they	Thank you for your comment. Considerations for people who are

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				demonstrate a clear benefit. We appreciate that there are significant concerns with a number of medications and a lack of evidence from randomised controlled trials in many cases. However, between us we have a multitude of patient cases that demonstrate consistent benefit, no escalation of dose, and maintenance of function and quality of life. We believe it is important to stress that all patients are provided with specialist assessment and follow-up to ensure that the medication they are prescribed is effective without significant burden in terms of side effects. We believe that pain specialists are the appropriate team to provide this assessment unless general practitioners have taken additional educational preparation.	already receiving these medicines and are reporting benefit and low harms have now been added to the recommendation to address these concerns. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered.
Royal College Of Nursing	Guideline	1.3.12	001	We agree that it is important that patients have counselling about continued use of potentially harmful medications. It is important that this consultation is done with sensitivity and in the recognition that patients are likely to be fearful and defensive. It is not appropriate to	Thank you for your comment. The committee agree these discussions are important. In the rational and impact on practice section of the assessment

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				have these consultations in single appointments. It is more common that many consultations will be needed before the patient is able to discuss the issues on an equal footing.	and communication recommendations we have highlighted that to fully implement these recommendations for people with chronic pain, longer consultations or additional follow-up may be needed to discuss self-management and treatment options.
Royal College Of Nursing	Guideline	1.3.13	006	We believe that the decision to stop medications and the process to withdraw them is a specialist concern and for some patients will require onward referral. We appreciate the development of further guidance for this.	Thank you for your comment.
Royal College Of Nursing	Guideline	1.3.14	008	Between us we have many patient stories of those who firmly believe that the use of cannabis has been transformative for pain management. We appreciate that the evidence does not support this patient-experience and we believe that a recommendation for high quality qualitative research should be made to properly explore the gap between the research and patient experience.	Thank you for your comment. The committee agreed that a research recommendation would be of benefit. The NICE guideline on Cannabis based medicinal products (NG144) recommends further research for the use of these drugs specifically for fibromyalgia however and therefore we have cross referred to this guidance for further research recommendations.
Royal College Of Nursing	Evidence Review B	General	General	We welcome the use of high-quality qualitative evidence to inform this guidance that demonstrates the centrality of the patient experience and communication skills to the success of chronic pain management,	Thank you for your comment.

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Royal College Of Nursing	Evidence Review B	1.4.1	016	Appendix reference source absent	Thank you for your comment. This refers to appendix E where studies that information was not extracted due to saturation being reached are listed. The full details of all associated references are all references are listed in the references section of the evidence reviews. For Evidence Review B this section begins on p37.
Royal College Of Nursing	Evidence Review C	General	General	There is no mention in this document of programmes that are delivered online or remotely. While the evidence based for these programmes is under-developed it is likely to be a growth area.	Thank you for your comment. There was not enough evidence to inform specific recommendations for online or remote programme delivery for any of the interventions.
Royal College of Occupational Therapists	Guidleine	General	General	The document does not include the importance of occupationally-focused interventions.	Thank you for your comment. Occupationally focussed interventions were not identified as a key intervention to consider during the scoping for this guideline however.
Royal College of Occupational Therapists	Guideline	004	013-017	Line 13 to 17 of the guidelines state: Ask the person to describe how pain affects their life, and how their life may affect their pain. This might include effects on:	Thank you for your comment. Interventions for day to day activities were not identified as a key intervention to consider during the scoping for this guideline. The

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				•lifestyle and day-to-day activities, including work and sleep disturbance •physical and psychological wellbeing •social interaction and relationships. The document then goes on to explore physical interventions, psychological interventions, social interventions and sleep interventions, as well as pharmaceutical and modalities. However, there is no exploration of interventions for day to day activities and work - including any recommendations for more research as, for example, the document does in other areas.	assessment recommendations do include providing information on self management however and all reviews considered the intervention's effect on function and health related quality of life which incorporated ability to perform activities of daily living.
Royal College of Occupational Therapists	Guideline	027 – 028	026 – 028 001 - 002	The importance of occupational therapy interventions focusing on work-related issues e.g. employment retention should be highlighted: https://www.rcot.co.uk/practice-resources/standards-and-ethics/ahp-health-and-work-report According to the office of national statistics, musculoskeletal conditions, which represents a high proportion of persistent pain problems, remain among the most common reason people have time of sick from work: https://www.ons.gov.uk/employmentandlabourmarket/p	Thank you for your comment and for this information. Thank you for your comment. Occupational therapy interventions focussing on work related issues were not identified as a key intervention to consider during the scoping for this guideline.

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				eopleinwork/labourproductivity/articles/sicknessabsenceinthelabourmarket/2018 Musculoskeletal conditions are also cited as a significant cause of long term sickness (27 - 31%) in the uk: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/817124/health-in-the-workplace-statistics.pdf The document "Is work good for your wellbeing: By G Waddall and Kim Burton" reviewing research on health and work, finds that work, adequately adapted if necessary, is good for health and wellbeing. National treatment recommendations should consider patients ADL needs, including work. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/209510/hwwb-is-work-good-for-you-exec-summ.pdf	
Royal College of Occupational Therapists	Guideline	General	General	In summer 2020, RCOT agreed continued endorsement of the 2nd Edition of Core Standards for Pain Management Services in the UK.	Thank you for your comment and this information.
Royal College of Physicians and Surgeons of Glasgow	Guideline	General	General	The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow has a membership of 15,000 and represents Fellows and Members throughout the United Kingdom. While NICE has a remit for England,	Thank you for your comment. The assessment recommendations in the guideline cover all types of chronic pain. The recommendations on

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				many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers of the devolved governments. The College recognises the area of Chronic Pain is difficult to assess. As defined, patients with chronic pain have various and variable symptoms with different precipitants and diverse aetiologies. It is a symptom complex and not a defined disease. The pathology of chronic pain has a wide spectrum. Potential management strategies are also numerous. Patients may seek help from many specialities of medicine, surgery and dentistry. All these specialities bring an expertise in managing these challenging patients. Therefore, in reviewing this area, it is difficult to survey the whole clinical experience. In developing a strategy, it is possible to generalise where generalisation is not relevant to the individual. Likewise, studies related to one form of chronic pain may not relate to the generality or the individual. In an area where there is a paucity of evidence, review of what evidence available may not be relevant to the real-life management of patients with the condition. The surrogate when the evidence base is poor will be custom and practice by acknowledge experts in the field.	specific management options are only for chronic primary pain however. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the

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				As stated above many specialists and other health professionals may be involved. Some of this expertise may not have beenutilised in the review of this subject. There was for instance no anaesthetists with an interest in pain management who provide the majority of pain services in the UK, neurologists or surgeons on the Committee. There appears over-representation of psychological expertise. These difficulties should be discussed and acknowledged in any review of the subject.	similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). Recommendations were made in accordance with Developing NICE guidelines: The manual as well as the methods chapter for this guideline. The committee agree they reflect best

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					practice and recommend the treatments that demonstrate benefit for people with chronic primary pain. The committee were recruited according to processes set out in the Developing NICE guidelines: The manual, and represent the range of expertise agreed appropriate to cover the scope of the guideline discussed at the stakeholder workshop.
Royal College of Physicians and Surgeons of Glasgow	Guidance	005	017	There is no mention of Fibromyalgia, Reflex Sympathetic Dystrophy (Complex Regional Pain Syndrome) or Chronic Facial Pain and whether this guidance is relevant or not. Page 11.1 does mention some of these specific diagnoses but does not mention fibromyalgia. CRPS1 has some specific treatments which can be very helpful, but which were not discussed.	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. Fibromyalgia and CRPS have been added as an examples in the context section of the guideline

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Royal College of Physicians and Surgeons of Glasgow	Guidance	010	013	Many patients consider the word chronic to mean severe and not long term (lasting three months). As this document will be read by patients, this needs to be stated	Thank you for your comment. The 'terms used in this guideline' section includes a definition of chronic pain, also noting this is sometimes called persistent pain or long term pain.
Royal College of Physicians and Surgeons of Glasgow	Guidance	025	007	It is unclear how the committee came to the view that NSAIDS were unhelpful. This may be related to literature search bias as discussed above. GI Bleeding risk can be addressed by the use of PPIs. There is no discussion of potential cardiac risks (low) of NSAIDS.	Thank you for your comment. There was some, albeit limited, evidence available for the use of NSAIDs for chronic primary pain. This evidence demonstrated no difference between NSAIDs and placebo for quality of life, pain or psychological distress and worse outcomes for function. This is detailed in the rationale accompanying the recommendation. The committee agreed this was consistent with their experience of the use of NSAIDs for chronic primary pain, and taken with the knowledge of potential harms, agreed it was appropriate to recommend against its use.
Royal College of Physicians and Surgeons of Glasgow	Guidance	General	General	It is disappointing that the conclusions of the committee suggest many treatment strategies are not helpful. It would be helpful if the committee produced a simple	Thank you for your comment. The committee did not include a treatment algorithm in the guideline

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				model treatment strategy in the form of a table or flow diagram.	as the treatment options are not recommended in any sequential order, but choice should be informed by a shared care and support plan developed with the person with chronic primary pain. A visual summary has been added to accompany the guideline which details topics that there are recommendations for and which population they apply to.
Royal College of Psychiatrists	General comment		Interdis ciplinary	The assessment and management of pain needs to be interdisciplinary- can the document highlight this. A unidisciplinary approach to managing pain increased the risk of doing things badly (as we don't know what we don't know) e.g a CBT therapist missing red flag signs, an anaesthetist missing opioid misuse, a physio missing PTSD	Thank you for your comment. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists

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					referral for specialist advice or assessment might need to be considered. The committee agree that a joined up approach between healthcare professionals is important.
Royal College of Psychiatrists	General comment		Self help resources	Should there be something about helpful self help resources…eg 'pain toolkit' www.paintoolkit.org…..youtubevideo 'understanding pain in less than 5 mins' . again anecdotal evidence suggests many people suffering with pain find these of interest/ support….could this be a recommendation for research…as well as peer lead/ patient led/ co-led self help groups/ movements?	Thank you for your comment. The committee agree self-management is an important aspect. Peer led pain management programmes were considered within the review, but there was insufficient evidence on these to inform a recommendation. The evidence for the pain toolkit and peer support groups was not specifically reviewed within the guideline however.
Royal College of Psychiatrists	General comment		Training / competencies	In order to improve care…the stated ambition of the guidance, we need to improve the skills of health and social care professionals in assessing and managing chronic pain. This is barely touched on in many curricula. We should be ambitious and advise that core competencies in the assessment and management of pain are developed and imbedded in all health care training programmes, with supervision for this work a core part of	Thank you for your comment. It is beyond the remit of the guideline to recommend what should be included in healthcare professional's curricula.

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				the framework. Safe prescribing needs to be a key component for prescribers.	
Royal College of Psychiatrists	Guideline	001	007	In terms of the reasons why the guideline should be developed I'd suggest including something like ' to promote a holistic bio-psychosocial approach to the assessment and management of chronic pain'……'using evidenced based approaches where available'. How it reads currently suggests the care plan should be based on what the sufferer wants, but we know that sometimes this can end up with unhelpful approaches such as ++ opioids/ epidurals which may inadvertently make a situation worse. Perhaps we need to add something about reducing unhelpful approaches and iatrogenic harm as an important factor in the path to improving people's lives/ ability to cope with pain. These factors play a huge part in the patients I see in a specialist pain clinic setting (especially multiples medications/ investigations/ operations/ unco-ordinated and confusing health care/ advice to rest/ not work etc)	Thank you for your comment. The overview page has been reworded and focuses on what the guideline covers.
Royal College of Psychiatrists	Guideline	004	002 **Bio-psychos**	I think the assessment section is quite weak. A full bio-psychosocial assessment is absolutely key to effective and helpful interventions. I'd suggest the section is organised along these lines and includes (not exclusively):	Thank you for your comment. The committee have edited the assessment recommendations in consideration of stakeholder

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			ocial assessment	b) in the 'bio' bit 1) ensuring all appropriate physical examination and investigations have been done to exclude other treatable causes of pain/ red flags (*this is because patients can develop serious disease that may get obscured/ missed because of the 'chronic pain ' diagnosis*) 2) full review of medication to address polypharmacy, inappropriate medication and unhelpful use or prescribing (*this is because a lot of people get prescribed lots of meds/ opioids and some take what is prescribed in a way that is not recommended)* 3) physical activity levels *(as so many people with pain are deconditioned)* 4) sleep 5) weight and diet b) in the psycho bit 1) current and past mental health 2) current and past suicidal thoughts/ plans *(as these are v common and pain/ physical health problems are common in those who sadly die by suicide. Also the most common prescribed medication implicated in completed suicide are opioids)* c) in the social bit 1) housing/ heating/ finances 2) support/ social contacts 3) meaningful/ pleasurable activities and interests	comments and added some additional recommendations to cover most of these aspects. Specific recommendations for investigations for treatable causes of pain have not been made as these are covered in relevant condition specific NICE guidelines which will be linked to from the guideline. A recommendation has been added to state that a diagnosis of chronic primary pain should be considered when there is no clear underlying cause or the pain or its impact is out of proportion to any observable injury or disease. The context section also highlights that the decisions about the search for any injury or disease that may be causing the pain, and about whether the pain or its impact are out of proportion to any identified injury or disease, are

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				4) cultural context 5) use of illicit medication/ excess alcohol/ cigarettes	matters for clinical judgement in discussion with the patient. The guideline also cross refers to the NICE guidelines on medicines adherence and medicines optimisation (CG76 and NG5) which include recommendations about medicine reviews.
Royal College of Psychiatrists	Guideline	008	013	Should there be a comment on capsaicin cream? Licenced for post herpetic pain/ neuropathic pain/ diabetic neuropathy and osteoarthritis of the knee….and used sometimes outside these conditions for chronic primary pain with some anecdotal benefit?	Thank you for your comment. Capsaicin cream was not prioritised as a medicine to include when agreeing the protocol for this review as the committee did not consider that it was widely used for chronic primary pain.
Royal London Hospital for Integrated Medicine (UCL)	Guideline	007	010 - 012	We welcome the analysis and guidance confirming acupuncture to be efficacious over sham, clinically effective and cost-effective in chronic pain. However, we are concerned about the overly prescriptive conditions imposed, particularly the setting (community-based only), in order to mandate the factors that are "likely to make the intervention cost-effective" (p20, lines 22-25) and limit the resource implications. We are surprised that NICE should stipulate so specifically where and by whom the service should be provided. The key criteria should be that the service is	Thank you. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to

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				delivered by suitably qualified professionals in suitable premises. We feel that NICE's role includes setting out what is intended by "suitable" in terms of professional standards, but not location or staff banding. We are unaware of equally prescriptive recommendations for non-drug interventions in other NICE guidelines, and indeed no such criteria were mandated for acupuncture in so CG150 (Chronic Headache), despite significant resource implications. This might even result in a practitioner being permitted to treat chronic headache but not other types of coexisting chronic pain in the same patient, simply due to the setting of treatment. For secondary care providers, tariffs are set nationally through the tariff setting process but may also be agreed locally through negotiation with commissioners. The tariff for acupuncture of £125 per session stated in in Appendix G, p37 line 38, is therefore not necessarily accurate. A service could be delivered more cheaply and local negotiations could reduce this tariff considerably, for instance using a group clinic model where several patients can be treated per thirty-minute session. Another unintended consequence of the "community-only" mandate is that NHS centres of excellence will be prevented from offering treatment clinics by commissioning bodies (which in our experience treat NICE recommendations as gospel, not guidance), with	structure services differently and aid implementation.

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				negative implications for the associated training, evaluation, audit, governance and standard-setting. The recommendations acknowledge the lack of an NHS acupuncture workforce, and the ATLAS clinical trial used for the cost-effectiveness analysis employed acupuncturists who were not healthcare professionals and whose training and experience was not clear. Since the removal of acupuncture from the 2016 CG59 update, the workforce has shrunk even further and there will certainly be inadequate (if any) community provision for a considerable time, with the result that many patients will not be able to access acupuncture at all. If, despite the above considerations, NICEs remains to specify a maximum cost per course of treatment, then rather than specifying secondary factors, the guidance should consider stating the actual cost as the summary recommendationand allow NHS commissioners and providers to determine how best to deliver the intervention at that cost.	
Royal Marsden NHS Foundation Trust	Guideline	General	General	We welcome many of the recommendations in the recent draft NICE guidelines. At the Royal Marsden, non-drug treatments for pain control as well as non-pain symptoms are widely appreciated and referrals for these come from a wide variety of professionals including oncologists, surgeons and clinical nurse specialists. Among these, acupuncture	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered,

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				has been offered within the chronic pain clinics at the RMH since 1980 and continues to prove popular with patients. Our acupuncture service is consultant-led and supported by a clinical nurse specialist for acupuncture and a part time nurse. Acupuncture is often offered as first line treatment for many pain and non-pain symptoms. The transition from 'last resort' to 'first line' occurred in the first 10 years of it being available and acupuncture referrals now outnumber the chronic pain clinic referrals. Strong opioids are commonly used for pain control in the acute phase of cancer treatment. There is robust evidence that acupuncture can have an opioid sparing effect for both pain and advanced cancer related dyspnoea. In our experience, acupuncture can be useful in weaning patients off opioids, in moderating opioid doses and where opioids are ineffective. Many of our patients have concurrent conditions including non-malignant pain, commonly musculoskeletal chronic pain conditions and primary chronic pain conditions such as fibromyalgia. We find acupuncture can be highly effective in management of these symptoms. We strongly support the recommendations that acupuncture should be available to patients with chronic	provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.

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				primary pain. From our experience we would further recommend that this low-risk, low-resource intervention should be more widely available where there is evidence of benefit. For hospital-based pain services such as ours, we recommend that the service is consultant-led.	
Royal Osteoporosis Society	Guidelines	001	008	The introduction to the guidelines states: "recommendations on managing chronic primary pain (as defined in ICD-11) for which there is no other NICE guidance". We are concerned about the use of these guidelines in their application to chronic pain following numerous vertebrae compression fractures (VCF) sustained as a result of Pregnancy/Lactation Associated Osteoporosis (PAO; PLO). There are no NICE guidelines for the treatment of PAO/PLO or for the management of long-term pain associated with numerous vertebrae compression fractures. The mechanisms of disease development in PAO/PLO are different to post-menopausal osteoporosis, both in relation to the development of the disease and in relation to the severity and number of vertebrae compression fractures sustained. Often women with fractures due to PLO/PAO continue to experience ongoing pain in the cervical, thoracic and lumbar spine, after compression fractures have healed. This chronic pain is often a result of spinal deformity from numerous compression fractures, impacting on the nerves and muscles. It would be prudent to view this as secondary pain to spinal	Thank you for your comment. Specific management of chronic secondary pain is not included within the scope of this guideline. The assessment section covers all types of chronic pain, but in the scoping stages it was agreed the specific management interventions would focus on chronic primary pain, so as not to overlap with existing NICE guidelines. We acknowledge NICE guidelines do not cover all chronic secondary pain conditions, but cannot provide further guidance on specific types of chronic secondary pain here. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant

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				fractures/deformity; however, given the lack of guidelines about chronic pain management in osteoporotic compression fractures (out with vertebroplasty/kyphoplasty NICE guidelines), we are concerned that these new guidelines for management of chronic pain following VCF sustained in PLO/PAO may be incorrectly applied.	recommendations in order to clarify and avoid any misinterpretation. A visual summary has also been added clarifying what populations are covered by each recommendation.
Royal Osteoporosis Society	Guidelines	008	013	We are concerned about the recommendation for the use of antidepressants in the treatment of chronic pain on two counts. 1. Concern that these guidelines be inappropriately applied to the treatment of chronic pain following VCF in PAO/PLO, as we disagree with the use of antidepressantsto treat chronic pain in this population. Chronic pain, defined as pain lasting three months or longer, does not fit with this population. Following numerous VCF (as frequently seen in this disease, described as cascade fractures) the healing of the bone can take up to a year plus to fully heal as evidenced on MRI scans which continue to show bone oedema at the site of sub-acute fractures beyond the 3 month mark. As such, pain which is experienced at 3 months plus can still be linked with pain as a result of healing bone/tissue etc. and should be managed as acute pain. Unfortunately,some women can continue to	Thank you for your comment. The recommendation for antidepressants is for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. Further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic to aid readers and avoid misinterpretation. The title has also been amended to reflect that

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				experience new fractures or further compression of old fractured vertebrae over the course of their lifetime. Therefore, the disease can result in lifelong chronic pain, with periods of acute on chronic pain. Lifelong access to effective pain relief (opiates) to manage, particularly the periods of re-fracture, are essential to maintaining mobility, functioning and quality of life in this population. 2. Chronic pain that continues following the healing of bone/tissue in this population is often secondary to deformity of the spine and associated structural changes to bones, joints and muscles. Whilst there are NICE guidelines for the treatment of neuropathic pain, (often experienced in this population due to structural change in the spine), there are no suitable guidelines for the management of non-neuropathic pain in this population. It is our belief that chronic pain in this condition would best be treated with similar guidelines to that outlined in the "Neck pain - cervical radiculopathy" NICE guidelines rather than these new chronic pain guidelines. The chronic pain seen in PLO/PAO results from structural change and as such better fits with the ICD-11 classification of Chronic secondary	chronic primary pain is also a focus of this guideline. Management of chronic secondary pain should be according to other relevant NICE guidance, where available. For conditions that are not already covered by existing NICE guidance, clinical judgement should be used to inform the most appropriate treatment based on the available related guidance and clinical experience.

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				musculoskeletal pain rather than chronic primary pain. However, there are no NICE treatment guidelines for chronic secondary musculoskeletal pain. It would be important that, in the future, treatment-specific guidelines for PLO/PAO are produced to appropriately meet the needs of this population. A member of this Patient advocate group for PLO, affiliated with the ROS, has given the following personal quote to express her concerns. The member's name has been redacted, given your guideline's request for confidentiality. However, should it be required, this member will gladly have the quote attributed to them; as such, NICE is free to contact our group if needed: *"I have lived with chronic pain for 29 years since my spine collapsed in labour due to PAO/PLO. Long-term use of opioids has been helpful and effective. I am not addicted, and over 29 years, have stopped and started them carefully under GP supervision, as required to assist with pain. I have also found lidocaine use particularly helpful, both patches and infusions and teriparatide bone treatment helpful in stopping ongoing fragility fractures and reducing pain. I am under the care of a pain specialist and pain clinic and metabolic bone specialists and other specialists, but my GP provides my general ongoing care. I am unable to have acupuncture for medical reasons (recurrent cellulitis from*	

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				current denusomab bone treatment). Exercise has been only partially effective in managing the terrible chronic pain I experience and exercise has to be specialist run and personally tailored to ensure it is safe for me and does not cause further fractures, given that I remain at high fracture risk. I experience chronic pain from the 24 fractures diagnosed on Xray (there were probably more fractures, but X-rays were stopped, due to radiation overexposure concerns). Over the years I have experienced 14 known vertebral fractures and 4.5 inch height loss, a hip fracture, metatarsal, metacarpal and many rib fractures. I now additionally have various other health conditions and illnesses arising directly or indirectly from my long-term condition of PAO/PLO. A Neuropsychologist has advised that antidepressants for the management of pain would not be beneficial for me as a PAO/PLO patient, and additionally that they are detrimental to bone health. As a rare disease patient, I am now a layperson with NICE, on the HST Committee and I am also a Patient Expert on the PIP Committee and a Patient Advocate with the ROS Research Academy."	
Royal Osteoporosis Society	Guidelines	023	012	The evidence reported for antidepressant use in management of chronic pain primarily involves studies that compare antidepressants to placebo. There is a scarcity of research including direct comparison of the use of antidepressants to the use of traditional pain medications (NSAIDs, paracetamol, Opiates, etc). These	Thank you for your comment. When setting the review protocol, the committee agreed that both comparison with placebo or each other would be included in the review. Very limited head to head evidence

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				chronic pain guidelines report limited effectiveness of NSAIDs, paracetamol, and opiates in managing chronic pain – alongside risks of potential harm utilising these medications. However, it is difficult to understand how the effectiveness of antidepressants compares with the effectiveness of traditional pain medications without head-to-head comparison studies. As such, it is difficult to understand how these guidelines can take a position of the most clinically effective management of chronic pain without directly comparable research to support this. The potential negative side effects of antidepressant use are becoming more reported in a wide array of recent literature. Given that potential harmful effects of traditional pain medications (dependence, GI bleeding) are cited as one reason to cease their use in chronic pain management, it appears short-sighted to omit recent reported harmful effects of antidepressant use (dependence, suicidality, cognitive difficulties, emotional blunting, negative effects on bone health-- specifically bone mineral density-- leading to increasing fracture risk in osteoporosis). Without referencing potential issues with withdrawing from antidepressant use, these guidelines fail to sufficiently highlight the other reported harmful effects of antidepressant use. Of concern is the evidence related to the negative effect antidepressant use can have on bone health, with the potential to increase fracture risk. This would make the use of	was identified for chronic primary pain. For decision making to inform the recommendation, the committee agreed comparisons with placebo were sufficient to demonstrate effectiveness. Head to head comparisons would be more informative only when one of the comparators already had proven effectiveness in the population of interest. Thank you for your comment. The committee agree that it is important side effects and harms of antidepressants are considered in any decision of whether to start using these. They recommend a decision is made only after a full discussion of risks and benefits. They also include a recommendation to discuss with the person the problems associated with withdrawal from these. The committee's discussion of these

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				antidepressants in the management of chronic pain contraindicated in anyone with risk factors for osteoporotic fractures, including those with a PAO/PLO diagnosis, or those with osteoporosis and osteopenia. It is also important to note the high co-occurrence of osteoporosis in those with an osteoarthritis diagnosis. Links below to relevant emerging research on the potential harmful effects of antidepressant use. https://www.sciencedirect.com/science/article/abs/pii/S0306460319309001 https://www.ingentaconnect.com/content/ben/cds/2018/00000013/00000003/art00006 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3442753/ https://www.sciencedirect.com/science/article/pii/S240552551730033X https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6069102/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3442753/	factors is included in the discussion of the evidence in Evidence review J.
Royal Osteoporosis Society	Guidelines	023	015	These guidelines report that "*Most of the evidence was for women with fibromyalgia. However, the committee agreed that for most medicines, response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions, even when*	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain.

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				evidence was available for only one condition." We are concerned about the suitability of a research from a fibromyalgia population being extrapolated to a general population of chronic pain sufferers. There is a high prevalence of depression/anxiety amongst Fibromyalgia patients, where it is unclear which condition pre-exists. It is possible that reported improvements in quality of life and perceptions of pain can in part be accounted for treatment of depression and anxiety. To illustrate, research by Bernick and colleagues in 2013 stated: *"Recent data indicate that fibromyalgia, anxiety disorders, and depression tend to occur as comorbid conditions. They also share some common neurochemical dysfunctions and central nervous system alterations such as hypofunctional serotonergic system and altered reactivity of the hypothalamic-pituitary-adrenal axis. Conversely, functional neuroimaging findings point to different patterns of altered pain processing mechanisms between fibromyalgia and depression. There is no cure for fibromyalgia, and treatment response effect size is usually small to moderate. Treatment should be based on drugs that also target the comorbid psychiatric condition."* We are concerned that other chronic pain illnesses, particularly secondary chronic musculoskeletal pain, do not have the same prevalence of co-morbid anxiety and depression, and as such, may not have the same central nervous system alterations that would suggest effectiveness of antidepressant use to treat pain. We believe it would be prudent to include	Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The evidence reviews for all of the interventions included all types of chronic primary pain where evidence was available. For some reviews there was a predominance of females with fibromyalgia, and in some cases a large number with chronic neck pain,

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				other types of chronic pain (types of secondary chronic pain that are not captured in their own NICE guidelines, such as secondary musculoskeletal chronic pain) in your systematic review, to ascertain whether your current guidelines can indeed be applied to those who do not have a fibromyalgia diagnosis. Furthermore, we are concerned that these guidelines run the risk of further compounding the gender inequality bias evident in the NHS. The evidence reported in these guidelines is primarily from a female population, and it is intended to be applied to a primarily female population (fibromyalgia, chronic pelvic pain). Evidence indicates that a gender bias already exists in health services, including the NHS. Research indicates that women's experience of pain is more likely to be classified as being associated with psychological processes, they are less likely to receive adequate investigations related to their pain, and are less likely to receive adequate pain relief compared to their male counterparts. A BBC article in 2018 reported the following: "When they're in pain, women wait longer in emergency departments and are less likely to be given effective painkillers than men. One study, for example, found that **women in the emergency department who report having acute pain are less likely to be given opioid painkillers**than men. After they are prescribed, women wait longer to receive them." These disparities in treatment become even more apparent when looking at	but evidence for other types of chronic primary pain was available. The committee have detailed in each relevant rationale and discussion of the evidence in the evidence reviews their consideration of the populations included in the evidence, and why, or where separate considerations are required. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary

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				the data comparing white women's experiences with the experiences of BAME women accessing healthcare in the NHS. BAME women experience some of the poorest health statistics in the UK. For example, an article by Inews in 2019 reported: "*BAME women are less likelyto be prescribed pain relief, more likelyto undergo debilitating surgery and less likely to be listened to, often suffering from a later diagnosis even when presenting early.*" The relevant references in relation to gender inequality bias discussed are available below: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5845507/ https://www.bbc.com/future/article/20180518-the-inequality-in-how-women-are-treated-for-pain https://inews.co.uk/opinion/comment/bame-women-are-let-down-by-the-health-system-nowhere-more-so-than-in-gynaecological-health-288985 We are of the view that these guidelines perpetuate gender bias already evident in our NHS system. As the PLO/PAO patient advocate group, we are particularly concerned about this gender bias should these guidelines be inappropriately applied to the management of chronic pain in PLO/PAO. PLO/PAO, by its nature, only affects women, specifically young mothers with newborn children. Lack of access to appropriate pain relief in this population (i.e.: beyond the 3 month mark) can result in	pain. If there was reason to believe that specific considerations were required, this was detailed in the discussion and in the recommendation. The ICD-11 definition states that chronic primary pain is associated with significant emotional (anxiety, anger, frustration or depressed mood) distress, and therefore the committee would note that this doesn't just apply to fibromyalgia. The committee agree that chronic secondary pain requires different management and cross refer to relevant NICE guidelines where these are available. The committee do not agree that these guidelines will perpetuate gender bias. Whilst they acknowledge that in some reviews the evidence base includes more females, there is

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				prolonging the period of immobility and poor functioning for women, impacting on their ability to care for their newborn child. This is particularly relevant for women with low income, those accessing disability payments, single mothers, or immigrant women. Without financial capacity to pay for support with childcare or access to family support, women with impaired functioning as a result of severe pain may be unable to care for their newborn child. This may result in temporary separation due to social work intervention, which can have a lasting impact on the development of thenewborn child, and on the mental health of the mother.	no reason that the effectiveness of interventions for chronic primary pain would differ according to gender. The guideline recommends the interventions demonstrated to be effective for chronic primary pain, and these should be available to both men and women equally within the NHS.
Royal Osteoporosis Society	Evidence Review J	008	Table 1	The evidence reported for antidepressant use in the management of chronic pain in these guidelines draws on a research database where: "*Outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months"*.From a reading of the evidence review J document, it appears that the median and mean outcome time in the included research papers was 12 and 11.7 weeks respectively. Of the 33 studies included in your review, only 5 of these studies had outcome data collected beyond a 16-week timeframe (24, 26, 27, 26, 24 weeks). Given that the average length of outcome from studies included in your review is 12 weeks it is difficult to understand how this evidence can be translated to real world application, as those who experience chronic pain, particularly those with a	Thank you for your comment. As per the protocol, the longest time point available in the papers was extracted where available. The committee discussed the lack of long term follow up data and noted in their considerations of the evidence that long term effectiveness was uncertain. This is true for all of the interventions considered in the guideline where evidence was only available for courses of treatments and long term follow up is lacking. The committee agreed that as part of a shared care

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				fibromyalgia diagnosis, often report average lengths of pain to be years (7-10 years) rather than months. How can effectiveness of antidepressants for pain management and quality of life for a very long-term illness (7 plus years) be inferred from researchthat does not look at outcomes beyond a 12-week mark?	and support plan between the person with chronic primary pain and healthcare professional the evidence for benefits and harms of all recommended interventions should be considered at all stages of care.
Royal Osteoporosis Society	Evidence Review J	042	020	The evidence used to support SSRI use for pain reduction is based on: "*Very low quality evidence from 3 studies with 150 participants showed a clinically important benefit of SSRIs compared to placebo at ≤3 months. Very low quality evidence from 2 studies with 65 participants showed a clinically important benefit of SSRIs compared to 22 placebo at >3 months*." As such the evidence these guidelines are using to support the use of SSRI antidepressants for pain reduction is based on 5 very low quality studies with a combined N of 215. We are concerned about the inclusion of only very low quality studies with a relatively small N to draw conclusions that recommend the use of SSRIs to manage chronic pain reduction.	Thank you for your comment. The quality rating is for the body of evidence informing the outcome of interest, not for the study. The risk of bias in the studies informing that outcome is one of the factors that contributes to the quality rating (more details on how this is rated are in the methods chapter). The quality of the evidence is one of the factors the committee take into account when forming recommendations. The committee note that there are some limitations in the evidence and have therefore recommended to consider antidepressants, rather than making a stronger recommendation to offer them for chronic primary pain.

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Royal Osteoporosis Society	Evidence Review J	042	048	In relation to potential adverse effects of SSRI use this review included "*Very low quality evidence from 1 study with 24 participants showed a clinically important benefit of SSRIs compared to placebo at ≤3 months. Low quality evidence from 1 study with 14 participants showed a clinically important benefit of SSRIs compared to placebo at >3 months"*.We are concerned that adverse effects of SSRI use have not been adequately reviewed, where only two very low quality studies were used to assess this, with a combined total of only 38 participants.	Thank you for your comment. Where there is an absence of evidence on a particular outcome relating to an intervention, the committee can use their expert consensus opinion based on their experience to help inform the recommendation. The committee highlighted in the recommendation that there should be a full discussion of the benefits and harms. The discussion of the evidence in chapter J details their considerations including noting "a number of precautions listed in the SPC, as well as the Medicines and Healthcare products Regulatory Agency safety guidance on SSRIs and SNRIs, including increased risk of suicide in those with a history of suicide-related events, or those with a significant degree of suicidal ideation, increased risk of withdrawal reactions and concerns regarding use during pregnancy. It was agreed that these factors should form part of the decision between risks and benefits

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					and appropriateness for the individual when considering these drugs."
Royal Osteoporosis Society	Evidence Review J	043	007	The evidence related to SNRI use to manage pain for this review was: "*Moderate quality evidence from 6 studies with 2194 participants showed no clinically important difference between SNRIs and placebo at >3 months*". Given the inclusion of 6 moderate quality studies with a high number of participants (2194) showed no clinically important difference between SNRI and placebo in pain management, it is difficult to understand how SNRI use could be advocated in these guidelines for the management of chronic pain reduction?	Thank you for your comment. The committee take into account the whole body of evidence for all critical and important outcomes across a comparison when determining whether or not to make a recommendation. The evidence statement highlighted in your comment is for pain reduction. It is followed by those for quality of life, where some studies demonstrate benefit in the short and long term. For sleep and psychological distress benefit was again observed in the longer term follow up. The committee agreed this was sufficient to inform a recommendation to consider the relevant SNRIs.
Royal Osteoporosis Society	Evidence Review J	043	033	The evidence related to adverse effects of SNRI use in the management of pain reduction include: "*Low quality evidence from 6 studies with 2367 participants demonstrated that more people discontinued from SNRIs compared to placebo at >3 months*" Whilst this evidence is from low quality studies, the large N (2367) has indicated	Thank you for your comment. The committee took this into account when considering the body of evidence on this topic. They considered that there was evidence of

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				potential harmful effects, and as such, we are concerned about the potential use of SNRIs for treatment of chronic pain.	benefit demonstrated in a number of outcomes, but did acknowledge the adverse events resulting in discontinuation. They therefore agreed this should be recommended as an option to consider, rather than the stronger recommendation wording of offer. They detail in the discussion of evidence in the evidence review "The committee agreed that the decision of which class of antidepressants to try should be based on a fully informed discussion with the person with chronic primary pain, taking account of the person's additional symptoms and the side effect profiles of these drugs and that the risk of withdrawal symptoms should be considered when prescribing these drugs". The recommendation also includes a statement that there should be consideration of all benefits and risks.
Royal Osteoporosis Society	Evidence Review J	043	043	The evidence for pain reduction from the use of tricyclic antidepressants is mixed. The research is from very low quality or low quality studies. There is evidence reported	Thank you for your comment. The committee noted that for tricyclic

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				of no clinically important benefit in pain reduction compared to placebo, as well as research reporting a clinically important benefit compared to placebo. Given the mixed evidence from low quality studies, we are concerned that it is too difficult to draw a conclusion about whether tricyclic antidepressants have any benefit in management of pain reduction. We are also concerned that the research related to potential harm from tricyclic antidepressants include: "*Moderate quality evidence from 1 study with 332 participants demonstrated that more people discontinued from tricyclics compared to placebo at ≤3 months. Low quality evidence from 2 studies with 319 participants demonstrated that more people discontinued from tricyclics compared to placebo at >3 months*." The research included both a large N moderate quality study and 2 low quality studies, but the total N from these combined studies was 651, and indicated potential adverse effects. As such, we are concerned about the application of tricyclics to management of chronic pain, as there is limited evidence about effectivenessof pain reduction and evidence of potential harm.	antidepressants (mainly amitriptyline) evidence from 6 studies showed a benefit of tricyclic antidepressants for quality of life, pain, sleep and physical function, but no difference for psychological distress, and harm due to adverse events resulting in discontinuation. Evidence was mainly available for short-term follow-up (less than 3 months), with limited evidence available for long-term effectiveness. Taking this into account as a body of evidence, they agreed it was sufficient to inform a 'consider' recommendation, but not a stronger recommendation to offer these for chronic primary pain. Full discussion of the committee's consideration of the evidence is detailed in evidence review J in the discussion of the evidence section.
Royal Osteoporosis Society	Evidence Review J	045 046	028 008	The research included in this review identified no potential harmful effect from Benzodiazepine or NSAID use.	Thank you for your comment. The comments on harmful effects of these medicines are from the committee's expert experience and opinion and are

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					well documented. The recommendations against their use were partly formed by this, and also the evidence reviewed which did not demonstrate benefit.
Royal Osteoporosis Society	Evidence Review J	048	015	When discussing potential harm related to long-term opiate use, this review reports: *"However, there are a range of other serious harms and problems, including cognitive impairment, falls and fracture, sexual dysfunction, endocrine changes, immune dysfunction, depression, sleep apnoea, and heart attacks, that have been suggested to be associated with opioid use."* We support the clear reporting about the potential adverse effects associated with a medication. However, we are concerned that this review has not included a wider body of evidence on antidepressants to sufficiently explore the adverse effects associated with their use, many of which are similar to those reported with opiate use (i.e.: cognitive impairment, sexual dysfunction, depression, dependence).	Thank you for your comment. The committee do agree that there are also side effects associated with antidepressants that should be considered. These are detailed in the BNF and relevant summary of product characteristics. The committee agreed it was important to state in the recommendation that a decision to start antidepressants should be based on a full discussion of the benefits and harms.
Royal Osteoporosis Society	Evidence Review J	56	14	This study reports that "*No evidence was identified for the outcomes of cognitive impairment, fractures and falls, sexual dysfunction/endocrine impairment, immune dysfunction, sleep apnoea, cardiovascular events, self-harm/suicide or depressive symptoms/mood disturbances*." The only reported negative outcome of opiate use was dependence ranging from 1.3% to 5.9%. It would be important to conduct head-to-head comparisons with	Thank you for your comment. The review of long term safety of antidepressants compared to opioids was not prioritised as an area to cover within the guideline. The committee cannot comment on whether such data is available at present although

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				antidepressant use to identify if the dependence rate differs. They also reported an all-cause mortality rate of 1.1%; however, as this is an all-cause mortality rate, it cannot be attributed solely (or at all) to opiate use.	agree it is an interesting area for research, that cannot be recommended in the guideline.
Royal Osteoporosis Society	Guideline	25	26	When discussing the use of local anaesthetic for chronic pain the following is reported in your guidelines: "*Evidence for local anaesthetics was limited. A small amount of evidence for short- term use suggested that there is either no benefit or that their use could result in worse outcomes for pain than placebo".* This does not clarify whether this was local anaesthetic delivered via patches/plasters or infusion treatment. There is evidence to support the use of intravenous lidocaine for chronic pain: https://www.ncbi.nlm.nih.gov/books/NBK531808/ We are concerned that the financial cost of both intravenous and local anaesthetic patches may be a primary reason for the decision to advise against their use. Should this be the case, it would be important that the guidelines are transparent about this decision-making process.	Thank you for your comment. When determining the protocol for this review question, the committee agreed that topical, intravenous or trigger point injections of local anaesthetics should all be considered and evidence was searched for each. The evidence identified was for topical lidocaine. No evidence for intravenous lidocaine for people with chronic primary pain was identified. The reference provided has been checked for any relevant studies but none are specific to chronic primary pain. The recommendation was based on the lack of evidence for clinical effectiveness of local anaesthetics, not the cost of these medicines. The rationale text highlights the reasons the committee agreed this should not be recommended.

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Royal Pharmaceutical Society	Guideline	General	General	There is some concern amongst our members about the use of the term 'chronic primary pain'. We recognise that chronic primary pain is an internationally agreed definition, however is not yet widely recognised or used in pain circles, let alone generalist services.We suggest improved clarity and information about the diagnostic terminology and the need to clearly differentiate between chronic primary pain and other pain conditions. We would suggest a change in title that reflects the contents of the guideline more accurately. We agree that it is good to tackle pain management but to focus so much on a certain type of pain, that is not yet well recognised, and may not be present alone is perhaps too soon and potentially unhelpful. Currently the guidance does not differentiate clearly enough between the chronic pain due to a known cause, which affects 30-50% of the U.K. population and the target group of patients with chronic primary pain with no known diagnosis which affects only about 5% of the population. It fails to acknowledge that chronic pains of both known and unknown cause may co-exist in the same person. Because of this lack of clarity, we are concerned that a large proportion of the population, who have chronic pain from a specific cause, will be denied appropriate analgesics as a result of non-specialists who may be under the erroneous impression that the guidelines apply to all chronic pain. We suggest improved clarity or	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. A recommendation has been added to highlight that chronic primary and chronic secondary pain can coexist and it is also included in the

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				information about the diagnostic terminology and the need to clearly differentiate between chronic primary pain and other pain conditions is included in the guideline.	definitions at the beginning of each section.
Royal Pharmaceutical Society	Guideline	Genral	General	Chronic primary pain may not always exist in isolation; there could be acute injury or flare ups, additional secondary chronic pain that may require additional medicines and this guideline does not recognise this. There is a lack of clarity on the range of conditions that are covered by the guideline. Some additional defining of the guidelines would be useful	Thank you for your comment, the committee agree that these points are important to add in the guideline. Additional recommendations have been included to highlight that chronic primary pain and chronic secondary pain can coexist and may require different management, they also add considerations for flare ups of pain. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order

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					to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Royal Pharmaceutical Society	Guideline	General	General	The fundamental principle of good health care is person centred care and shared decision making. The guidance as is could lead to medicines that have not passed the evidence test being stopped which goes against the personalised care principle. Some people may be currently benefiting from these medicines, so each case needs to be assessed individually and that needs to be made clearer in the guidance. The statement referring to reviewing people currently using these medicines should be strengthened by adding that practitioners should ensure patients are continuing to gain benefit (functional improvement being the primary outcome). We would recommend strengthening the wording around the need to individualise care, ensuring that medicines are only offered as a trial with the need to have a functional goal and that where	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged

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				medicines are not shown to be beneficial in respect of reducing pain intensity AND allowing increases in function, that they should be carefully withdrawn to avoid causing unnecessary harm. As medicines experts, we advocate for the safe, rational and evidence-based use of medicines. We welcome regular medication reviews and the safe withdrawal of ineffective medicines or those that are demonstrating harm to the patient. However more emphasis should be placed on a potential withdrawal of medication being patient centred and with consideration to the Individual circumstances. .	and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
Royal Pharmaceutical Society	Guideline	General	General	The guidelines don't lay out how patients should be treated pre-diagnosis. Should chronic pain be treated as chronic primary pain until otherwise diagnosed? If it is suspected that they have a condition like endometriosis or IBS, should they be treated as having chronic primary pain until the diagnosis is confirmed, or should they be treated as they would be once diagnosed? We would recommend that NICE includes a statement that investigations should be offered/completed, to rule out causation before the diagnosis of chronic primary pain is made.	Thank you for your comment. The assessment section has been amended to include more clearly some recommendations for the assessment when considering the diagnosis. We note a holistic assessment is important and an individualised approach required. Each person's individual symptoms and presentation will be different and require different consideration and investigations as appropriate. This guideline should also be used

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					alongside other NICE guidelines, including CG138 Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. This covers more recommendations on assessment of people using services in general, including when they don't yet have a diagnosis.
Royal Pharmaceutical Society	Guideline	General	General	In terms of framing the recommendations it might be easier to frame as 'we recommend that prescribers do not initiate the following medicines for chronic primary pain'	Thank you for your comment. The committee agree that it is important to acknowledge that some people will already be receiving these medicines. The recommendation has been reworded as suggested. More detail has also been added to the recommendation with considerations for people already taking these.
Royal Pharmaceutical Society	Guideline	General	General	We do welcome the use of counselling, acupuncture and exercise, as part of the management of chronic pain. All of these have the potential to be a valuable part of an individual's treatment. Other alternative therapies such as EMDR are already being used by the NHS in conditions such as PTSD and post-natal psychosis, and it is starting to be used successfully to assist chronic pain patients for whom talking therapies are not suited. We would like to	Thank you for your comment. The committee considered the use of EMDR for chronic primary pain within the evidence review. No evidence was identified and the committees view was that it was not commonly used for chronic primary pain and therefore

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				see NICE giving guidance that includes a wider range of approaches so that patients and doctors can find an approach that suits each individual. If evidence is not available for a wider range of approaches we would recommend that the guidance identify additional areas that would benefit from research of their use in chronic primary pain.	was not a priority area for further research.
Royal Pharmaceutical Society	Guideline	General	General	It is good to see the issue of chronic primary pain being addressed.	Thank you for your comment
Royal Society of Medicine	Guideline	018	025-030	If you only look at limited evidence, you will only have limited evidence. There is a mass of evidence that hypnosis, correctly applied, and EMDR, works well for chronic pain.	Thank you for your comment. Reviews for specific management options in the guideline were for people with chronic primary pain only, and therefore the protocols (and searches) were restricted to chronic primary pain. Only one relevant study on hypnosis was identified for this review. There were no relevant studies identified for EMDR in chronic primary pain. Evidence for other types of chronic pain (chronic secondary pain) was not relevant to this review.

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Royal Society of Medicine	Guideline	018	026	The author would like to challenge the notion that there is little evidence to show the benefit of hypnosis for the treatment and management of pain. Over the last thirty years, empirical support for the use of hypnosis in pain management has flourished (Jensen & Patterson, 2014). Clinical outcome studies on both acute and chronic pain have demonstrated that hypnosis is effective beyond placebo treatments. Also, the use of hypnosis to improve quality of life in people with chronic pain often involves focusing on outcome variables other than just pain relief, including improved sleep, relaxation and positive affect (Jensen, 2011; Patterson, 2010). In addition, hypnosis has been shown to produce changes in brain activity in areas which are involved in processing pain—specifically, the thalamus, anterior cingulate cortex (ACC), insular cortex, primary and secondary sensory cortices and the prefrontal cortex (Apkarian et al, 2011). Neurophysiological studies have also reported that hypnotic analgesia reduced pain by modulating activity in specific areas of the brain while producing shifts in general brain states (Williams & Gruzelier, 2001). Hypnosis has been shown to be effective in the treatment of acute pain induced in the laboratory setting (Ewin, 1986) and in dealing with acute procedural pain	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The references provided have all been checked for their relevance to the

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				(Patterson et al., 2006). A meta-analysis published last year looked at 85 studies with 3632 participants and showed significant and ongoing pain control using hypnosis. (Thompson et al., 2019) In addition, there have been a number of studies which have shown excellent results in the use of hypnosis for the management and treatment of chronic pain (Tomé-Pires & Miro, 2012). Researchers have also found that participants reported high levels of treatment satisfaction (for example, Jensen et al., 2006) and, after the study, many subjects were able to manage chronic pain using self hypnosis. Hypnosis can have the effect of significantly reducing the intensity of chronic pain for up to 12 months in some patients. For this group, there seems to be evidence of long-lasting changes in the way that the brain processes pain; for others, self hypnosis can be used as a form of self management, and this can lead to significant changes in the intensity of pain, better sleep (Smith & Haythornthwaite, 2004), reduction in depression and/or anxiety (Alladin, 2010) as well as improving quality of life	review protocol. The majority are literature reviews in topics broader than chronic pain. The RCTs referenced are also not in populations with chronic primary pain, and are therefore not relevant to include in this guideline review.

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				(Turk et al., 1998). Clinicians are able to enhance the efficacy of this process by giving suggestions of immediate pain relief as well as the long-term benefits of this process; moreover, specialists can easily provide patients with suggestions of 'automatic' reductions of pain, the multiple benefits of well being and associated reduction of distress. Hypnosis has been shown to be effective in the treatment of almost every type of pain condition over the centuries, across the world (Pintar & Lynn, 2008). And studies have shown that the use of hypnosis can significantly reduce health care costs (Lang et al., 2000; Montgomery et al., 2007). Evidence on the efficacy of hypnosis for the reduction, management and elimination of pain can be found in high-ranking, peer-reviewed journals across the globe. Alladin A. Evidence-based hypnotherapy for depression. International Journal of Clinical and Experimental Hypnosis. 2010;58:165–185. Apkarian AV, Hashmi JA, Baliki MN. Pain and the brain: Specificity and plasticity of the brain in clinical chronic pain. Pain. 2011;152(3) Suppl:S49–S64.	

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				Ewin DM. Emergency room hypnosis for the burned patient. American Journal of Clinical Hypnosis. 1986;29(1):7–12. Jensen MP. Hypnosis for chronic pain management: Therapist guide. Oxford, England: Oxford University Press; 2011. Jensen MP, McArthur KD, Barber J, Hanley MA, Engel JM, Romano JM, Patterson DR. Satisfaction with, and the beneficial side effects of, hypnotic analgesia. International Journal of Clinical and Experimental Hypnosis. 2006;54:432–447. Jensen MP, Patterson DR. Hypnotic approaches for chronic pain management: clinical implications of recent research findings. American Psychologist, 2014; 69 (2): 167-177. Lang EV, Benotsch EG, Fick LJ, Lutgendorf S, Berbaum ML, Berbaum KS, Spiegel D. Adjunctive non-pharmacological analgesia for invasive medical procedures: A randomised trial. The Lancet. 2000;355(9214):1486–1490.	

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				Montgomery GH, Bovbjerg DH, Schnur JB, David D, Goldfarb A, Weltz CR, Silverstein JH. A randomized clinical trial of a brief hypnosis intervention to control side effects in breast surgery patients. Journal of the National Cancer Institute. 2007;99:1304–1312. Patterson DR. Clinical hypnosis for pain control. Washington, DC: American Psychological Association; 2010. Patterson DR, Hoffman HG, Palacios AG, Jensen MJ. Analgesic effects of posthypnotic suggestions and virtual reality distraction on thermal pain. Journal of Abnormal Psychology. 2006;115:834–841. Pintar J, Lynn SJ. Hypnosis: A brief history. Malden, MA: Wiley-Blackwell; 2008. Smith MT, Haythornthwaite JA. How do sleep disturbance and chronic pain inter-relate? Insights from the longitudinal and cognitive-behavioral clinical trials literature. Sleep Medicine Reviews. 2004;8:119–132. Thompson, Trevor; Terhune, Devin Blair; Oram, Charlotte; Sharangparni, Joseph; Rouf, Rommana; Solmi, Marco; Veronese, Nicola and Stubbs, Brendon. 2019. The	

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				effectiveness of hypnosis for pain relief: A systematic review and meta-analysis of 85 controlled experimental trials. Neuroscience & Biobehavioral Reviews, 99, pp. 298-310. ISSN 0149-7634 [Article] Tomé-Pires C, Miró J. Hypnosis for the management of chronic and cancer procedure-related pain in children. International Journal of Clinical and Experimental Hypnosis. 2012;60:432–457. Turk DC, Okifuji A, Sinclair JD, Starz TW. Differential responses by psychosocial subgroups of fibromyalgia syndrome patients to an interdisciplinary treatment. Arthritis Care & Research. 1998;11:397–404. Williams JD, Gruzelier JH. Differentiation of hypnosis and relaxation by analysis of narrow band theta and alpha frequencies. International Journal of Clinical and Experimental Hypnosis. 2001;49:185–206.	
Royal Society of Medicine	Guideline	018	030	The draft guideline claims that hypnosis is not widely used in the treatment of chronic pain: we would like to challenge this assertion:	Thank you or your comment. The reviews for specific interventions included in this guideline are all for

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				It is evident that chronic pain management comprises a complex range of interventions and has to be customised for each patient presenting to the clinician. There are many effective and evidence based interventions clinicians have at their disposal including drugs, CBT, hypnosis and others. But currently, hypnosis is not included in the NICE guideline and so remains marginalised in mainstream practice in the UK. However, in the **UK**, hypnosis is actually used by many clinicians including GPs, dentists, physiotherapists, anaesthetists and other health professionals working in pain clinics as well as oncologists and nurses working in cancer care. They manage difficult cases such as post herpetic neuralgia and phantom limb pain. (Oakley et al 2002; Bamford,C. 2006) Many have been trained by The British Society for Clinical and Academic Hypnosis which admits only health professionals to it's courses. (BSCAH) It would be impossible to list each individual by name but a few examples: The experienced anaesthetist, **Dr Rebecca Berman**at Stanmore Hospital runs a back pain clinic using hypnosis and**Dr Tim Johnson**at the hospital in Northampton runs a pain clinic also using hypnosis. For 5 years, **Dr Les Brann**, a GP in Essex ran a pain clinic at his practice using hypnosis, funded by the NHS and receiving referrals from	the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The comment relating to use of hypnosis was specifically for chronic primary pain rather than chronic pain more generally. The committee agree in their opinion, hypnosis is not currently used to manage chronic primary pain in most cases. All of the references provided have been checked for their relevance to

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				the local hospital pain service. He and his team kept an audit showing the benefits of hypnosis including cost effectiveness, reduction in the use of analgesics and in many cases, enabling patients to return to work. (Brann et al, 2008;) and in 2012, Dr Brann wrote a chapter on pain in The Handbook of Contemporary Clinical Hypnosis explaining the ways chronic pain can be treated with hypnosis, backed up by research.(Brann, L., 2012) In many other countries hypnosis is a well accepted and established approach to managing chronic pain: **The International Society of Hypnosis**has a membership of 36 hypnosis societies around the world and **The European Society of Hypnosis**has a membership of 47 hypnosis organisations in Europe. These societies represent thousands of clinical practitioners in many countries and aim to bring clinicians together, to improve research, discussion, and publications pertinent to the scientific study and clinical application of hypnosis. At the **University Hospital in Liege,** Belgium, Professor Marie Elizabeth Faymonville runs a large pain clinic seeing around 3000 patients per year. As well as other interventions hypnosis is used extensively, mainly in a group setting. She and her team research and publish	the review protocol for inclusion. Specific details are as follows: Bamford et al. is a single arm trial without a comparator group and therefore does not meet the protocol study design inclusion criteria. Brann et al. 2008 is an abstract only and therefore has been excluded. Brann et al. 2012 is a book and therefore does not meet the protocol study design inclusion criteria. Oakley et al. was excluded as the population (phantom limb pain) and study design do not meet the protocol criteria. Patterson et al. is a book and therefore does not meet the protocol study design inclusion criteria.

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				their findings. Eg, (Gregoire et al.,2020; Nyssen et al., 2015; Vanhaudenhuyse et al., 2015) In **Turkey,**Ali Özden Öztürk President of Society of Medical Hypnosis (THD), Turkey; member of European Society of Hypnosis (ESH); Chair of ESH CEPE (Committee on Educational Programmes in Europe) and member of International Society of Hypnosis (ISH). Dr Öztürk uses hypnosis for all his patients presenting with pain. At the **University of Washington in Seattle**, USA, Drs Jensen and Patterson and their team employ hypnosis as an important part of their pain management service. Both have published text books on pain (Jensen,2011; Patterson, 2010) and many original research papers about hypnosis for chronic pain. Eg (Jensen,M,2009). They authored a review of the literature on the use of hypnosis in chronic pain looking at 89 published works describing in some detail the effects of hypnosis on the brain and the wider benefits. (Jensen, M., Patterson, D. (2014**).** The **US Department of Veterans Affairs**recommend hypnosis on their website: "A summary of double-blind studies suggests Clinical Hypnosis as a tool to consider as possibly efficacious or better for additional areas: pain management, headache	Saltis et al. is not an RCT and therefore does not meet the protocol study design inclusion criteria. Vanhaudenhuyse et al. is not a randomised study and therefore does not meet the protocol study design inclusion criteria. Weinrib et al. Is a conference abstract and therefore cannot be included.

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				and migraine, asthma, sleep disorders, depression, dermatological conditions, anxiety, procedural pain and anxiety, and other areas."(va.gov) A quote from the website of the **American Psychological Association**: "Research shows that hypnosis works as part of a treatment program for a number of psychological and medical conditions, with pain relief being one of the most researched areas, as shown in a 2000 study by psychologists Steven Lynn, PhD, Irving Kirsch, PhD, Arreed Barabasz, PhD, Etzel Cardeña, PhD, and David Patterson, PhD. Among the benefits associated with hypnosis is the ability to alter the psychological components of the experience of pain that may then have an effect on even severe pain." (apa.org) **Dr. Aliza Weinrib,**Ph.D., is a registered clinical psychologist and research associate in the Human Pain Mechanisms Lab. Her research is grounded in her clinical work at Toronto General Hospital. As co-chair of the Canadian Psychological Association's Opioid Task Force, Dr Weinrib contributed to the task force's position paper on addressing the opioid crisis in Canada. Hypnosis is one of several interventions available to patients on the opioid withdrawal programme.	

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				Dr Allan Cynais a Senior Consultant Obstetric and Paediatric Anaesthetist at **the Adelaide Women'sand Children's Hospital, South Australia**, Clinical Associate Professor at the University of Sydney, and President elect of the Australian Society of Hypnosis. Dr Cyna uses hypnosis extensively for pain management, both acute and chronic. He edited a book on communication for anaesthetists. (Cyna, 2010) and co-operated in writing a chapter in 'Pain Medicine' about hypnosis for pain relief. (Saltis,J et al 2017) In New Zealand, at **The Auckland Regional Pain Service**, TARPS, hypnosis is one of the interventions used. (healthpoint.co.nz) So it would seem that just in this brief summary one can see how much hypnosis is utilised for chronic pain by well respected clinicians, researchers and organisations around the world and to a growing extent in the UK. It is recognised internationally as a successful intervention for chronic pain management but for some reason remains unacknowledged by NICE. As we are all aware, there is a growing problem with opioid use and combined with the limited benefits of analgesic drugs in general, a new way forward is desperately needed. This could be a turning point for chronic pain management in the UK. We recommend bringing hypnosis into mainstream practice as a part of	

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				pain management and acknowledging the demand from those suffering from lifelong pain. References: apa.org/research/action/hypnosis Bamford,C. (2006) A multifaceted approach to the treatment of phantom limb pain using hypnosis. *Contemporary Hypnosis*, 23(3), 115-26. Brann,L., Makrodt,K., Joslyn, M. (2008) Hypnosis for Chronic Pain. Paper presented at the European Society of Hypnosis Conference, Gozo, Malta. Brann,L. et al: 2012, Pain, *Handbook of Contemporary Clinical Hypnosis;* 293-313 www.bsach.com Cyna, A., (2010) *Handbook of Communication in Anaesthesia & Critical Care*: Oxford University Press Grégoire, Faymonville, Vanhaudenhuyse, Charland-Verville, Jerusalem, Willems, Bragard. Effects of an intervention combining self-care and self-hypnosis on fatigue and associated symptoms in post-treatment cancer patients: A randomized-controlled trial. *Psycho-Oncology*.2020;1–9.	

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				healthpoint.co.nz/public/pain-management/tarps-the-auckland-regional-pain-service/pain-management Jensen,M., Patterson, D: Hypnotic Approaches for Chronic Pain Management: *The American Psychologist*,Feb-Mar 2014;69(2):167-77. Jensen,M: 2011, *Hypnosis for Chronic Pain Management*, *Therapist Guide*, Oxford University Press, Jensen,M., Barber J., Romano, J.M., Molton, I,R., Raichle, K., & Osborne, T,L., (2009). A Comparison of self-hypnosis versus progressive muscle relaxation in patients with multiple sclerosis and chronic pain. *International Journal of Clinical and Experimental Hypnosis 57,198-221.* Nyssen, M-E. Faymonville Hypnosis and pain modulation. In Pain in the Conscious Brain. Garcia-Larrea, L. & Jackson, PL. Wolters-Kluwer – *IASP*, *Philadephia*2015. Oakley,D.A.,Whitman,L.G.,Halligan, P.W. (2002) Hypnotic imagery as a treatment for phantom limb pain: Two case reports and a review. *Clinical Rehabilitation*,16, 368-77 Patterson,D: 2010: Clinical Hypnosis for Pain Control, *American Psychological Association*, Saltis,J., Suyin G., M., Cyna,M. (2017) Hypnosis for Pain Relief, *Pain Medicine* (pp.571-574)	

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				va.gov/WHOLEHEALTH/professional-resources/Clinical_Hypnosis.asp Vanhaudenhuyse A, Gillet A, Malaise N, Salamun I, Barsics C, Grosdent S, Maquet D, Nyssen AS, Faymonville ME. Efficacy and cost-effectiveness: A study of different treatment approaches in a tertiary pain centre. *Eur J Pain*. 2015 Nov;19(10):1437-46. Vanhaudenhuyse, A., A. Gillet, A-S. Weinrib, A. (2018, September). Psychological approaches to reducing opioid use for people with pain. *Health Canada/Government of Canada Symposium on the Opioid Crisis*,Toronto, ON.	
Royal Society of Medicine	Guideline	019	01-002	It is a bizarre statement to make that if a treatment is not widely used you cannot recommend it. May be if it works all the more reason to recommend it, so it is more widely used. I expect not enough clinicians are trained it , perhaps because money is not forthcoming through a misunderstanding of its nature.	Thank you for your comment. This statement relates in part to consideration of the benefit of further research. It is the committee's opinion that hypnosis is not widely used for chronic primary pain and therefore

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					considered that a research recommendation was of limited value.
Sapphire Medical Clinics	Evidence Review J	008	General	We are concerned by the limited evaluation of the role of cannabis-based medicinal products [CMBPs] in chronic primary pain due to the narrow defining scope. Evaluation of CBMPs within Evidence Review J has been limited to nabilone and nabiximols, rather than adopting the framework used within the NICE guideline on Cannabis-based medicinal products [NG144]. These medications, whilst having licensed indications, are not designed to be utilised within the context of chronic primary pain and thus has given rise to the paucity of studies uncovered on CBMPs when these inclusion criteria were applied. CBMPs encompass a range of medications containing a diverse range of active pharmaceutical ingredients at varying concentrations available via multiple routes of administration. Characterisation of CBMP effectiveness according to one or two therapies will limit the applicability of any analysis in pain conducted on that basis. However, we do appreciate it is the position of NICE as an organisation to typically only consider those medications with a UK marketing authorisation. Similarly restricting the scope of the evidence review upon which this guidance is based to randomised controlled trials limits the rich evidence that can be provided on longitudinal assessments of adverse events,	Thank you for your comment. Oral cannabinoids (nabilone, nabiximols oromucosal spray) were included within the protocol for the review of pharmacological interventions for chronic primary pain, and the committee agreed there was insufficient evidence for a recommendation, but that further research was important. During the development of this guideline the NICE guideline for cannabis based medicinal products was commissioned and published. This guideline covers the use of these for a range of conditions and therefore it was agreed appropriate to cross refer to this for all guidance and considerations for cannabis based medicinal products.

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				patient generated health data including patient reported outcome measures and analysis of cost effectiveness within the context of quality adjusted life years. Ultimately this evidence review highlights the need for further high-quality research into treatments for chronic primary pain, not just in the context of CBMPs, but for all pharmaceutical and non-pharmaceutical modalities. However, it would be prudent to extend the scope of NICE evidence reviews to include non-randomised data in the interim as this may provide further evidence to guide clinical prescribing decisions and to inform research in the future considering the size of population that could benefit from an effective therapeutic and the paucity of treatments that have received a strong recommendation within this guideline as a whole.	
Sapphire Medical Clinics	Evidence Review J	008	Table	'Nabiximols' has been spelled incorrectly	Thank you for your comment. This has been corrected.
Sarcoidosis UK	Guideline	General	General	Sarcoidosis is a 'rare' multi system disease of unknown origin. Diagnosis of sarcoidosis has its challenges and many patients once diagnosed have multiple consultants and attend a range of specialist clinics. Our members consistently report an absence of clinicians taking a whole system approach to their multiple and varied presentations with no specific lead for the assessment and management of chronic pain.	Thank you for your comment. The recommendations for assessment of people of chronic pain state that this should be a holistic assessment of the person and include the importance of fostering a collaborative and supportive relationship with the

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				In order to have important conversations regarding assessment and management of chronic pain there would have to be an identified clinician/role who will facilitate such conversations.	person with chronic pain. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and

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					harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits.
Sarcoidosis UK	Guideline	004	013	Our members advise there is an absence of dialogue or consideration as to how their chronic pain affects them	Thank you for your comment. The committee agree this should be included in assessments of all people with chronic pain and have included recommendations to highlight this.
Sarcoidosis UK	Guideline	004	018	Our members advise these discussions do not take place.	Thank you for your comment. The committee agree that evidence reviewed suggested that there are shortcomings in people's experience of assessment of chronic pain. They therefore agreed it was important to include recommendations on this topic.

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Sarcoidosis UK	Guideline	005	007	An individual care plan focused on chronic pain would be a welcome initiative, but we question who would be responsible for its production, monitoring and management.	Thank you for your comment. The committee agree that the healthcare professional undertaking the assessment should develop the care and support plan jointly with the person with chronic pain.
Sarcoidosis UK	Guideline	006	001	We welcome the recommendation for increased research into pain management programmes. In our survey of 379 members with sarcoidosis the vast majority had not been offered a referral to pain management services. 44% of members reported they would like to access a pain management service. Of those who had received a referral to pain management services almost all attended. Results of efficacy on chronic pain for those who have attended pain management services are mixed so there is clearly a strong need for evaluation of current services and the development of a range of proven interventions which should be available universally at each pain management service.	Thank you for your comment. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research.
Sarcoidosis UK	Guideline	006	005	We welcome the recommendation for increased research on social interventions in the treatment of chronic pain. In the survey of members 80% of respondents cited social support (from the charity and support groups) as critical to their acceptance and management of chronic pain. In terms of social support from family and friends there was strong evidence that family and friends lacked the understanding of the effects of living with chronic pain to	Thank you for your comment. The committee agree that this is an important area for further research. The review searched for published literature on specific social interventions provided for people with chronic pain, rather than informal social support networks. Evidence for

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				provide meaningful social support. A third of respondents did report benefitting from social support within their family and friends however there was a strong requirement for social support from an independent party.	these interventions was lacking specifically for people with chronic pain.
Sarcoidosis UK	Guideline	006	010	Many of our members take regular exercise with 33% reporting daily exercise and 15% exercising 3 or 4 times per week. Unfortunately, the levels of exercise reported did not translate into positive effects of exercise on their chronic pain. Only 7% reported significant benefit by taking exercise, 17% some improvement but 44% reported exercise actually worsens their chronic pain. There would need to be appropriate exercise regimes available which take into account underlying conditions and symptoms which may be adversely affected by some types of exercise. Access to exercise programmes, their availability and cost are significant factors which will need to be addressed. Encouraging individual continued exercise post any programme can be increasingly supported by technology and online support.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more

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					easy navigation between the recommendations for different topics.
Sarcoidosis UK	Guideline	007	001	Psychological support for those with chronic pain is to be welcomed, however 69% of our members surveyed had never been offered any psychological support. Of the remainder only 3% had been offered ACT, 4% meditation, 10% mindfulness, 14% CBT and 15% talking therapy. 84% of our members reported they would engage in psychological support interventions if they were made available.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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Sarcoidosis UK	Guideline	007	007	Acupuncture: only 22% of our members report being offered acupuncture for their chronic pain, however over 80% did say they would consider acupuncture if it were made available to them. Of those who had tried acupuncture, the results were varied so if this is to be offered in relation to chronic pain more robust evidence is required of its efficacy.	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
Sarcoidosis UK	Guideline	007	013	The cap of 5 hours maximum - albeit flexibly broken down – is an unrealistic and unhelpful limit. For those who have lived with long-term chronic pain, progress may be slower and there will be individual circumstances which require a longer course or indeed periodic 'boosters' in the long-term management of their chronic pain.	Thank you for your comment. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee

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					agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
Sarcoidosis UK	Guideline	008	004	We have a number of members who have reported positive effects on their chronic pain from using TENS machines etc. We believe electrical physical modalities should continue to have a place in the management of chronic pain and further research is therefore required.	The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification

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					has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Sarcoidosis UK	Guideline	008	008	There is a strong belief amongst our members for continued Manual therapy to assist with their chronic pain management. This can focus on mobilisation, but it remains critically important to our membership.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the

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					guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Sarcoidosis UK	Guideline	008	014	40% of our members surveyed have never been offered Anti-depressants, 50% have been prescribed and taken anti-depressants. Of those who have taken anti-depressants 8% reported they had made them feel worse and less than 40% saw limited positive effects on their health and wellbeing overall. In terms of the effects of anti-depressants on chronic pain only 15% reported an improvement.	Thank you for your comment. The evidence reviewed in this guideline suggested antidepressants may be of benefit to people with chronic primary pain. The recommendation is to consider their use after a full discussion of the benefits and harms. This should be a shared decision between the healthcare professional and person with chronic primary pain.
Sarcoidosis UK	Guideline	009	010	There is significant concern regarding the withdrawal of strong medication including opioids for the management of chronic pain amongst our membership. Whilst a diagnosis of sarcoidosis is rarely the only condition the patient is suffering from, the relationship between sarcoidosis and chronic pain is not properly understood. There are significant concerns a patient presenting with	Thank you for your comment. It is important to note the reviews for specific interventions included in this guideline (and related recommendations) are all for the

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				chronic pain may be assessed by a clinician who lacks understanding of this rare disease and may assume the pain is chronic primary pain thereby precluding current pharmacological treatment options. Prescription pain relief is used, daily and frequently by more than two thirds of respondents. In terms of opioids 40% of our members surveyed use these drugs occasionally, and 20% frequently and daily. The duration of long term strong prescription painkiller use varies significantly 12% taking it for more than five years, 6% for more than one year, 11% for 3 months up to a year.	chronic primary pain population only, rather chronic secondary pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Sarcoidosis UK	Guideline	010	003	Significant concerns in our membership about discussions and decisions being taken by clinicians to stop anti-depressants and pain relief medication without proper consideration or knowledge of sarcoidosis.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. The recommendation for pharmacological

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					treatment therefore does not apply for the management of sarcoidosis. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Sarcoidosis UK	Guideline	010	008	A number of respondents report effective use of cannabis as a method of managing their chronic pain so further research into this area is essential.	Thank you for your comment. The committee agree that further research is required and cross refer to the NICE guideline on Cannabis based medicinal products (NG144) where this research recommendation is included.

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Shingles Support Society	Guideline	010	014	At last, there is a definition of chronic primary pain. This is however, too far down the document. It leads to the 'news' that has been seen where the vital word 'primary' has been left out.	Thank you for your comment. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline.
Shingles Support Society	Guideline	027	011	"Possible barriers to successfully managing chronic pain" - Does this guideline include all pain treatment? Or should this line include 'primary'?	Thank you for your comment. The review of factors that may be barriers to successfully managing pain was for all types of chronic pain. To help clarify this a visual summary has been produced to accompany the guideline indicating what populations are covered by each recommendation topic.
Shingles Support Society	**Guideline**	**General**		The Shingles Support Society supports the use of evidence-based medicine, however the way this guideline has been reported means that people with diagnosed conditions, for whom pain treatment was working/controlling pain/permitting a good QOL are being denied their drugs. This was found through a survey online (SurveyMonkey) that we were involved with, open between 28th August and 11th September. We had replies from 124 people. 6 of them in the comments box reported that their doctors had already started to make it difficult to get the pain treatment that was	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate to avoid misinterpretation of the guideline. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings

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				maintaining their QoL citing 'new guidelines'. Here are three: 8/29/2020 12:38 PM "My new GP told me about new draft guidance for chronic pain. He didn't mention chronic primary pain. He has been trying to reduce my opiate use (which I don't necessarily think is a bad thing). However, I don't have chronic primary pain. I know what causes my pain, so he appears to be using Chronic Primary Pain guidelines to reduce my opiate use for Non-Primary pain. Again, I don't think a review/investigation of my opiate use is unreasonable but I am surprised that he seems to be applying the primary pain guidance more broadly than just primary pain. 8/30/2020 11:47 AM I feel that if I am left with no pain relief it will leave me with no other option but to end my life. I can barely function some days even with pain relief and there is no way at all I can function with none. I'd rather be dead than have my children watch me screaming the house down in pain. That's not fair on them. 8/29/2020 1:01 PM I live with primary chronic pain. I do or have done EVERYTHING the consultation says. I exercise daily, acupuncture never worked, practice meditation and	throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.

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				mindfulness, use physical therapies and had therapy. I work in mental health. I also have to take antidepressants and opioid medication in order to be mobile enough to do my job. The muscular spasms cause damage to my joints so keep needing surgery. If I didn't take painkillers I couldn't work so taking them away is bloody ridiculous. Pain management services are very poor in my area and even the new service was so bad I was discharged because I "can't be treated due to complexity of My condition". None of those proposing what they are have obviously ever lived with pain. I believe that medication is one part and the patient has to take an active part, but every person is different. I have a fabulous GP and have to take slow release Oxycodone alongside co-codamol for breakthrough pain. This is alongside Citalopram, Amitriptyline and diazepam for muscle spasms that are so severe I cannot move.	
Shingles Support Society	Guideline	General		We are extremely concerned that the way the information has been presented, both in the draft guideline and to the wider public, does not focus sufficiently on the fact that this is for chronic PRIMARY pain. We have already seen news reports where the vital word 'primary' has been left out.	The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order

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					to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
Sickle Cell Society	Guideline	General	General	Overall these guidelines are measured and appropriate The guideline recommends reading alongside guidance on other conditions such as rheumatoid arthritis. There is NICE guidance on SCD which includes a chapter on management of chronic pain. We strongly suggest that this guidance now needs to be referenced/linked to the SCD chronic pain guidance. Furthermore, we also suggest that it may now be timely to update the SCD chapter.	Thank you for your comment. The NICE pathway will link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Sickle Cell Society	Guideline	General	General	There is limited reference to psychology interventions that could help with chronic pain. We would like to see more reference to this possibility.	Thank you for your comment. The committee have recommended that ACT and CBT can be considered for managing chronic primary pain. They also note some promising effects from mindfulness, psychotherapy, CBT for

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					insomnia and relaxation therapies and so included research recommendations for each of these in chronic primary pain to inform future updates of the guideline.
Sickle Cell Society	Guideline	General	General	There is evidence that chronic pain in SCD is usually attributable to a specific cause such as leg ulcers, avascular necrosis or follows a pattern closer to that of chronic secondary pain as defined by WHO.	Thank you for your comment.
Sickle Cell Society	Guideline	General	General	We believe the guidance is helpful in recommending avoidance of long term analgesics such as opiods	Thank you for your comment.
Sling The Mesh	Evidence Review A	002.5 to 003.5		We are concerned that recommendations by NICE are being based on moderate to low quality evidence	Thank you for your comment. Recommendations are made in accordance with the methods set out in Developing NICE guidelines: The Manual. When making the recommendations, the committee consider the quality of the evidence, including the elements that inform this, the magnitude of the effect and the size of the body of evidence. The evidence identified in this review helped inform recommendations in the assessment section of the guideline, together with evidence from review B on communication.

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Sling The Mesh	Evidence Review A	004.3 to 004.5		We are concerned that NICE are basing recommendations here on no evidence	Thank you for your comment. The lack of evidence on these risk factors informed research recommendations, in acknowledgement of the lack of evidence.
Sling The Mesh	Evidence Review A	005.1		We are concerned that psychological distress is not being taken seriously. Mesh injured patients suffer severe psychological distress as a result of the pain they are in. Pain which has been caused by a mesh implant.	Thank you for your comment. For the review of risk factors, the committee had to prioritise a small number of critical outcomes as each outcome required a separate review for each risk factor. The committee agreed that pain and quality of life were the two critical outcomes. They do acknowledge the importance of psychological distress and stated that this was a confounding factor in these reviews. Psychological distress is included as an outcome that was important for decision making in all of the reviews of management options.
Sling The Mesh	GENERAL	GENERAL	GENERAL	Patients suffering irreversible, life changing pain from a mesh implant often do not have a conclusive diagnosis of mesh pain. This is because, sadly, many are told by medics that the pain is in their head or that there is no way the mesh can be blamed for causing their pain. Patients are then sent for a series of scans and tests that	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain.

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				prove inconclusive. The only reason these tests and scans prove inconclusive is because no test can prove anything as it is impossible to see the damage mesh is causing to nerves, tissues, organs. It cannot be conclusively proved that the plastic material of the mesh implant is causing things like autoimmune diseases, urinary tract infections, painful skin lesions, food intolerances, IBS. Yet pain, infections, erosion, dyspareunia, auto immune and neurolgical pain is seen on a mass scale, not only in Sling The Mesh, but all mesh groups globally. To deny this cohort of patients any pain medication, which gives them some hope of comfort so that they can live life, is terribly cruel. They have been harmed once by a treatment they were assured was safe. Now they are dealt a second blow from NICE who want to take away pain medication from those with no clear cut reason for their pain. These guideline proposals take away the patient from the centre of their care. It additionally compounds the mantra that we see in Sling The Mesh daily - that patients are told the pain is all in their heads – therefore they must have some sort of psychological disorder. When the fact is tthis: heir mental and emotional wellbeing is affected from being in constant pain. Sling The Mesh is also concerned that instead of recognised pain meds, doctors will be recommended to prescribe anti-depressants for pain – this off lable use of	Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The recommendations for pharmacological management are therefore not for management of people with chronic pain as a result of a MESH implant. This is considered within the NICE guideline for Urinary incontinence and pelvic organ prolapse in women.

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				drugs is worrying. It further compounds the theory that for people suffering chronic pain, it is all in their heads. If mesh patients have their pain medication taken away from them, under these proposals they will be left with treatment options of exercise, anti-depressants, acceptance therapy or 5 sessions of acupuncture. What use is exercise to a person who has lost the ability to exercise because of a mesh implant. How insulting. Within these guidelines we want mesh injuries to be recognised as a condition /illness suffered by patients including women from pelvic and hernia mesh and for men suffering from hernia and incontinence sling mesh given for men who suffer bladder weakness following prostatectomy after prostate cancer. Also for patients suffering from rectopexy mesh, breast reconstruction mesh and for the transgender community who have been affected by mesh implants.	
South East London CCG	Guideline	008	014	Is there guidance on the duration of this treatment? Who would review the efficacy of this treatment – would this be carried out by GPs in primary care or by a specialist?	Thank you for your comment. The committee considered that efficacy of antidepressants should be reviewed at 4-6 and duration determined by review. They considered that there is

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					no evidence that the management of people with chronic primary pain has to be done by a specialist. Antidepressant prescribing can be in primary care.
South East London CCG	Guideline	General	General	Who is this guidance aimed at? Chronic primary pain can be quite a specialised area, who would be making the diagnosis and recommendations for management? Would this be done by a specialist or is this guidance for GPs in primary care?	Thank you for your comment. This guideline is for all healthcare professionals in all settings where NHS or local authority funded care is provided as detailed in the scope. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists

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					referral for specialist advice or assessment might need to be considered.
Tees Valley, Durham and North Yorkshire Neurological Alliance	Equality impact assessment		003.5	Adverse impact on people with disabilities - whilst the recommendation includes the need to tailor exercise therapies to the preferences, needs and abilities of the individual, recognition should be given for a range of conditions where exercise is detrimental to long term mobility unless supervised by a skilled therapist or practitioner. This assumption could drive a set of preconceived ideas that any long-term condition can benefit from exercise, regardless of the consequences. As a pan-neuro disability organisation, there is poor professional understanding of the limitations of chronic pain associated with Dystonia, brain tumour or haemorrhage, Acquired Brain Injury, Multiple Sclerosis, Ataxia, Post-Polio Syndrome, functional neuropathy or musculoskeletal disorders. We support a pain-management peer group, some of whom have 8-10 comorbidities plus a neurological disorder. Feedback from the stakeholder pain management group - '*there are many and complex reasons for chronic pain and it seems to me that NICE is attempting to classify and pigeon hole, there is little evidence that the proposals cater for the complexities*'.	Thank you for your comment. The recommendation is for a supervised exercise programme and therefore assumes the person delivering the programmes is appropriately trained to do so. It is important to note that the reviews for specific interventions included in this guideline and the associated recommendations are all for the chronic primary pain population only, rather than all types of pain. This includes the exercise recommendation. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each

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				The World Health Organisation (2012) reported that neurological conditions were the leading cause of disability in the UK. There is a dearth of evidence on Disability Adjusted Life Years (DALY) which could go some way to contributing knowledge about the cyclical nature of managing pain and being sleep deprived which restricts the energy necessary to engage with exercise.	recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
Tees Valley, Durham and North Yorkshire Neurological Alliance	Evidence review A	056	034-035	With no evidence identified for the prognostic value of adverse childhood experience (ACE) or substance addiction/dependence/misuse, please could some links be made for the evidence submitted for FASD. There is a high incidence of ACE in FASD young people with associated mental health co-morbidities, obsessive behaviours and substance abuse linked to poor understanding of consequences yet, used as a form of pain relief for chronic headache. This may be a small cohort but should be recognised as a specific client group within this guideline.	Thank you for your comment. The committee agree that previous trauma or experiences in a person's life are important to consider in the assessment of someone with chronic pain. A recommendation has been added highlighting the importance of discussing stressful life events, including previous physical or emotional trauma.
Tees Valley, Durham and North Yorkshire Neurological Alliance	Evidence review B			The review findings were endorsed by our stakeholders but they still wanted to refer to the lack of professional knowledge about their neurological conditions, disorders or disabilities that led to a shortfall in being able to develop a meaningful, supportive relationship with medical practitioners.	Thank you for your comment. The committee cannot comment on specific experiences with healthcare professionals but agree that a holistic assessment to fully understand all aspects is required.

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Tees Valley, Durham and North Yorkshire Neurological Alliance	Evidence review C	052 055	030-035 1.7.9	Feedback from the stakeholder pain management group - 'The *impact of sleep on chronic pain and the circle of pain with no sleep, no sleep pain isn't really addressed enough at primary care or through the pain management clinics'*. This factor is an important ingredient for the mix of interventions that could make up a self-management programme that must not rely solely on exercise or reducing pharmaceuticals. Access to IAPTs as a psychological intervention is not appropriate for people with life-long neurological conditions where people need to adapt to the likelihood of deteriorating into profound disability. Cost effectiveness and resource use; Feedback from a stakeholder pain management group - *'Our pain-management 10-week course at the Hospital clinic was absolutely essential to how we perceived our pain and how we could manage it because you joined up with like-minded people, did not feel so alone. We have repeated some of the techniques for ourselves over the years and for new members of the group who felt they were left in limbo following the course.'* Pain management programmes will not be cost-effective unless there is a metric for quantifying the balance between repeat engagement with pain clinics or some other prevention measure that is linked to self-	Thank you for your comment. Sleep was included as an outcome in the protocol for all reviews of interventions. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence

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				management and quality of life. It was disappointing to the group that yet again, patient voice and the value they place on pain management programmes was set aside in favour of exercise/fitness programmes which would serve to marginalise them further from interventions that could help them manage their day-to-day life. It was also disappointing that the flavour of the full guideline was about discouraging the use of opioids without reference to the benefits for people facing a life-long journey managing chronic pain. This requires concerted management at both primary and acute level. Pain management programmes should contribute to the evidence base on their efficacy and impact on long term self- management techniques adopted by participants. Currently, there is no onus on service delivery to do this due to capacity issues and commissioning specifications being geared to short time periods. This is unhelpful for people with life-long conditions. It is welcomed that there is a recommendation that the use of opioids should be monitored and a withdrawal strategy should be in place as part of a care pathway, could *co-producedcare pathway* be added? Many people do this for themselves due to lack of protocol from their medical practitioner.	did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which

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					were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline. The committee agreed that the review did not demonstrate effectiveness of opioids for chronic primary pain, but there was evidence of harm and so they agreed it was appropriate to recommend against their use. The committee agreed that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or

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					significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. Recommendations have also been added to section 1.1 about developing a shared care and support plan which the committee agree is an important element.
Tees Valley, Durham and North Yorkshire Neurological Alliance	Evidence review D	007	001.6.015	Whilst the NHS long term plan may have committed to social prescribing through Primary Care Networks, there is no lead for the neurological client group in the whole of North East England and no commitment to include the neurological client group on the long term condition agenda. The central tenet of the social prescribing agenda is still short term, quick-fix and heavily reliant on the Link workers having a good knowledge of local support organisations purely for signposting not achieving outcomes.	Thank you for your comment. We agree that further research in the use of social prescribing specifically for people with chronic pain is required.

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				There is a dearth of skilled knowledge about neurological disorders and pain. The social prescribing setting concentrates on the public health issues of obesity, diabetes, heart disease, cancers, COPD, the elderly and not people who have potentially disabling neurological disorders. A research topic on this is welcomed.	
Tees Valley, Durham and North Yorkshire Neurological Alliance	Evidence review F	125 129 130	1.7.35	The outcomes identified are appropriate. Currently, very little support is given to people who would like to reduce medications but have nothing offered by Clinicians as an alternative except IAPTs. There should be psychological therapies to inform people that are effective for their particular client group but as always, these recommendations seek to homogenise a complex set of issues instead of understanding the issues and offering choice. Cost effectiveness and resource use; Whilst evaluating CBT and ACT against the QALY, where is the cost of doing nothing on DALY for people facing long term chronic pain through disability? Some recognition of this would be welcome. Other factors; Surely the main aim of psychological therapies is to build coping strategies that can subsequently inform a self-	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also

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				management pathway that contributes to improving quality of life and wellbeing? The body of these guidelines should provide stepping stones for life with chronic pain and co-morbid conditions, some people lose their employment due to lack of pain management care pathway. In the light of Covid-19, these guidelines should reflect the impact of the potential tsunami of neurological symptoms and pain that has been predicted.	be considered by NICE where relevant support activity is being planned. While the burden people with chronic pain face is recognised, quantifying this using DALYs is not part of the NICE guideline process. More details about the methods NICE guideline development can be found on the NICE website. The committee agree that there should be an individualised approach to chronic pain management, informed by a holistic assessment and by means of developing a shared care and support plan between the person with chronic pain and the healthcare professional. This approach is reflected by the recommendations in section 1.1 of the guideline.
Tees Valley, Durham and North Yorkshire	Evidence review J	62	4.1.23 038-043	The quality of the evidence; The effectiveness of medications in the long term is very individual, depends on interactions with other medications, allergies, cooperation between medical	Thank you for your comment. The evidence reviewed in this guideline, and committee expert opinion was that there is insufficient evidence that

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Neurological Alliance				practitioners for a multi-disciplinary approach to co-morbidities and drug compliance. It is far too arbitrary to consider a generalised approach for this guideline based on one condition. Again, this generalised approach will leave an unacceptable margin of error and likely create a system that fails to deliver duty of care for a wide range of conditions. Feedback from the stakeholder pain management group - *'There is not a "catch-all" remedy here, there seems to be a dismissive attitude to the effectiveness of medicinal treatments'*.	these medicines are helpful for the majority of people chronic primary pain and there is evidence of harms. The committee agreed that recommended management options should focus on those with evidence of benefit. Resource should be directed towards more beneficial management options.
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "The research on pain medication in chronic pain is weak. A sizeable proportion of patients find medication helpful without significant side-effects. Opioids are a good example - intermittent use (less than 10 days per month) at low dose - remain effective, and help patients stay mobile during flare-ups"	Thank you for your comment. The committee agree that there was a notable lack of evidence for a number of pharmacological interventions (including opioids), and limited evidence for some others. Although the committee are aware of some anecdotal reports that some people benefit from opioids, their clinical experience and consensus view was that these are not helpful for the majority of people with chronic primary pain and there is evidence of harms from their use. These

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					guidelines provide recommendations for the population with chronic primary pain. Unfortunately research to date does not enable this group of responders for different interventions to be identified and therefore recommendations for more targeted prescribing are not possible. It should be noted that this review and recommendation is for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline.

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The British Pain Society	General	General	General	***Graphic representation of Patient comments 'on what medication helps':***	Thank you for your comment and this information. The guideline recommendations are based on systematic reviews of the evidence and the expert opinion of the committee interpreting that evidence. The recommendations for pharmacological treatment options are for chronic primary pain only. There was no evidence of the effectiveness of opioids in this population, but there was evidence of harm. The committee's opinion was that starting opioid treatment should not be recommended for the management of chronic primary pain. The rationale for decisions made for this and other treatments are detailed in the rationale linked to these recommendations in the guideline. For other types of chronic pain, recommendations in other relevant NICE guidelines should be followed.

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				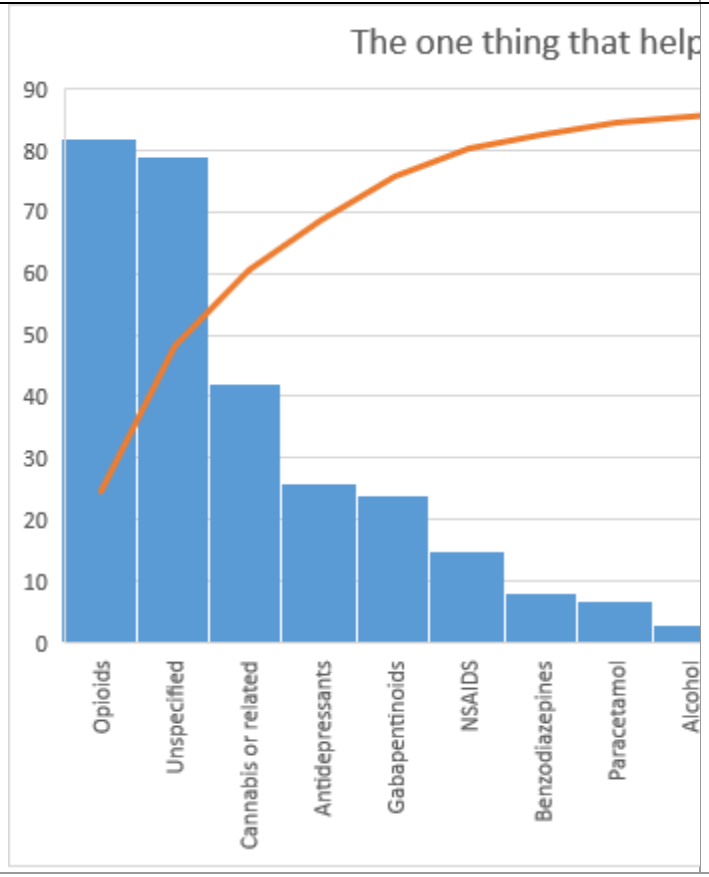	

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The British Pain Society	Guideline	001.2	General	Our greatest concern is that Physicians have enough issues with diagnosis and this guideline will confuse them further. Patients have picked up on this and feel this will worsen this and their future care The lack of definitions, and the lack of clarity surrounding the different types of chronic pain is deeply concerning. When the consultation documents were published many patients assumed that chronic pain encompassed all chronic pain, which is what the title of the draft document implies. However, the draft guidance itself appears to be aimed primarily at chronic primary pain. Conflating Chronic Primary Pain and Chronic Secondary Pain in this way will only serve to confuse patients and their busy clinicians. Detail from ICD - 11 as to how to make the diagnosis isn't included and in fact there is no research to support how to do this as yet We have included some quotes from our members: *"There should be more emphasis on the definition of both pain generally and the different classifications of chronic pain as set out by ICD-11. These definitions are new and many people, clinicians and patients alike, are confused or naive about these new definitions."* *"..Already taken many years to get a diagnosis in the experience of patients – lots of labels but no diagnosis – now separation of chronic pain into a heterogenous group of*	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. Recommendations have also been added for when to consider a diagnosis of chronic primary pain and to acknowledge that chronic primary

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				disorders has helped diagnosis. This (guideline) is a backwards step."	pain and chronic secondary pain can coexist.
The British Pain Society	Guideline	004	002-017	Section 1.1: The committee are to be commended for the very welcome and overdue emphasis on careful, sensitive and collaborative working in their recommendations on the assessment of chronic pain. In response to our BPS patient survey, Q 12. Has your chronic pain been assessed and investigated?, there were 766 responses: "Thoroughly" in 47%; "Partly" in 50%; "Not at all" in 3%. In response to Q 13. If your chronic pain has been assessed and investigated "Thoroughly" or "Partly" please identify who has assessed or investigated your pain - 749 responses (multiple allowed): GP 81%; Pain specialist/Pain Management Team 60%; Physiotherapist 49%; Neurologist 31%; Other hospital specialist 48%. These data back up our assertion that pain specialists and PMPs are a key source of support for patients in formally assessing and investigating their pain, more so than any other specialty.	Thank you for your comment. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. The committee also agreed that the evidence reviewed in this guideline did not enable a recommendation to be made for or against pain management programmes.

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The British Pain Society	Guideline	004	006	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.1: The BPS patient survey found that some respondents felt it was very important that they were treated as individuals, and that their needs would depend not only on where they were in the journey but also because of their knowledge, experience and background. "*Everyone should be listened to and not labelled under a category or condition you have but treated as a whole person as someone who has had chronic pain for a very long time their physical wellbeing can affect their mental health and vice versa*".	Thank you for your comment. The committee agree it is important that people with chronic pain are treated as individuals. This is reflected in the recommendations in Section 1.1 including those to develop a care and support plan based on the person's priorities, abilities and goals amongst other factors such as what they are already doing that is helpful. Recommendations are also included to explore people's strengths, and their understanding of their condition.
The British Pain Society	Guideline	004	008	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.1: The BPS patient survey strongly supports the need for good communication with patients. However, many patients have felt dismissed and disbelieved by the health practitioners they have met. "*Please listen to people with chronic pain whose lives have*	Thank you for your comment. The committee agreed that evidence demonstrated that there were shortcomings in some people's experiences of interactions with healthcare professionals for chronic pain. The assessment recommendations were included to highlight the importance of good

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				been forever radically altered by this chronic pain. Someone who doesn't live with chronic pain might find it very difficult to understand the shift in mindset and priorities that come with living with chronic pain. Please don't make judgements without at least trying to understand how living with chronic pain changes someone." "*The importance of good communication in handling chronic pain issues I believe cannot be understated*." Feeling disbelieved was a highly recurrent theme in the survey results and was clearly linked to the sense of abandonment that many experienced. "*Feel pushed aside as if I am making it up"* "*I feel I want to scream sometimes because I have sometimes been treated as though my debilitating condition isn't important or doesn't exist."* A small number of respondents described how they had sought to return to a service or health professional only to find their route back cut off. These comments were often embedded into passages in which the respondent acknowledged their pain and co-morbidities were complex.	communication to help address this issue.

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				"*after 20 years suffering with crps and getting passed from one specialist to another and because I "react" very badly to every medication / procedure they have thrown at me, I have been dumped by the system... cast off with my pain, GP is sympathetic but useless, the pain clinic says there is nothing we can do for you (except send me to mindfulness classes that I have to travel 30 miles to do 3 or 4 times a week!)*" Most respondents wanted compassionate and empathic health professionals who would at least acknowledge their situation. "*Understanding of the impact of pain on people's lives is extremely important, so much that I almost put that as the number one thing, but honestly I could live without the understanding but would truly suffer without pain management through NSAIDs"* Once the patient had found a health professional who they felt listened and treated them with respect they felt able to move on. "*It was only when I went to a private pain clinic who referred me to a physiotherapist who was trained to deal with people with chronic pain and knew how to handle communication with such patients that I started to feel as though I could control my own condition and reduce my medication*."	
The British Pain Society	Guideline	004	018	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line***	Thank you for your comment. The committee agreed that evidence

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				by line coding guided by the framework of the NICE guidelines. The quotes included in this feedback are verbatim,but some have had minor corrections to obvious typographical errors for clarity but where ever possible quotes are not edited. Section 1.1.3: BPS patient survey respondents felt that HCPs might ask them about their pain and their understanding but not one of them felt that what they had to say was accepted or respected. "*Trusting that doctors will be sensitive to a patient's experience of pain is really unwise. I broke my foot earlier this year and as one would, I went to urgent care. Because I live with chronic pain they latched onto that and decided I was a malingerer and refused to xray. I was belittled when I described how the new pain was different.*" "*The medical community need to learn a lot more about the impact of pain on a patient and trust the reports they are receiving."* The encounters they described left them feeling stigmatised and hopeless. On the other hand, finding an HCP willing to take them seriously was extremely helpful. "*An understanding of how pain becomes chronic has helped, but being believed and not belittled has probably made the*	demonstrated that there were shortcomings in some people's experiences of interactions with healthcare professionals for chronic pain. The assessment recommendations were included to highlight the importance of good communication to help address this issue.

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				biggest difference." Several respondents talked about their work as health professionals and how this was often dismissed by the health professionals they were consulting with. "*I had very good knowledge as had been trained in chronic pain management as a health professional. So I knew how to use alternatives and self-help*."	
The British Pain Society	Guideline	004 005	018-020 001-003	Section 1.1.3: It must be recognised that not all causes of pain can be diagnosed and a 'label' provided for the patient. This then disenables a classification of this patient and it needs to be stated within the document that these patients would require an individual management and treatment plan excluding them from specific stated guidelines thus preventing them from being shoe-horned into an incorrect and ill-fitting category.	Thank you for your comment. The committee agree and have added a statement to highlight that the cause of pain may not be identified. The committee also include a recommendation for when to consider a diagnosis of chronic primary pain, and do not require a cause to define chronic primary pain. A recommendation is also included to highlight that the initial diagnosis may change with time and should be re-evaluated if presentation changes.
The British Pain Society	Guideline	004 005	018-020 001-003	Our BPS survey of patients living with chronic pain revealed that many are not satisfied with how their pain has been explained to them. In response to Q 15. Has your chronic pain been explained to you to your satisfaction? – 767 responses.	Thank you for your comment. The committee agree the evidence demonstrated that there are shortcomings in people's experiences

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				The replies were "Yes in full" 36%; "Yes, but only partly" 43%; "No, not all" 21%. These data underline our point that patients only poorly understand what their clinicians have so far told them about their pain. From our patient survey responses and our Patient Voice Committee, we believe that the language of the current draft guidance will only aggravate this lack of understanding.	of communication with healthcare professionals. They intended to help address this by many of the recommendations included section 1.1. The committee have reworded these recommendations taking into account stakeholder comments.
The British Pain Society	Guideline	004	General	In assessment of chronic pain we welcome the approach - emphasising the biopsychosocial approach. However, no tools provided to support this. Such tools are available and we would recommend an evaluation of these. Without such tools we are concerned that clinicians will be unable to carry out a structured assessment. Most assessment is in primary care where use of templates is the norm. The Chronic Pain Navigator Tool produced by Pain Concern was designed to meet this need and to be used by both patients and clinicians https://painconcern.org.uk/navigator-tool/	Thank you for your comment. Tools for assessment were not raised as priority areas to include within the guideline during scoping or when setting the protocols and therefore recommendations cannot be made.
The British Pain Society	Guideline	005	004-006	Section 1.1.4: is overly negative. The emphasis on just whether the pain may improve or get worse ignores the well-known fact in the pain specialist community that with chronic pain, functioning and participation in daily life are equally important as pain severity or frequency. PMPs are very good at stressing this aspect and enable patients to improve their level of functioning and	Thank you for your comment. On consideration of stakeholder comments the assessment recommendations have been edited and some additional consensus recommendations added. This includes exploring people's strengths

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				activities of daily living, without necessarily altering pain perception *per se*. It concerns us that the Guideline Committee failed to acknowledge and address this key aspect of pain management. Furthermore, there needs to be acknowledgement that things can change for the better and that some people do recover. It is very important to give patients hope that their lived experience can improve despite the presence of pain, and it is felt that the wording of this statement does not convey this. There is a balance to be struck between on the one hand helping the person come to terms with the likelihood that their pain is likely to be a long term condition, but on the other hand helping them to see that there is a lot that can be done to support them with managing this and that peoples' experience of pain can change over time. It is felt that the wording currently does not strike the right balance.	and what they are already doing that is helpful. The recommendations added on developing a care and support plan highlight that this should be based on the person's priorities, abilities and goals. The committee agree the focus should not just be on whether the pain improves or gets worse. A sentence has been added to the recommendation to highlight that quality of life can improve even if pain remains unchanged.
The British Pain Society	Guideline	005	004-006	We were dismayed that although 'self-management' of chronic pain is mentioned twice in the Rationale section, it does not appear anywhere in the Recommendations. This is disappointing, as although it is by definition not an intervention to be given by a HCP or service per se, patients do need help in learning how to self-manage their pain and where to go for guidance on this. Thus we feel there needs to be specific guidance on enabling patients to self-manage and take control of their	Thank you for your comment. The committee agree that self-management plays an important role. A recommendation has been included to discuss the person's strengths, and the skills they have to manage their pain and what helps when the pain is difficult to control. The committee also agreed it was important to

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				own pathways, especially in CPP, avoiding the use of short term therapies which may be disenabling by creating patient reliance and delaying acceptance of chronic pain being a long term condition. Our BPS survey of patients revealed that this is an area that needs significant improvement. Q 18. Have you ever had advice and help on self-management of your pain? – 768 responses: "Yes, in full" in 32%; "Yes, but only partly" in 50%; "No, not at all" in 19%. And a further question in the patient survey was: Q 111. Would you like to learn about taking more control of your pain (self-management)? – 698 responses "Yes in 59%; "No" in 23%; "Not sure" in 19%.	consider this when developing a shared care and support plan.
The British Pain Society	Guideline	005	004-006	The language is noted to be all about managing, coping, doing things to people with pain. It puts the person living with pain in a passive role. It is important the focus in the guidance is on learning how to live well, how to live a more fulfilled life and on people becoming proactive partners in their own health care.	Thank you for your comment. The committee agree that people should have a proactive role in management of their pain. These recommendations have been edited to emphasise patient involvement and highlight that this should be a shared decision making process.
The British Pain Society	Guideline	005	007	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line***	Thank you for your comment. The committee agreed that evidence

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				by line coding guided by the framework of the NICE guidelines. The quotes included in this feedback are verbatim,but some have had minor corrections to obvious typographical errors for clarity but where ever possible quotes are not edited. Section 1.1.5: BPS patient survey respondents felt that partnership working was essential but that healthcare professionals did not take them and their knowledge seriously. "*My pain management treatment hurt me and I was ignored I worked yet no support given. I have great ideas to make it better but what do I know I'm a pain patient."* The wanted a treatment plan, but there was acknowledgement by some that this might be difficult to achieve. "*Provide full ongoing treatment plan just as would happen for another long term chronic eg diabetes*." "*Where is the time going to come from for a care plan to be drawn up? It's not easy to see the same GP in many health practises, the high turnover and high usage of locum GPs means this is near impossible especially in practises run by commercial organisations like Virgin Health Care.*"	demonstrated that there were shortcomings in some people's experiences of interactions with healthcare professionals for chronic pain. The assessment recommendations were included to highlight the importance of good communication.

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The British Pain Society	Guideline	005	007-008	It is laudable that NICE has recommended HCPs to develop a care plan with the patient. Our BPS survey of patients revealed that this is happening rarely: *Q 16. Have you received a care plan for your chronic pain? – 764 responses:* "Yes in Full in 11%; "Yes but only partly" in 30%; "No, not at all" in 60%.	Thank you for your comment. The committee agree this is important to include. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, to implement recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The British Pain Society	Guideline	005	04-6	Within the assessment there needs to be reference to social assessment as well as biological and psychological assessment. Intensive work with people to change other areas of their lives, to enable them to live more fulfilled lives, improve wellbeing, general health, will then influence pain in other ways or puts pain in a different	Thank you for your comment. The committee agree this is important. Consideration of social factors has been added to the recommendations.

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				place in patient lives, so that it is less 'all dominating' or negatively intrusive.	
The British Pain Society	Guideline	005-006	017-007	Section 1.2: It is noted that pain management is not the prime motive of some of the existing NICE guidelines referenced in this section and therefore cannot be relied upon to provide a complete pain management structure for these specific indications. It must also be stated that the further recommendations stated in this document cannot be transferred into the wider scope of pain conditions.	Thank you for your comment. This list is not intended to be all inclusive, but links to some of the most relevant NICE guidelines for conditions that cause chronic pain.
The British Pain Society	Guideline	005-006	017-007	Section 1.2: There is an unrealistic expectation that non-specialists will be able to navigate through an increasing numbers of condition specific Guidance documents and promoted care pathways and the concern is that this document could be used instead as a single default for all pain related problems although this would not have been the committee`s intention. There needs to be better signposting within the document to prevent this occurring.	The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in

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					the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
The British Pain Society	Guideline	005-006	017-007	Section 1.2: It is noted there is no statement on the education of patients and clinicians with regards understanding of the reasoning behind treatments being offered or not, and their role in the overall patient centred management life plans.	Thank you for your comment. These recommendations did include highlighting recommendations from the NICE patient experience guideline, in particular the need to enable people to actively participate in their care, including: communication, information, shared decision making. The assessment recommendations included in this guideline have been strengthened further and include exploring people's understanding of their pain and the outcome of treatments as well as explaining the evidence for possible benefits, risks and uncertainties of all management

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					options when first developing the care plan and at all stages of care.
The British Pain Society	Guideline	005-006	017-007	Section 1.2: It is noted there is no reference to gender and its biological, psychological and social impacts on pain management and treatment.	Thank you for your comment. The committee agreed that different recommendations for assessment and management were not required based on gender. They are not aware of evidence to suggest that effectiveness of interventions differs according to gender.
The British Pain Society	Guideline	005-006	017-007	Section 1.2: Previously NICE guidance has been taken by commissioners as an opportunity to reassess budgets. The document needs to emphasise that patients are not denied trials of reasonable treatment to see if they positively respond. In return, Clinicians have an obligation to discontinue treatment that is not helping to improve function and reducing pain intensity after fair trial. We would find it helpful if NICE rephrased many of the 'Do not offer' recommendations to "Consider xxx in the context of a clinical or n of 1 trial". N of 1 trials is a well-established way of exposing patients carefully and with du regard to harm as well as potential benefit in the pain field.	Thank you for your comment. The evidence reviewed in this guideline, and committee expert opinion was that there is insufficient evidence than these medicines are helpful for the majority of people chronic primary pain and there is evidence of harms. The guideline evidence reviews are intended to inform population based recommendations for the NHS. The committee therefore agree that recommended management options should focus on those with evidence of benefit for most people. The committee discussed the use of n of 1

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					trials but agreed that this was not practical in clinical practice. Unless these trials have a control period, it would not be possible to determine whether any positive benefit seen in an individual was due to the placebo effect which is known to be particularly strong in chronic pain. Trials of treatments that are not demonstrated to be effective could lead to harm, particularly when there is a risk of dependence and withdrawal symptoms. Resource should be directed towards more beneficial management options.
The British Pain Society	Guideline	006	002	In our BPS survey of patients, we asked the following questions, which revealed that most patients had not experienced a PMP, but of those that did, it was mostly seen as positive and only a small minority felt it had caused significant harm.: Q 20. Have you been in a Pain Management Programme (PMP)? – 767 responses: 'Yes' 43%; 'No' 53%; 'Don't know' 4%. Q 21. How helpful was the PMP to you? – 323 responses:	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain.

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				"Very helpful 20%; 'Partly helpful' 47%; 'Not at all helpful' 33% Q 22. Has the PMP harmed you in any way? – 324 responses: 'No, not at all' in 63%; 'Yes but I want to continue' in 8%; 'Yes and enough to want to stop' in 15%. ***These data are supplemented by qualitative responses: The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.2.1: BPS patient survey patient had mixed experiences of pain management programmes. Many found the programme to be helpful and were concerned that the guidelines might be interpreted by commissioners and health care practitioners in a way that prevented referral of others. "*CBT and pain programme come in to far down the line. These therapy's should be quicker to access to prevent psychological issues"* "*I'm very lucky compared to others but I still would struggle if the PMP resources were taken away from me and I had to rely on GP for drug suggestions and therapies*"	The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.

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				"*My PMP was about 22 years ago, run by two physios. The recommendation of certain exercises and meeting others living with pain was great. I have evolved ways of managing life with the meds and numerous other adaptations. I am very concerned that others with pain aetiology that is not yet well understood will be left stranded by the Daft NICE GDL*" However, the responses to the survey demonstrated how variable experiences had been. Some people were refused a place on a PMP. *"I was sent to a pain management program but I was told I was too positive to benefit from it and my mental health history posed a risk to others."* Some could not attend because of the geographical distance of the PMP from their home or the after-effects of undertaking the exercise component. "*The pain management program and pain clinic are 50-60 mins drive away. At BEST It takes more than a week to recover from one short appointment let alone an exercise class. This was the reason I couldn't' attend a pain program daily*. "	

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				Some felt that the heterogeneity of the groups was not helpful, or otherwise found the group setting unhelpful. "*Pain management needs to cater for individual. Have attended 4 in patient over years, each one has never catered for me as an individual. Everyone had different problems, but we was expected to do same exercises etc.*" "*The way pain management was handled was far, far too general. The group sessions I did included people with joint pain, fibro pain, nerve pain, gastrointestinal pain etc. each one of these individuals experienced their pain in a completely different way and found very different things helpful. However the management team tried to train us all to manage our pain in the same way which was just unrealistic and made us all feel as though we weren't being heard or respected*." "*Negative attitudes from other patients has been frustrating and distracting especially in group settings*."	
The British Pain Society	Guideline	006	002-004	Section 1.2.1: The BPS is fully supportive of further research into Pain Management Programmes (PMP) but the lack of further detail is likely to have an impact on current commissioning decisions. The BPS is of the opinion a bridging statement to "ConsiderPMP" is required, whilst further research is pursued. PMPs provide support for the psychosocial aspects of	Thank you for your comment. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have

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				persistent pain and if there is a movement towards supporting these aspects of management within the guidelines the lack of consideration would impair service support for patient delivery.	decided not to recommend further research.
The British Pain Society	Guideline	006	002-004	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards PMP: "I am surprised by the small number of studies embraced in the review (8) given that there is such a wealth of information in the literature. There was scope for much wider comment and in particular from patients in respect of their experience. I compare this to other areas discussed where there is comparatively little information to draw on and yet where speculative comment is put forward (eg regarding ACT). If PMPs were to be reduced down on the basis of this commentary (noting a lack of evidence) I would first and foremost feel that a group of people whose lives could be changed dramatically are being badly let down on the basis of a surprisingly narrow scope of reviewed evidence."	Thank you for your comment. There were a total of 26 studies included in the review, as detailed in evidence report C. The rationale statement referencing 8 studies related to the number of these that demonstrated a benefit in terms of quality of life.
The British Pain Society	Guideline	006	002-004	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.***	Thank you for your comment. The review of evidence for pain management programmes was

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				Respondents were asked about the recommendations with regards PMP: "Our PMP annual audit outcomes (including over 300 patients) show significant benefit to patients on PROMS and Patient satisfaction. Research has shown combined physio and psychology approaches benefit patients (as per NICE back pain guidelines). Psychology only and physio only treatments not as effective as combined, joined up care for complex pain patients."	considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for

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					low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.
The British Pain Society	Guideline	006	006	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.2.2: No comments were received about social interventions for pain management from the BPS patient survey respondents.	Thank you for your comment.
The British Pain Society	Guideline	006	006-007	Section 1.2.2: The committee were aware of evidence for social interventions in conditions other than chronic pain, but they agreed that this evidence could not be extrapolated as the issues faced by people with chronic pain are likely to be different from those populations. The BPS applauds the committee for admission that evidence in other patient groups cannot be extrapolated to chronic pain populations.	Thank you for your comment.
The British Pain Society	Guideline	006	006-007	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Social interventions:	Thank you for your comment. The review protocol covered a broad range of definitions of social interventions as the committee were aware this is an emerging area. No evidence was identified relevant to chronic pain however.

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				"Social prescribing is a subset of social interventions. We offer link-ups with the areas listed above but the best elements of social intervention are not covered in the above questions. The research evidence is thin but it exists if the term peer support is included in the scope of social interventions, as is the subjectively powerful influence of patient volunteers in PMP engagement and delivery of treatment. I consider that these are a major advance in the evolution of PMPs and it would be a big backward step for these elements to be lost."	
The British Pain Society	Guideline	006	006-007	In our BPS patient survey we asked about experience of 'social prescribing'. The responses showed that few had received these: Q 24. Have you received a social prescription for your chronic pain or underlying condition? – 758 responses 'Yes' from 8%; 'No' form 90%; 'Don't know' from 3%. ***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Social interventions: "Again this has been tricky with COVID as not all social prescribing services are currently available and Social Prescribers are finding new ways of working. Social Prescribing frequently taps into what is meaningful	Thank you for your comment and for this information. The committee hope that future research on this topic will help inform updates of this guideline.

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				for the person enabling them to set goals, interact with others and think to the future. Primary Care continues to increase its investment in social prescribing; we would not want people with pain to be excluded."	
The British Pain Society	Guideline	006	010	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines*** Section 1.3: BPS pain respondents found hydrotherapy helpful but it was often inaccessible. "*I was told to do some hydrotherapy and this helped with my pain*" "*Pay for hydrotherapy privately which has been scuppered by lockdown is invaluable in keeping me mobile*"	Thank you for your comment. The evidence review did not demonstrate whether one type of exercise was more effective than another. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.

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The British Pain Society	Guideline	006	011	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.1: BPS patient survey respondents provided comments that demonstrated they wanted group activities for homogenous groups rather than heterogenous groups (these comments are included in 1.1.2 as they also relate to the exercise component of PMPs). Many respondents who talked about exercise as an isolated therapy felt that it had been very helpful. "*I've had physiotherapy exercises, a brief course of sessions. They were helpful and what I learnt still helps. Biggest help is exercise which I have had no help or advice from health professionals.*" But some felt that there was a lack of understanding about their specific condition that led to exercise advice not being appropriate to them. "*Exercise has been the most helpful thing that I have done yet I had to figure it all out by myself because the support and knowledge just wasn't there surrounding exercising with hEDS."*	Thank you for your comment. The committee agree that people's abilities and preferences should inform the type of exercise and that tailored programmes might be required. The implementation of this and arrangement of the groups would be determined by local services. The committee agree that the risks and benefits of all treatments should be discussed with the person when making a shared decision about whether to try an intervention.

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				However, a few respondents felt exercise was an unhelpful suggestion when it made their pain or fatigue worse. *"I saw one physio who assessed me, advised I go to a local sports complex and when I was exercising 3-4 times a week, to go back to him. He didn't understand that some days I can hardly get out of bed. I didn't go back to him."* *"I exercised regularly at the beginning of my fibro journey but the exercise itself was making my pain worse which is the reason I first went to the doctors, "* *"I can't really separate my pain experience from my experience of chronic fatigue, and many of the exercise regimes don't take that into account. I've used Tai Chi to keep mobile for the pain but have to rest during class because of the fatigue."* A research recommendation arises from the comments to explore exercise and activity recommendations for people who experience fatigue as a major component of their pain.	
The British Pain Society	Guideline	006	011-017	Sections 1.3.1 and 1.3.2: A large proportion of chronic pain patients have already been through musculoskeletal pathways but have then been referred onto Chronic Pain services due to lack of response/increased pain with	Thank you for your comment. The committee agree that there is no evidence that the medicines recommended against for chronic

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				exercise. There is a place for medication use to allow the introduction of exercise therapies which would then be the long term management course. The current guidelines disallow the use of short term medication to facilitate a patient`s management plan. Adjuncts to pain control, whilst not in their own right, a long term solution to optimal pain management, may be highly useful in facilitating patients in the start of this journey, particularly where they may have short term (3 months) recognised value. Considering some interventions as a package of care may be highly valuable, especially where risk is low and dependency is unlikely. Initial changes in lifestyle behaviour are often prone to short-term setbacks and a non-linear level of progression. Adjuncts to care at this stage may ease this transition process and improve effect and outcome.	primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. They do recommend that exercise is tailored to the person's abilities and agree that the programmes should be adapted to enable people to participate.
The British Pain Society	Guideline	006	011-017	Sections 1.3.1 and 1.3.2: As acknowledged, there are positive cost benefits to exercise, activity and movement with little agreement about additional specifics of type. Risk and harm is very low. Activity and formal exercise is a lifestyle issue and significant health benefits (and thus wider societal benefits) are lost when patients gradually drop out of exercise programmes over time (for multi-factorial reasons). Delivery of medically supervised exercise / activity is widely variable across the UK. Access to and availability	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				of "de-medicalised" exercise / activity within community programmes and outside of health facilities are highly variable and carry cost to individual or local services if subsidised as a means of facilitating longer term behavioural changes. De-medicalised activity support for this heterogeneous patient population is reliant upon the practitioner having contemporary, accurate understanding of persistent pain and pain management approaches if such lifestyle changes are to be effective and embedded for long term maintenance.	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The British Pain Society	Guideline	006	011-017	Section 1.3.1 and 1.3.2: Delivery of, capacity and willingness to engage in activity class work (medically and non-medically delivered) will be heavily influenced by the peri-post COVID era. Remote and online resources will require development and this will influence cost – effectiveness evaluation. There is a lack of specialised chronic pain physiotherapists and this will require significant training and up-skilling to deliver the resources described. Has the current lack of delivery and future resource requirements been accounted for in the current cost effectiveness evaluation? It is not apparent in the current set of documents.	Thank you for your comment. Detailed methods for the cost effectiveness analysis are available in the separate 'Exercise modelling report'. The costs in this were based on resource use from the trials used to inform effectiveness and current UK unit costs. Costs primarily related to staff time. The analysis was undertaken before COVID and so does not explicitly address the issues you raise. However, it is considered likely that in many cases staff costs would remain the primary cost driver. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS

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					services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
The British Pain Society	Guideline	006	011-017	Section 1.3.1 and 1.3.2: It is noted most of the exercise studies are about FMS- only 1 or 2 studies includes men. Ethnicity of participants is mainly not reported, there is a distinct gap in the literature. Trials do not routinely include elderly population in exercise for chronic pain which is the majority of the treatment population in many hospitals. How can this be extrapolated to include all types of chronic pain and for all genders and sub-populations?	Thank you for your comment. The committee note that clinical trials and controlled studies often do not represent older populations. All of the reviews can be impacted by these limitations. The committee also acknowledge that the evidence informing the exercise review was largely from populations with fibromyalgia or chronic neck pain. The committee considered that response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions. However it was also

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					considered that the most appropriate type of exercise may depend on the type of pain condition and it should therefore be tailored to individual needs and preferences. This is detailed in the committee's discussion of evidence in the evidence review and has been added to the rationale in the guideline for clarity. Details about the settings and where available the ethnicities of the participants, are given in the evidence tables in appendix D for all included studies. The applicability and generalisability of the evidence was considered by the committee in their discussion of the evidence.
The British Pain Society	Guideline	006	011-017	Section 1.3.1 and 1.3.2: A further concern raised is that most of the FMS studies either exclude people with significant psychiatric problems, suicidal ideation or baseline data suggests that participants have mild-moderate depression. This is not reflective of the population that are seen in pain clinics in secondary / tertiary care. Could the guidelines include a caveat that the exercise recommendations have excluded people with significant mental health presentation?	Thank you for your comment. The committee note that clinical trials and controlled studies frequently exclude people with comorbidities. All of the reviews can be impacted by these limitations. The committee highlight in the recommendations in the assessment section (1.1) that there

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					should be a holistic assessment and also that people's preferences and priorities for managing multiple conditions should be taken into account when developing a care and support plan.
The British Pain Society	Guideline	006	011-017	Section 1.3.1 and 1.3.2: We would draw to NICE's attention that the Chartered Society of Physiotherapy (CSP) stopped using the word exercise a few years ago. The word itself can increase pain in some people. The CSP recommends increasing activitylevels.	Thank you for your comment. The committee discussed the most appropriate terminology for these recommendations. It was agreed that the recommendation for supervised group exercise should retain this term. Physical activity or activity levels has a different meaning to readers and would not reflect what the evidence has demonstrated to be effective. It was agreed that the recommendation for continuing beyond the end of the formal programme should be reworded to 'remain physically active'.
The British Pain Society	Guideline	006	011-017	Section 1.3.1 and 1.3.2: There is no mention of the need to promote increased activity levels in everyday life. Focusing on exercise for a problematic body part is a linear approach. The document should be promoting full body movement, increasing general fitness levels, enabling people to move outdoors and in a social context.	Thank you for your comment. The committee agree it is important to encourage people to remain physically active and included a recommendation to that effect. The

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				Simply doing linear exercises in a physiotherapy department may have a place initially but isn't sufficient nor sustainable in the long term.	guideline also cross refers to the NICE guidelines on physical activity and behaviour change: individual approaches, where this is also addressed.
The British Pain Society	Guideline	006	011-017	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards exercise for CPP: "This is often delivered in conjunction with psychological therapy to improve mood, motivation and increased acceptance. Physical exercise programmes help individuals to increase their fitness and function, leading to an improved quality of life and sense of self efficacy."	Thank you for your comment. This review considered evidence as a single intervention, and demonstrated effectiveness of exercise programmes for people with chronic primary pain in this context.
The British Pain Society	Guideline	006-010	008-010	Section 1.3: The guidance is now no longer with regards Chronic pain, but chronic primary pain (CPP) only. There must be better use of layout, font etc. to ensure that this change of emphasis has occurred and does NOT relate to all chronic pain patients to avoid confusion within clinicians, commissioners and patients.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant

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					recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Pain Society	Guideline	006-010	008-010	Section 1.3: It must be noted that the ICD-11 classification is a coding tool to allow for appropriate interpretation of clinical condition occurrence introduced in 2019. It was designed to enhance the importance of chronic pain and highlight its prevalence. Its aim was to provide capacity to measure incidence, prevalence, and impact to help in identification of human, financial, and educational needs required to address chronic pain in primary care. This would then allow for opportunities to match evidence-based treatment pathways to **distinct chronic pain subtypes**to be enhanced. The timeframe between its introduction and the evidence assessment for this guideline would make it unsurprising there is no significant evidence base to support a broad heterogeneous category of the classification. The draft guidance has not viewed CPP as several distinct chronic pain subtypes but as single	Thank you for your comment. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such

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				homogeneous entity with no associated evidence based rationale and therefore have ignored the primary aim of the original classification.	that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). The search terms used to identify literature were broad to identify any of the conditions that may fall under this definition. Inclusion criteria was not based on the use of the term 'chronic primary pain'. The details of the populations included within the

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					studies were reviewed, considering whether they were under the umbrella term of chronic primary pain, as listed in ICD-11 at the time of development. Full details of the search strategies are provided in appendix B of the evidence reports.
The British Pain Society	Guideline	006-010	008-010	Section 1.3: All the approaches mentioned are long-term approaches and although we know this is necessary there is still a need for some short-term approaches that can get people through a crisis or that will enable them to actually get started on things like increasing activity levels and other programmes of treatment… or to get them through the waiting period for a treatment programme of psychology or Pain Management Programme (PMP).	Thank you for your comment. The committee have added a recommendation for considerations of a flare up of pain. The recommendations for developing a care and support plan also include providing information on self-management options.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: The intention of this aspect of the review was to identify the evidence for independent psychological therapies, to inform services as to which are effective for the assessment and management of **all**chronic pain.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification

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					has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: There are some methodological questions which challenge the conclusions reached by the GDG. The criteria applied in the initial search has led to the exclusion of some higher quality trials (e.g. Smeets et al 2006, which was a good large trial which demonstrated cost effectiveness).[1] This may be because of a misinterpretation of the intervention or because the focus was on more 'specific' conditions, such as low back pain or neck pain. Apart from the risks associated with a dualistic approach, there is a wider problem of definition, in that clearly defining or diagnosing these conditions, where pain is attributed to specific anatomical structures, in order to distinguish them from CWP or CPP, is extremely problematic, (Brinjikji et al 2014)[2]as is the	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the

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				agreement on what constitutes 'Fibromyalgia', on which the conclusions of this review were largely based. 1. Smeets_R, Vlaeyen_JWS, Hidding_A, Kester_ADM, Van Der Heijden_G, Van Geel_ACM, et al. Active rehabilitation for chronic low back pain: cognitive-behavioral, physical, or both? First direct post-treatment results from a randomized controlled trial. BMC Musculoskeletal Disorders 2006; 7:1-16. Brinjikji W, Luetmer PH, Comstock B, Bresnahan BW, Chen LE, Deyo RS, Halabi S, Turner JA, Avins AL, James K, Wald JT, Kallmes DF and Jarvik JG Systematic Literature Review of Imaging Features of Spinal Degeneration in Asymptomatic PopulationsAm. J. Neuroradiol. 2015 Apr; 36(4):811-6.	guideline indicating what populations are covered by each recommendation topic. Smeets et al. was therefore excluded from the psychological therapy review due to being for low back pain. It was however included in the pain management programme review. Brinjikji et al. was also excluded for not being chronic primary pain. This would also not match the population for the pain management programme review due to focusing on asymptomatic populations rather than chronic pain.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: The review also focused on content of the intervention, (ACT or CBT), rather than the skills or background of those delivering the programme, which has been highlighted as potentially having significant effect on outcome by an earlier systematic review (Pincus and McCracken, 2013).[3] 2. Pincus T, & McCracken, L. (2013). Psychological factors and treatment opportunities in low back	Thank you for your comment. The review objective, as stated in the protocol, was to determine the effectiveness of the included psychological therapies for chronic primary pain. In the interpretation of the evidence the committee noted that the experience of the person delivering the intervention can have

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				pain. Best practice & Research. Clinical Rheumatology. Vol 27 (5) 625-35.	an impact on the effectiveness of the intervention. This is detailed in the committee's discussion of the evidence in Evidence review F. The guideline recommendations assume that the healthcare professionals delivering the interventions are appropriately trained to do so. This has been added to the recommendation for clarity.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: Thus the basis for the conclusions reached by the GDG that both ACT and CBT are comparable and cost effective, are therefore under question.	Thank you for your comment. As noted in the response above, this was discussed and taken into account in the committee's interpretation of the evidence, detailed in evidence review F. The committee agree that there is sufficient evidence of benefit to recommend that their use can be considered, although not enough for a stronger recommendation to offer these to all people with chronic primary pain.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: The GDG also acknowledged a problem with assessing the efficacy of independent psychological approaches to chronic pain, which is that in much of the published research, as is the case in clinical	Thank you for your comment. The committee do acknowledge this is true in some research studies, but

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				practice, elements of psychological therapies are typically combined e.g. CBT + relaxation + pain education.	there was also evidence available to inform effectiveness of the interventions individually for chronic primary pain.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: This combined approach would typically take the form of a Pain Management Programme (PMP). PMPs have justifiably only received a research recommendation in the guideline, as the evidence for such combined approaches was deemed unclear by the GDG. How much input is required, such as the length of the intervention or the number of sessions or which components work best for who, is not clear and requires further research.	Thank you for your comment. These recommendations are for either CBT or ACT, based on the evidence reviewed for these as standalone interventions. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research on this topic.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: With regard to the impact of the guideline in its present form on NHS services; stand-alone psychological therapies rarely form a significant part of an NHS pain service offering, for the following reasons: • **Pain is generally agreed to be a multifactor biopsychosocial construct.**Offering stand-alone	Thank you for your comment. The committee agreed when setting the protocol that the effectiveness of therapies individually needed to be determined for chronic primary pain. The evidence for pain management programmes with combined therapies

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				psychological therapy is not the most effective way for an NHS pain service to meet the needs of the majority of people with chronic or long-term pain, where for example, poor activity management, physical deconditioning, sleep disturbance, drug dependence and social withdrawal are common co-morbidities. As indicated above, this combination of difficulties is typically addressed through a multidisciplinary Pain Management Programme (PMP), underpinned by a biopsychosocial model. This model acknowledges the reciprocal relationship between the factors, which typically interact to form a number of vicious circles, making fragmented uni-disciplinary or uni-factor approaches ineffective. • **Engagement.**The stigma of pain being perceived as a 'psychological' problem is a common prejudice and makes it difficult to engage many people in multidisciplinary pain services with a psychological component, let alone independent psychological therapy. In addition to this misunderstanding, many patients' primary goals are to reduce pain severity. This is understandable; however the aim of psychological-based interventions is not to address this directly, but to improve functioning, mood and quality of life. Engaging patients in such an approach,	was reviewed separately within the guideline. In consideration of stakeholder comments, the evidence in that review has been reanalysed to separate the chronic primary pain population, to be consistent with other reviews within the guideline. The committee agree that for this population most of the evidence did not show an improvement in quality of life and there was no evidence of benefit for pain, physical function or psychological distress. They therefore did not include a recommendation on the topic. There was however sufficient evidence to recommend that ACT and CBT can be considered. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not

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				which does not appear to align with their primary goals of pain reduction, requires a skilled multidisciplinary and often multi-session, approach. For most people engagement is more successful when the psychological therapy is offered as part of a package, alongside more 'acceptable' components such as exercise, drug optimisation and sleep management. **Lack of psychology resource.**In any event there are not enough HCPC registered trained practitioner psychologists working in NHS pain services to offer the number of effective stand-alone CBT or ACT psychological interventions which would be required, should the guideline be implemented in its present form	reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline. The committee agree that a holistic assessment and person centred approach is important for the management of chronic pain. This is highlighted in the recommendations in section 1.1 of the guideline. The committee agree that there is variation in the delivery of some of the recommended services across the

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					NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The British Pain Society	Guideline	007	002-006	Section 1.3.3 and 1.3.4: In the guidance on Pain Management Programmes (PMPs) for general chronic pain, PMPs are defined in a clear way (Evidence Review 3, Section 1.3, Table 1. PICO characteristics of review question). However, in the guidance on Psychological Interventions for chronic primary pain (Evidence Review 6, Section 1.3, Table 1. PICO characteristics of review question) these interventions are defined solely by their label. This is important as a number of these latter interventions could be categorised as Pain Management Programmes, but the decision was made to only consider them as a psychological intervention, perhaps weakening the evidence for PMPs, in the process.	Thank you for your comment. The committee acknowledge that there is no consistently accepted definition of a pain management programme and that definitions and interventions can overlap. The protocol for psychological therapies including CBT and ACT only considered these when delivered without a physical component with interaction between the two components, which was a key

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				This distinction between Pain Management Programmes and psychological interventions is blurred in the clinical field. For example, over 80% of UK PMPs describe themselves as employing an Acceptance and Commitment Therapy (ACT) approach or a mixture of ACT and CBT. This is likely to also be confusing for patients, managers and commissioners. This potential confusion should be addressed in the guidance. To compound matters, the guidance on PMPs talks about psychological interventions as being primarily delivered on an individual basis (Evidence Review 3, Section 1.7.1.3, page 54, lines 37-40) and this being one reason why they might show more consistent effects than PMPs, which are delivered in groups. This is important because it is untrue and does not reflect the evidence that the committee considered. An examination of the studies described in Table 2, in Evidence Review 3, Summary of studies included in evidence review, page 9 onwards, reveals that many of these interventions (particularly those involving ACT and CBT) were delivered in groups. Again, it is argued that this reflects the definitional confusion, detailed above.	distinction between this and the pain management programme review in the guideline. The committee considered that this is clearly defined in each protocol. The statement about psychological interventions primarily being delivered on an individual basis has been reworded, we agree the evidence base did report a lot of group based psychological therapies and this statement could be misinterpreted to mean that psychological therapies are delivered 1:1. The intention was to reflect on their use as standalone interventions compared to when combined as part of pain management programmes.
The British Pain Society	Guideline	007	002-006	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.***	Thank you for your comment.

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				Respondents were asked about the recommendations with regards psychological therapy for CPP: "It is a major arm of the service, often enabling individuals to prepare to participate in a PMP where otherwise they would not be able to engage. It is a separate-standing option for those who cannot work in a group."	
The British Pain Society	Guideline	007	002-006	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines*** Respondents were asked about the recommendations with regards psychological therapy for CPP: "This is part of the biopsychosocial model of care that our service relies upon to deliver a reflexive multidisciplinary approach to long term problematic pain be it primary or secondary or both. Thinking and reflection allows for choice and ownership in clients - the aim is to empower clients to take control and manage and moderate their own lived experience of pain. Without psychological expertise and approaches this is in danger of being lost."	Thank you for your comment.

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The British Pain Society	Guideline	007	002-006	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards psychological therapy for CPP: "Biomedical approach to chronic pain is insufficient due to the huge impact pain has on people's emotions, thoughts, feelings, beliefs, behaviours, relationships, etc"	Thank you for your comment. The committee agree that a holistic approach to chronic pain is required, not purely a biomedical approach. This is reflected by the recommendations in section 1.1 as well as by the non-pharmacological interventions recommended.
The British Pain Society	Guideline	007	002-006	Section 1.3.5: It is acknowledged that the variance in type, intensity and country of clinical practice varied significantly in the evidence assessment. Benefits were not demonstrated beyond 3 months. Clinical risk is low however there appears to be little recognition that Acupuncture is a passive treatment which often engenders dependency (and challenges service sustainability). There is however recognition that the modality is labour intensive. This therefore appears to conclude with a series of clinical caveats (no more than 5 hours input, B7 delivery (or less), community based provision, ongoing repetition not to be picked up by NHS services). This is an approach which is at odds with previous NICE recommendations on Acupuncture and which would have significant resource implications. This "pragmatic approach" is not offered to	Thank you for your comment. The committee agreed that there was variance in type and intensity of interventions included, as well as country that the studies were conducted in. This is also true of the evidence informing the other non-pharmacological interventions recommended in the guideline. The committee were not aware of significant risk of dependency to acupuncture, but do acknowledge that it is largely a passive treatment. That

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				other modalities with similar shortcomings (or fewer), covered within this guidance and we would ask if the evidence base is felt sufficient for this recommendation then this 'pragmatic approach' should be extended to other treatments considered within this guidance.	does not however detract from the benefits observed in the review. The committee agreed that overall the large body of evidence from the clinical review demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.

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					The committee were also aware that implementation of acupuncture would have a greater resource impact than some other interventions recommended for chronic primary pain. They therefore agreed it was important to state in the recommendation conditions under which delivery of acupuncture was demonstrated to be clinically and cost effective, to aid commissioners. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost effectiveness evidence supporting the recommendation.
The British Pain Society	Guideline	007	003	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.***	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree

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				Section 1.3.3: BPS patient survey respondents were equivocal about the role of CBT. Many had found the approach helpful but also wanted access to other therapies and treatments. Fewer respondents mentioned ACT than CBT but the sentiments about it were positive, and when positive sentiments were made about either CBT or ACT it was in the context that what had been learnt was still being applied helpfully some time later. *"Despite having completed a PMP, which I found extremely helpful, multiple courses of CBT and ACT that I make use of on a daily basis, and regularly practicing mindfulness, I still feel that occasional use of these pharmaceutical/ electrical modalities is a valuable and necessary part of my pain management toolkit*" "*It's hard enough living with chronic pain. But not getting pain killers than can, and does work for many people is a killer in and of itself. CBT is there because we know these conditions are psychologically taxing. To take away a treatment that helps people, to be put on waiting lists to see psychologists when you can't even get out of bed is devastating."* It was also noted that these approaches were often offered very late in the patient's pain journey or impossible to access at all.	that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. It is important to note that the review and recommendations are for chronic primary pain only. For management of other conditions, or secondary chronic pain, other relevant NICE guidelines should be followed.

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				"CBT and pain programme come in to far down the line. These therapy's should be quicker to access to prevent psychological issues" *"It's all very well suggesting that exercise, diet, CBT and other therapies will help over painkillers but this is not news and GPs are currently not recommending them as treatment or helping so what's the point?"* This latter sentiment should be considered in light of a general feeling from the respondents that what they want is access to a range of therapies and treatments, and their fear that the guidelines will make it harder or impossible for this access to be available or offered. Some felt that CBT was actually or potentially harmful and underlined the complexity of chronic secondary pain in terms of the work that might be needed with a patient before they are ready to move into a particular therapy. "*UK support for ME/CFS is harmful to patients, recommending CBT and GET. These 'treatments' are both abusive and inhumane to ME patients. I was offered CBT for TMD and declined as it is essentially a hypnotherapy with no benefit."* "*CBT is equally unsuitable as there is no screening it's contraindicated in trauma as it triggers PTSD. This making it*	

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				unsuitable for many cases of pain as they were started following traumatic events. (I'm a trained therapist)" Fewer respondents mentioned ACT than CBT but the sentiments about it were positive, and when positive sentiments were made about either CBT or ACT it was in the context that what had been learnt was still being applied helpfully sometime later. "*Despite having completed a PMP, which I found extremely helpful, multiple courses of CBT and ACT that I make use of on a daily basis, and regularly practicing mindfulness, I still feel that occasional use of these pharmaceutical/ electrical modalities is a valuable and necessary part of my pain management toolkit.*"	
The British Pain Society	Guideline	007	008	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.5: BPS patient survey respondents were largely positive about the results of acupuncture. "*Over the last ten years I have found drugs to not help at all, they made me worse. Whereas lifestyle control and having privately had acupuncture and myofascial release has made the biggest difference to managing pain.*"	Thank you for your comments and we note that most of your respondents were positive about acupuncture. Regarding the evidence base, the committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some

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				And some found the idea of acupuncture poorly evidence with one respondent feeling that one panellist may not have been impartial. "*Acupuncture has very low quality evidence.*" *"And they should stop endorsing quackery, like acupuncture. It was absurd that NICE appointed to a guidance group an acupuncturist with a private practice."*	moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The committee member with expertise as an acupuncturist declared this on appointment and withdrew

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					from discussions relating to making recommendations about acupuncture. This is stated in the declaration of interests register and in the relevant meeting minutes. It is not correct that he has private practice (either now or in the past), all of his work is within the NHS.
The British Pain Society	Guideline	007	008-015	Section 1.3.5: Earlier this year an extensive review of acupuncture systematic reviews was published. This was a narrative synthesis of all the systematic reviews of acupuncture for chronic pain from 1989 to 2019, covering 177 reviews on various conditions. It found evidence that was conflicting and inconclusive, due in part to recurring methodological shortcomings in the included RCTs. Most of the reviews included RCTs with inadequate sample sizes and high risk of bias. On the basis of these findings there was surprise that acupuncture has been recommended as a treatment for chronic pain conditions. Paley, C.A.; Johnson, M.I. Acupuncture for the Relief of Chronic Pain: A Synthesis of Systematic Reviews. *Medicina* **2020**, *56*, 6	Thank you for your comment. We have read this article. It is of note the authors themselves comment '*We appreciate that the non-systematic approach is vulnerable to selection and evaluation biases and opinion-orientated arguments'.*
The British Pain Society	Guideline	007	008-015	Section 1.3.5: NICE came out against acupuncture in the CG59 and neuropathic pain guidance. What new evidence supports this recommendation?	Thank you for your comment. The committee were aware of the recommendation and evidence review underpinning the recommendation in

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					NG59. The review for this guideline excluded evidence in people with low back pain and therefore included a different evidence base. The evidence in this review for chronic primary pain was more favourable for acupuncture than that in NG59 for low back pain and sciatica. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. It is unclear which recommendation you refer to for neuropathic pain. The NICE guideline for neuropathic pain in adults CG173 covered pharmacological management only.
The British Pain Society	Guideline	007	008-015	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.***	Thank you for your comment. The committee agree that individualised treatment is required. They

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				Respondents were asked about the recommendations with regards Acupuncture: "The evidence base for acupuncture for CPP is limited, though it can help individuals. Treatments should be individualised"	particularly note that the type of acupuncture or dry needling should depend on the individual needs of the person with pain.
The British Pain Society	Guideline	007	012	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.5: One BPS patient survey respondent expressed some disquiet about the level of training that some offering acupuncture had had. "*Acupuncture and massage given by practioners who have done 6 week courses. "*	Thank you for your comment. The guideline recommendations assume that all people delivering the interventions recommended should be appropriately trained to do so. This has been added to the recommendation for clarity.
The British Pain Society	Guideline	007	013	Section 1.3.5: While some BPS patient survey respondents had managed to get a short course of acupuncture from the NHS most had to pay privately. They were keen to see acupuncture, when it helped, offered as an ongoing treatment. "*I've been lucky in the past that my GP did acupuncture for flare ups of chronic neck pain…."*	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment,

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				"*Acupuncture is the best management for me, but it's expensive*." "*I have to pay private for acupuncture that my family help to fund. "* "*Once you have done a course you are left to your own devices need top ups, acupuncture helped but left me with insomnia. "* "*I have had to pay privately for physio, accupuncture and massage therapy. They are the only things that work for me."*	such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The British Pain Society	Guideline	008	002-007	Section 1.3.6: We agree there is currently little justification for therapeutic Ultrasound for persistent pain problems	Thank you for your comment.
The British Pain Society	Guideline	008	002-007	Section 1.3.6: There is little indication to support Interferential Therapy which is delivered as a 1:1 treatment for short duration and is entirely passive in nature. It`s effects are very transient and are not likely to facilitate significant engagement in more active rehabilitation strategies	Thank you for your comment.
The British Pain Society	Guideline	008	002-007	Section 1.3.6: With regards TENS we accept that the evidence base is contradictory and there is little agreement about stimulation parameters, time periods of	Thank you for your comment. The evidence base for acupuncture informing the recommendation was

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				treatment and indeed optimal pad placement however the evidence base is no more, no less than the vagueness around Acupuncture care which is treated entirely differently in this document.	considerably greater than that for TENS. Only 2 relevant studies were identified for TENS and no difference was observed between sham or usual care. For acupuncture a total of 32 studies were included and consistent benefits were seen for health related quality of life and pain when compared to sham or usual care. The committee do acknowledge there was variation among the interventions included within the review and include this in their discussion of the evidence in the review chapter (Evidence report G). They agreed that this was reflected in current practice, which showed a similarly wide variation in terms of type of acupuncture, length of sessions and duration of treatment programme. The evidence base was agreed great enough to inform a recommendation to consider acupuncture, rather than a stronger recommendation to offer acupuncture

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					to all people with chronic primary pain.
The British Pain Society	Guideline	008	002-007	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards TENS: "We find that TENS helps around 30% of patients manage their pain more effectively. It is relatively cost effective and easy to use."	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.

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The British Pain Society	Guideline	008	002-007	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines*** Respondents were asked about the recommendations with regards TENS: "Tens is a cheap, ambulatory, self-guided alternative to medication. It does not work for all but for the ones it does work for it can be life changing. I have just heard about a prisoner who I have treated who has had back pain for many years. She was poorly managed on 70ml methadone, started purely for pain, a TENS machine now means she is running exercise sessions for other inmates and is coming down on her methadone. Anecdote I know, but there are thousands of stories like this"	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
The British Pain Society	Guideline	008	002-007	Section 1.3.6: TENS is a non-dependency treatment in which the patient is operator. The patient is given an active management role in their own self-management	Thank you for your comment. The review considered published RCT

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				strategy. Risks are negligible. Costs are minimal. As a treatment that patients could be trialled with (brief level of supervised input) or directed towards self-purchase, and used as an adjunct to optimal self-management / engagement in other physical and psychological rehabilitation strategies it has its merits. We would not advocate repeat patient attendance for short duration treatments of TENS delivered in a health care setting as stand-alone pain care but believe it has a role as a self-delivered treatment.	evidence for TENS in people with chronic primary pain. Only 2 studies were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
The British Pain Society	Guideline	008	004	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.***	Thank you for your comment. The review considered published RCT evidence for TENS in people with chronic primary pain. Only 2 studies

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				Section 1.3.6: BPS patient survey respondents found that TENS was a useful adjunct treatment which they felt valuable because it contributed to pain relief, it was under their control, and it came at a low financial cost. "*I view my use of TENS and paracetamol as similarly helpful in managing short-term flare-ups, but with little to no negative effects (none that I'm aware of). Furthermore, these are both low-cost and available without prescription, so it would be perfectly possible for a clinician to recommend these options without the cost being a burden on the NHS. Indeed, I pay for both of these treatments out of my own pocket - a TENS unit costs £20, and paracetamol is about 50p a packet.*"	were identified relevant to the review protocol and no difference between TENS and sham TENS or usual care was demonstrated for most of the patient reported outcome measures. Although there was a difference seen in pain in the short term and long term follow up from one very small study, but the committee considered that this was not sufficient to base a recommendation on due to limitations in the evidence and lack of effectiveness in any other outcome. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
The British Pain Society	Guideline	008	009	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.7: BPS patient survey respondents talked about massage therapy, chiropractic and osteopathy as	Thank you for your comment. The committee agreed that at the moment there is insufficient evidence to recommend manual therapies are used for chronic primary pain within the NHS, but further research is

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				being beneficial components of their pain management strategy but many were unhappy that they had to pay for these services. "*I pay for an osteopath which is very expensive so my treatments are limited to how much I can afford*." "*Though Osteopathy and Codeine are only used when the pain becomes too much, I could not live without them when needed*."	required to inform future updates of the guideline. The committee don't believe that people should be encouraged to spend their own money on services for which there is insufficient evidence.
The British Pain Society	Guideline	008	009-012	Section 1.3.7 – Manual therapy: As an adjunct to facilitating movement patterns via a short term, low risk, localised "tissue effect" there can be value, often to simply demonstrate the integrity of underperforming / problematic tissues and that range of movement can be obtained and functionally utilised. It does not have a place as an isolated, repeat treatment in the longer term for persistent pain. It is recognised that patient expectation can traditionally be for "hands-on" therapeutic care, particularly since the Physiotherapy profession was created from Medical Masseurs. It also offers direct contact which by its very nature is a sign of care and compassion. This can foster a level of care dependency and challenge care sustainability. Significant uncertainty surrounds the benefits of manual therapy and its physiological direct tissue effect or its	Thank you for your comment. The committee agreed the evidence reviewed within this guideline was insufficient to recommend for manual therapies for chronic primary pain at present. They recommend further research is required to inform future updates of the guideline. The evidence base was considerably smaller than for acupuncture and more inconsistent in terms of the effects demonstrated.

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				wider biopsychosocial impact. Therefore, as a time limited, targeted package of care (in the same way Acupuncture is supported in this document), we believe that manual therapy has its place for some patients.	
The British Pain Society	Guideline	008	009-012	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Manual therapy for CPP: "another element of a biopsychosocial management plan where the team work as a team individualising care to the patient"	Thank you for your comment. This review was for the effectiveness of manual therapies for chronic primary pain as a standalone intervention.
The British Pain Society	Guideline	008	014	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.8: BPS patient survey respondents wrote quite generally about using medicines for pain management although a small number discussed specifically antidepressant medications. All patient comments about antidepressants were associated with limited or no pain relief, burdensome side effects.	Thank you for your comment. The committee agreed that there was no evidence that the majority these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain

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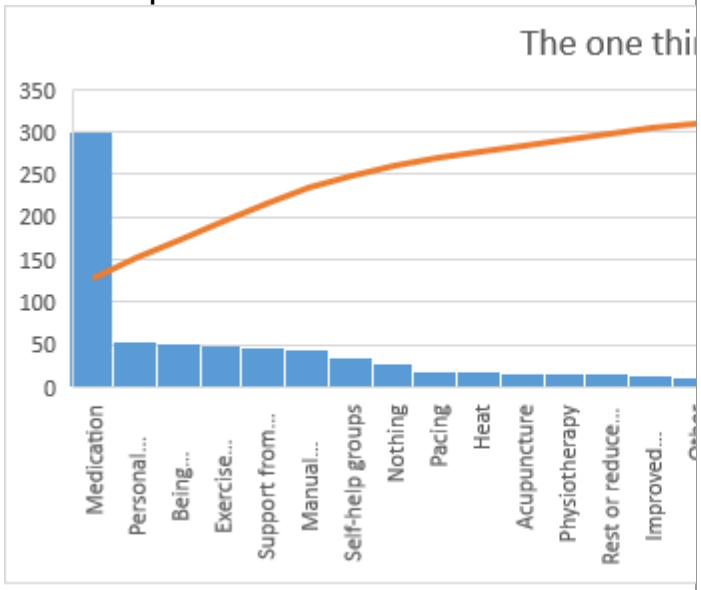
				Please note that of all the interventions for chronic pain, 'Medication' was rated as the 'one thing that helps the most'. And within 'medication' category, 'Opioids' were the group that helps most. **Graphic representation of Patient free text comments 'on what helps':**  	and better outcomes for people with chronic primary pain. Antidepressants were the only medicine that the committee agreed the evidence suggested benefit. Benefits were observed for quality of life, pain, sleep and psychological distress. It is highlighted that this review and recommendation is for chronic primary pain only. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will

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					also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: The BPS applauds the recommendation that any medication cessation should be a shared decision with the patient. However, we would have expected there to be more guidance about how this should be initiated, and what parameters would lead a HCP to enter this discussion. BPS understands that NCIE will produce a separate guideline about medication withdrawal next year; perhaps it is premature in that case to stress the need to withdraw pain medication without giving the opposite arguments for continuing them, under close observation. BPS is also mindful of the situation that arose in the USA in the past few years, where as a result of the 'opioid epidemic' (a situation largely unique to USA with its much freer access to opioids), the CDC imposed a draconian measure to withhold and withdraw opioids medications across the board, often without any consultation with the patients. This led to a surge of patients who were well managed safely with opioids for pain being summarily denied them, and some of whom sought illegal sources or tragically attempted/committed suicide.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations and research recommendations on this topic cannot

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				Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49.	be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: We would advise that at the time of individual assessment medicine efficacy should be part of the overall review and cessation of non-beneficial medicines occur. All medication which is commenced by a clinician must be reviewed regularly by that clinician and cessated if significant side effects or lack of effect.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged

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					and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The guideline also cross refers to the NICE guidelines on Medicines Optimisation and Medicines Adherence for recommendations on medicines review.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: There is a known cohort of patients with CPP who respond to one or more of the medications not recommended, allowing them to lead a full and relatively normal lifestyle. There needs to be a statement with regards ongoing management of these patients as they have often failed other treatments recommended when previous attempts have been made to reconcile medication use.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a

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					shared plan to continue safely can be agreed.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: There is a culture of withdrawing services before replacement services/alternatives are set up. There needs to be a proper structure for deprescribing and support groups lead by trained professionals to support people over the longer-term before we cut medications abruptly. Has this support structure requirement been cost analysed and funding identified to provide this very necessary support?	Thank you for your comment. The committee agree that medicines should not be stopped abruptly. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights

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					that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline. The cost of implementing the recommendations is considered in the resource impact assessment produced by NICE alongside the guideline.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: This section will cause a lot of distress to people living with pain – there may not be any clear evidence available BUT medication can make the difference between a just bearable existence and one that becomes completely unbearable. The document is very abrupt and the committee needs to identify an awareness of the distress this will cause and identify the actions it recommends with regards support, costings and delivery of these medication changes.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration and that medicines should not be stopped abruptly. The recommendation on stopping treatment has been reworded to include considerations for both people

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					who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee agree there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: Whilst there is a more intensive consideration of individual medicine management within these documents the BPS thinks it is important there is a statement from the committee within this document on the ongoing management of those patients currently being managed well with medicines. In this group we would suggest trials of medications listed in the guidelines, but make it clear that there needs to be	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration and that medicines should not be stopped abruptly. The recommendation on stopping treatment has been reworded to

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				a) evidence of improvement both in pain and function with the use of the medication that outweighs side effects b) regular review to ensure that the medication trialled remains effective	include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: NICE have previously quoted a figure of £30,000 per QALY. A one point improvement on a numeric pain scale (0 to 10) is approximately 0.1 QALY, so for cost effectiveness, a medication/treatment can cost up to £6000 per year and only need to improve pain by 2 points. None of the medications listed are as expensive as this.	Thank you for your comment. The committee agreed that there was no evidence that the majority of these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. Given this, the evidence was not considered to support a likely increase in QALYs. The committee agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: Mirtazapine should be included in the antidepressant list. It is an alfa 2 presynaptic blocker which increases noradrenaline and serotonin with hardly	Thank you for your comment. Only 1 relevant trial (reported in 2 studies)

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				anticholinergic side effects. Highly tolerated at 15 mg in the elderly people also stimulating appetite. It also helps with sleep problems associated with pain while other treatments are in place. Clinically, it appears to be a good drug to use above Amitriptyline in younger people too.	was identified that was relevant to the evidence review. Although indicated potential benefit for quality of life and pain relief, the evidence was of a very small sample size (n=40) and very low quality and therefore was not considered sufficient to be recommended.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: Local anaesthetic plasters are useful in painful scars with neuropathic pain and localised areas of chronic neuropathic pain such as herpes zoster, post-surgical, post radiotherapy, CRPS. The lack of trials does not mean it does not work. A reduced continuous treatment of several weeks in the initial period of chronic pain can be useful but not as long term maintenance.	Thank you for your comment. This evidence review and recommendations are for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline (including neuropathic pain) was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is

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					also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. CRPS is included within the chronic primary pain population. The committee recommend that further research is required for local anaesthetics for CRPS as their consensus opinion was that there may be benefit in this population.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: Pregabalin/gabapentin should be allowed in radicular neuropathic pain flare ups within chronic pain. Current evidence would support treatment for a few weeks and then discontinue.	Thank you for your comment. This section of the guideline is for people with chronic primary pain only. Other secondary pain causes are covered by other NICE guidelines for example CG173 for pharmacological management of neuropathic pain and NG59 for low back pain and sciatica.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: Did the committee consider recommending that nabilone should be tried in CPP patients? It is noted there is at least one RCT suggesting benefit.	Thank you for your comment. During the development of this guideline the NICE guideline for cannabis based medicinal products was commissioned

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				• Skrabek RQ, Galimova L, Ethans K, Perry D. Nabilone for the treatment of pain in fibromyalgia. *J Pain*. 2008; 9(2):164-173. doi:10.1016/j.jpain.2007.09.002 BPS notes that NICE has referred to their existing guideline on cannabinoids. We believe that, unlike the situation with other classes of prescribed drugs being not recommended and therefore possibly withdrawn, there could possibly be swing towards seeking to obtain cannabis based medicines or plant cannabis. This would be a very unfortunate and potentially harmful unintended consequence of the draft guidance.	and published. This guideline covers the use of these for a range of conditions and therefore it was agreed appropriate to cross refer to this for all guidance and considerations for cannabis based medicinal products. The rationale included in the guideline explains that the committee agree further research is required for cannabis based medicinal products for chronic primary pain. The research recommendation for this is already covered in the NICE guideline on cannabis-based medicinal products and therefore is not duplicated here. The NICE pathway will directly link to this guideline so ensure recommendations are joined up.
The British Pain Society	Guideline	008-010	014-010	Section 1.3.8-1.3.14: No direct reference is made to injections either with LA or with LA/steroid combinations. There is only the reference in the general drugs section that these are not recommended 'by any route'. The committee need to be specific. Are they clearly saying no TPIs? 5 hours of acupuncture will be more expensive than 20 minutes of TP injection 3 times	Thank you for your comment. No evidence was identified for injections of local anaesthetics alone or combination with corticosteroids. This was detailed in the evidence review J but the route of administration and

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				per year, even if injection is carried out by a clinician above the band specified for Acupuncture delivery.	evidence has been clarified in the recommendations and rationale.
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "Whilst there is ongoing focus on medication, particularly opioids there is still a potential role for carefully managed medication use. As indicate in the guidelines, chronic pain is complex and it is very difficult to measure these different facets in isolation from one another. Prescribed medication would seldom be the only thing a patient receives from our service."	Thank you for your comment. Thank you for your comment. The committee agreed that there was no evidence that the majority these medicines were of benefit for the management of chronic primary pain, and there is evidence of harm. They agreed that directing towards treatments where there is evidence of benefit would result in better management of chronic primary pain and better outcomes for people with chronic primary pain.
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "I feel people need a well-rounded tool kit before you look at deprescribing medication and often medication	Thank you for your comment. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based

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				allows someone to put strategies into place when they are really struggling"	on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits.
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines*** Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "Although I spend most of my prescribing time, deprescribing, some people obtain benefit from pain medication. For some this may be a short term solution that allows them to manage a flare-up, engage in non-pharmacological self-management and so on"	Thank you for your comment. The committee do not agree that there is evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new

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					symptoms and any factors contributing to the flare-up (for example, stressful life events).
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "Chronic pain requires an individualised approach to each individual patient and medication can sometimes help sometimes harm. We are able in our clinic to support safe exploration of options and seek at all times to use as little medication as possible. Patients who have a medication strategy for flare up tend not to 999 or seek OOH or ED support."	Thank you for your comment. The committee do not agree that there is evidence that the interventions recommended against for chronic primary pain, are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigate new symptoms and any factors contributing to the flare-up (for example, stressful life events).
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.***	Thank you for your comment. The committee were aware of the relevant Cochrane reviews and their

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				Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "The use of several antiepileptic and anticonvulsant medications is supported by good evidence: Cochrane reviews etc. The current NICE guidance appears to 'cherry pick' the included studies in its analysis, discounting most of the included studies in the aforementioned Cochrane reviews. It is not clear why these studies have been discounted after achieving inclusion in what many would see as the 'gold standard' in this field."	conclusions. They were fully considered when undertaking this review and all of their included studies were checked for relevance for inclusion in this guideline review. A key difference was the inclusion of studies with an enriched enrolment design / placebo run in phase. When setting the review protocol for the pharmacological review included in this NICE guideline the committee agreed these should be excluded, the reasons are set out below. Placebo run in studies: While this can be a useful methodology employed in a proof of concept study, it does not provide a generalizable estimate of the efficacy of the medicine in the general population. There are two main concerns: 1, such trial designs will likely increase the observed magnitude of effect of the medicine compared to the placebo

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					group as placebo responders are removed. Whilst the placebo response in pain is known to be high, this is reflective of how the general population are likely to respond, and so excluding these gives a biased estimate of effectiveness gained from these trails compared to those without a placebo run in phase. 2 – the side effect profile of many of these medicines (including pregabalin) are notable. Having a placebo run in phase can effectively unblind study participants as they are able to notice the difference between tablets received. This again biases the results of the study, generally in favour of the active intervention when in a clinical trial setting. Enriched enrolment design: The committee considered that including enriched enrolment design studies would not provide the committee with an overview of the effect of pharmacological interventions for people with chronic

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					primary pain and would not support their decision making for this population as a whole. By including studies that only recruit known responders there are difficulties with interpreting the data for a patient population, particularly for people that have not been prescribed the drug of interest previously. By the nature of these studies people that don't respond (but are diagnosed with chronic primary pain) are not included. The effect of this is to likely increase the observed magnitude of effect of the medicine in a population when it is known not to be effective for some people. It does not provide a generalizable estimate of the efficacy of the medicine in the general population. In addition, the concerns re the side effect profile stated above (in our discussion about placebo run in studies) also apply here. The committee are aware this has resulted in the exclusion of some studies of pregabalin in people with

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					fibromyalgia. For the reasons stated above, they believe this is appropriate when making evidence based medicine for a population with chronic primary pain.
The British Pain Society	Guideline	008-010	014-010	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Pharmacological Management of CPP: "The review is limited and this is partly because the literature included as reference but also because the aim of NICE guidelines is not necessarily in line with what is available to patients or best practice. Most detrimentally, it would seem contradict current treatment regimens which have been working for a large pain population who are not only vulnerable but have difficulties finding effective treatment as it is. The draft guidance presented in the media has already influenced public opinion in regards to pharmaceutical treatments (the fear mongering in relation to addiction is only damaging for the millions that safely use some sort of medication) and worse yet could go on to influence purse-holders who determine funding for various treatments.	Thank you for your comment. It is important to highlight that the pharmacological review and recommendations (and those for all specific interventions in the guideline) were for chronic primary pain only, not all types of chronic pain. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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				The area of pain coaching that I sometimes work in has suicide as a consequence of poor pain management. The fear I have heard expressed by the pain patients who live with pharmacological treatment as part of the management is terrifying. As a chronic pain patient myself as well as being a pain professional, I am disappointed with the draft guidance. As someone who conducts systematic literature reviews for a living, I can see how they came to their conclusions but also the weaknesses in the work due most likely due to lack of clarity around the existing situation of pain management. It is complex and the reviewers need to go back and do better."	included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. This improved clarity is intended to help readers and users of the guideline, including the media, to help ensure it is appropriately interpreted.
The British Pain Society	Guideline	009	0012	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines*** Section 1.3.11: The BPS patient survey respondents gave a clear indication that they were extremely worried that this guidance would lead to the removal from them of opioid drugs that they perceived were helping them manage their pain and have a tolerable quality of life. "*I do not take anything which doesn't make a difference to*	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving benefit and

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				my pain and ability to live with it. I work regularly with my Dr to analyse my medications and reduce to the low level possible to balance quality of life with side effects and potential future harm. I do not take enough to remove my pain, just enough to not make every day unbearable. Removing my pain medications would mean life would be unbearable - I have tried reducing below my current regime and cannot do anything at all other than lie in bed, squirming in agony." "*Terrified my meds will be taken away. They've all that's given me any quality of life back".* *"I have tried EVERYTHING before the painkiller I am on. Nothing helped.* *I couldnt move from bed due to pain.* *With the painkillers I can get up, I can move, I don't want to be dead like I did before as it was so bad.* *if they take the painkiller away I will have to suffer again. They can't do that! That would be prescribing me death!"* Many provided comments that withdrawal of these drugs and making them inaccessible might lead a patient to resort to buying drugs online or on the street where this is no support or monitoring. "*My friends with the same condition have had their pain killers removed and are now turning to buying them online.*	low harms it is recommended that a shared plan to continue safely can be agreed. The committee were mindful of the need to support people who have been receiving these medicines for a long time. They also highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible, if a shared decision has been made to do so. The committee agree that shared decision making and a collaborative supportive relationship between the healthcare professional and person with chronic primary pain is an essential part of good pain management. They highlight in the recommendations in section 1.1 the importance of not invalidating the

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				My friends aren't addicts but just in agonising pain, one bas uncontrolled seizures when her Pain isn't controlled. Before she had a set amount from the GP but now she could buy any dose (she is sticking to what she used to be prescribed). I don't want to have to do this but can't live with that level of pain." The survey respondents had also experienced stigma associated with taking opioid drugs. "*There is often a misconception that all long term opioid users are addicts. While we may be addicted to the medication we are not addicts because we do not take it to get 'high'. Without it I would not be able to do the little I currently manage and would probably be bed riden. Although an addict would suffer from withdrawal they would still be able to go about the days as normal.... BIG DIFFERENCE. Please don't tar us all with the same brush....."* "*The stigma of needing stronger pain relief than over the counter is prevalent*"	person's experience of pain and taking their individual experience and goals and preferences. The recommendations are not intended to attach stigma to the use of medicine where required, nor to assume everyone who uses opioids long term are addicts. The guideline reflects evidence for best practice, but should be implemented in shared discussions with the person with pain to support them to manage their pain in the most safe and effective way.
The British Pain Society	Guideline	009	008	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.***	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include

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				Section 1.3.10: BPS patient survey respondents had had trouble in reducing and stopping several types of drugs including antidepressants. Those who had tried to come off these drugs felt that there was insufficient guidance to withdrawal and that the advice that was available encouraged too rapid reduction. "No antidepressant has ever had any pain relief effect on me, all that happens is a dependency on the antidepressant and the awful withdrawal when having to switch medication or stop it. " "The guidance should not be released until the guidance on safely withdrawing from drugs is in place. In my experience GPs have a very unrealistic understanding. I know slow regular reductions have worked for me. Saying things like 10% every 3 days is a recipe for disaster on things like amitryptiline, MST and Pregablin. "	considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to

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					support people to reduce or stop safely in the absence of this guideline. The evidence reviewed in this guideline did suggest that antidepressants can be beneficial for people with chronic primary pain. The recommendations on developing a shared care and support plan highlight this should be in collaboration with the person with pain and there should be a full discussion of benefits and harms of all treatment options. This should include taking into account options that have already been tried.
The British Pain Society	Guideline	009	013	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.11: Few BPS patient survey respondents commented about non-steroidal anti-inflammatory drugs specifically but those who did wanted to be able to make use of these drugs as part of their multi-modal management. *"I think the guidance against NSAIDs and paracetamol is*	Thank you for your comment. The committee do not agree that there is evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in

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				incredibly short-sighted - I acknowledge that they're not long term solutions but many chronic pain sufferers, including myself, simply could not function on a day to day basis if these medications were not available." "*I do not accept that people should not be given opioids, paracetamol, ibuprofen etc. to manage pain. What they should be encouraged to do is use them the way i have always done - taking them at times of greatest need, so as not to create dependence, and lessen heir impact. I have almost always paid for My own ibuprofen, by the way*".	the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up.
The British Pain Society	Guideline	009	015	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.11: BPS patient survey respondents reported negative experiences with anti-depressant and anti-convulsant medication. They reported disabling cognitive effects and difficulty coming off these drugs. Some felt that these drugs were much harder to withdraw from than opioids. "*I take Antripitline 20mg which is for pain management and migraine prevention, however taking the tablet as a antidepressant would have a lot of side effects, fatigue being*	Thank you for your comment. The committee agree that it is important the side effects, harms and potential for withdrawal symptoms are considered for these medicines. For the gabapentinoids the committee agree it is very important that the class C status and harms are highlighted. These are not recommended for people with chronic primary pain in the guideline, but the committee have included a recommendation for people that are already receiving these, including that

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				the main one. Antidepressants have so many side effects that taking them gives you more issues that when you started. " The survey respondents also experienced troubling side effects that they feel they were blamed for. *"Most off label drugs have horrendous side effects for do many people but they are not listened to, mainly because these conditions affect women. They also majority of the time cause weight gain, and not slight several stones in weight, which only makes chronic conditions worse. But again this is ignored, then the patient again mainly women are blamed that it is the weight which is making their conditions worse."* "*Drugs like pregablin given out with no warning of class c status or side effects such as weight gain. I have pcos, I gained 1 stone for each week I took these drugs and ended up much worse. When I brought it up the pain specialist started 'gas- lighting' me*"	there should be a discussion of the evidence and of benefits and harms and a shared decision on whether to continue. For the antidepressants, the committee agreed that it is important a decision to start taking these is based on a full discussion of the risks and benefits. They agree the side effect profile should be considered when deciding which to use. For all of these, the committee agree the problems associated with withdrawal need to be considered and discussed with the person with chronic primary pain and include a recommendation to state that.
The British Pain Society	Guideline	009	018	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.***	Thank you for your comment. The committee agreed there was no evidence of benefit of local anaesthetics for chronic primary pain, and therefore these should not be recommended. There was a

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				Section 1.3.11: One patient in the BPS patient survey talked about lidocaine patches and how their withdrawal has had a major impact on their life. "*Versatis patches really improved my daily life (by relieving my allodynia). I was able to kiss my husband again and do 'normal' activities like have coffee in the garden with a friend and stand at a bus stop. Unfortunately a few years ago they banned them. I now rarely socialise with others in person and can't be as active as I used to be, I stay indoors a lot more and miss out on going outside with my young children regularly. I have developed a vitamin D deficiency (in summer) and it has impacted my enjoyment of life and wellbeing. When I ask about it, I get told "the guidelines say that they don't help and x/y/z is what you should have*".	suggestion form expert consensus opinion that these may be beneficial in the management of CRPS, and therefore a research recommendation was included for their use in this population. The committee agree that a holistic assessment should be undertaken for all people with chronic pain, and a shared care and support plan should be developed, based on a discussion of priorities, abilities and goals, and what has worked well in the past. There should be a discussion of the benefits and harms of all treatments that have been demonstrated to be effective for the relevant type of pain.
The British Pain Society	Guideline	010	001	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.12: The BPS patient survey respondents do not all wish to continue with the medication. Many have found the medication to be unhelpful and are happy to	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who

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				not continue with it. There are also some who wish to continue and their comments suggest that they need to be supported to come to the conclusion that the benefits are gradually being outweighed by the risks. These discussions are difficult and probably need specialist support to help patients develop the necessary understanding of the issues. "*GPS won't increase my meds even though my pain has increased so I'm left with nowhere to go*"	are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee agree these discussions can be difficult, however it is important that healthcare professionals are supported in this, including in primary care. The recommendations included in this guideline and the upcoming guideline on safe prescribing and withdrawal management are intended to support and enable healthcare professionals in these decisions and discussions.
The British Pain Society	Guideline	010	003	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line***	Thank you for your comment. The committee agree that evidence

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				by line coding guided by the framework of the NICE guidelines. Section 1.3.13: The comments from BPS patient survey respondents demonstrate that decisions to withdraw medications are not being made in partnership but rather with a paternalistic attitude. The respondent's comments (some of which are included above) demonstrate how vulnerable this group of people are, and how they are left to cope without support following the withdrawal of treatments.	reviewed in the guideline on communication between people with chronic pain and healthcare professionals supported you concern that there are shortcomings in people's experience of consultations with healthcare professionals. The committee therefore agreed it was important that the recommendations on assessment and development of a shared care and support plan are central to this guideline. These recommendations reinforce the need for shared decisions. This is again reflected in the section on pharmacological management particularly in the recommendation for the review of people who are already receiving these medicines. This highlights considerations both for those who aren't receiving benefit and also those who are and report low harms again restating the importance of a shared decision.

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The British Pain Society	Guideline	010	008	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Section 1.3.14: The BPS patient survey respondents would like to trial cannabis and CBD products, or have found these helpful. "*People who do not live with chronic pain seem to make the rules - the NHS would rather make me a zombie on amatryptaline, Gabapentin and Lyrica rather than prescribe medical cannabis. I have to rely on dodgy street dealers because of this out dated system. I wish my pain on them*" One respondent was not sure about pain relief with cannabis-related products but felt that their function and quality of life had been improved. *"Sativex, and cannabis, needs to be decriminalised. People are on opioids that would fare much better on occasional cannabis use. I was treated like some sort of druggie thrill seeker by one nurse, but a chronic pain doctor took me seriously. I still couldn't tell you if it lessens my pain, or just makes me care less about the level of pain I'm in, but the end result is the same...I can sleep better, I'm not stressed or anxious, and stabbing pains reduce in intensity"*	Thank you for your comment. The committee agree that further research is required and cross refer to the NICE guideline on Cannabis based medicinal products (NG144) where this research recommendation is included.

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The British Pain Society	Guideline	010	010-013	3.13.13 Shared Decision Making people have the right to be involved in discussions and make informed decisions about their care. *"Any chronic pain sufferer will tell you that this just does not happen in the real world. They just get told their drugs are going to be stopped."*	Thank you for your comment. The committee agree that shared decision making is central to good management of chronic primary pain. The assessment recommendations and recommendations on developing a care and support plan now state this more clearly. The committee also agree that medicines should not be stopped without a shared discussion with the person. Recommendations in this guideline for people already taking these medicines have been reworded to clearly state that this should be reviewed as part of shared decision making. This recommendation includes considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms.
The British Pain Society	Guideline	014	010	*"The committee seems not to have taken account of the complexity of education and self-management for chronic pain. Getting people to adopt, and adhere to, self-management techniques (and the cognitive and behavioural*	Thank you for your comment. The committee agree people should be able to make informed decisions on

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				changes these require) is quite difficult enough without withdrawal of appropriate pain medications which can support the patient through these changes. "	which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits. They agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little

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					benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible.
The British Pain Society	Guideline	022	001-018	1.3.16 Electrical Physical Modalities TENS is a good example of a tool in a Flare-Up Plan. The big difference between it and the other modalities mentioned is that it is an active strategy as part of self management whereas the others are passive techniques needing to be delivered by an HCP.	Thank you for your comment. The committee agree that there is no evidence that the interventions recommended against for chronic primary pain are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigation of new symptoms and any factors contributing to the flare-up.
The British Pain Society	Guideline	024	017-025	**Opioids for chronic primary pain** Generally we are supportive - See Opioids aware guidance and NICE KTT 21 - much of what is here is already contained within these documents.	Thank you for your comment. There are areas that may need support and investment, such as training costs, to

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				This will be a small group of patients – guidance is to withdraw carefully – what tools and resources (including workforce) will be made available for general practitioners to achieve this? What incentives will there be for PCN's to do this? Some areas have pharmacists - could a recommendation be made for PCN's to provide this level of support? It is unclear from the guidance when to refer for an expert opinion on this	implement some recommendations in the guideline. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible.
The British Pain Society	Guideline	025	010-025	**Anti-epileptics for chronic primary pain**: this is at odds with the Cochrane review on Fibromyalgia and doesn't match the patient experience in some instances. *"I have discovered that discontinuing the use of gabapentinoids has resulted in the reduction of my physical function, mobility and quality of life. "*	Thank you for your comment. The committee were aware of the relevant Cochrane reviews and their conclusions. They were fully considered when undertaking this review and all of their included studies were checked for relevance for

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				Again was Andrew Moore's work considered here?	inclusion in this guideline review. A key difference was the inclusion of studies with an enriched enrolment design / placebo run in phase. When setting the review protocol for the pharmacological review included in this NICE guideline the committee agreed these should be excluded, the reasons are set out below. Placebo run in studies: While this can be a useful methodology employed in a proof of concept study, it does not provide a generalizable estimate of the efficacy of the medicine in the general population. There are two main concerns: 1, such trial designs will likely increase the observed magnitude of effect of the medicine compared to the placebo group as placebo responders are removed. Whilst the placebo response in pain is known to be high, this is reflective of how the general

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					population are likely to respond, and so excluding these gives a biased estimate of effectiveness gained from these trails compared to those without a placebo run in phase. 2 – the side effect profile of many of these medicines (including pregabalin) are notable. Having a placebo run in phase can effectively unblind study participants as they are able to notice the difference between tablets received. This again biases the results of the study, generally in favour of the active intervention when in a clinical trial setting. Enriched enrolment design: The committee considered that including enriched enrolment design studies would not provide the committee with an overview of the effect of pharmacological interventions for people with chronic primary pain and would not support their decision making for this population as a whole. By including studies that only recruit known

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					responders there are difficulties with interpreting the data for a patient population, particularly for people that have not been prescribed the drug of interest previously. By the nature of these studies people that don't respond (but are diagnosed with chronic primary pain) are not included. The effect of this is to likely increase the observed magnitude of effect of the medicine in a population when it is known not to be effective for some people. It does not provide a generalizable estimate of the efficacy of the medicine in the general population. In addition, the concerns re the side effect profile stated above (in our discussion about placebo run in studies) also apply here.
The British Pain Society	Guideline	026	012-019	**Withdrawing medicines/How the recommendations might affect practice** There should be greater emphasis in the guidance on the harm that can occur The guidance needs a lot more on tools to support the clinician and patient in doing this	Thank you for your comment. The committee agree that people should be supported to withdraw from these medicines if a shared decision has been made to do so. The recommendation has been reworded

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				""*withdrawal of medicines should be reviewed exclusively on a case-to-case basis, with focus on the needs of the patient outweighing the cost effectiveness of the action. I feel that more research should be obtained before blindly concluding that withdrawing medication, such as anti-depressants, will 'have wider benefits both to an individual and to society by, for example, enabling people to return to the workforce'"*	to state that people should be encouraged and supported to stop or reduce where possible. The evidence for best withdrawal of these medicines has not been reviewed within the guideline. The committee agree it is appropriate to highlight the upcoming guideline on safe prescribing and withdrawal management whilst recommending here that people should be encouraged and supported to reduce or stop where possible.
The British Pain Society	Guideline	1.2.1	General	Pain Management Programmes (PMP): PMP is a multidisciplinary solution . PMP applies to all pains PMP's are based on specific psychological treatment to achieve behaviour change in the areas where chronic pain management is thought to be effective.eg most (85%) are based on these Cognitive Behaviour Therapy or /Acceptance and Commitment Therapy .The nature of a PMP is to learn effective self-management of pain, of which the implementation into daily life takes considerable time. Although it is not a 'quick fix' solution, it does provide the permanence of many significant long-term benefits and improvement. We wondered if the 8	Thank you for your comment. The review included 26 studies, as detailed in evidence review C. The 8 studies referred to in the rationale were the only ones that demonstrated a benefit in quality of life. The committee's opinion was that it was important and appropriate to review psychological therapies as a standalone intervention as well as

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				studies selected to represent the PMP were adequately reflective of the success of this long-term process. As 85% of PMPs that are delivered in the UK follow either a CBT or and ACT approach, and therefore would be considered as psychological therapy, that the studies considered in this section do not represent the clinical reality of the UK situation. This is potentially harmful for the provision of pain management programmes as the guidance might lead to these services being de-commissioned. This also reflects the definitional confusion in the document, which specifies in some detail what might comprise a pain management programme, but is satisfied with psychological therapies defining themselves by the labels the authors have chosen. Examination of some of these studies of psychological therapy suggest that they would meet the definition of a pain management programme. We are concerned that the definitions of what is a PMP and what is psychological therapy from the British Pain society should be used. We are also concerned that the guidance does not reflect the lived patient experience for example: *'there were no benefits observed in terms of physical function and psychological distress. Where benefits were observed, they were only small' to be greatly uncharacteristic of my own, and numerous other graduates experience*	when included as part of a pain management programme. This was in part because the two reviews were in different sections of the guideline scope; the pain management review covered all types of chronic pain, whereas the guideline was also covering specific pharmacological and non-pharmacological interventions for chronic primary pain only. It was agreed important to include psychological therapies within these interventions. The definition of pain management programme agreed by the committee for the review protocol was 'any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two'. This was deliberately not too specific to exclude too many studies, but the committee agreed there

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				We are concerned that this guidance also does not really shed light on how this will be applied to all chronic pain - a number of patients have come back to say they have found PMP very helpful as below: "*although the benefits of Pain Management Programmes on pain may be hard to quantify for cost-effective purposes and duration, it doesn't mean that they are not a) cost-effective in the long-term, b) sustainable, or c) the most effective treatment of Chronic Primary Pain available to date. "* .	needed to be a physical component as well as psychological. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of

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					life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may

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					be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline.
The British Pain Society	Guideline	1.3.1 /1,3. 2	General	Managing chronic primary pain : Patients agree exercise is helpful but often through working with someone who understand pain physiology (sensitised nervous system) and in the context of pacing - this is often applied thoughtlessly so context is important ….we would suggest that patients are given the tools to manage flare ups first and how they do exercise before contemplating exercise. A physiotherapist who has had training in delivering physiotherapy using psychological principles may be a good suggestion. There is some evidence to support this both from the Clinical and Patient perspectives	Thank you for your comment. The committee agree there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. They also agree that it is important that assessment and care and support plan development includes considering flare up of pain, and have now added a recommendation in section 1.1 to address this.
The British Pain Society	Guideline	1.3.3 . and 1.3.4	General	**Hypnosis, pain education and sleep hygiene for chronic primary pain:** What is meant by pain education ? Was the British Pain Society definition of Pain Education used? It is unclear. We feel that a primary care doctor is unlikely to know what is understood by this .	Thank you for your comment. The protocol included any study definition of pain education. The specific details of the interventions are given in the evidence tables and in the summary of included studies in evidence review F.

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				It is concerning that only one study is cited on mindfulness despite the wealth of evidence to supports its use in chronic pain. This is because the guideline group focussed on chronic primary pain, however this diagnosis is too early in its life cycle to consider grouping treatments into it. Sleep hygiene – whilst the one study included showed an effect the group threw the work out. This yet again demonstrates how psychological interventions can in no way ever match up to other trials. ""Pain education, incorporating aspects of sleep hygiene has been an invaluable tool of my successful pain management and has allowed me to self-manage my condition, without having to regularly visit my GP."	The committee have expanded on the discussion of this in the discussion of evidence in the evidence review for clarity. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. The conditions that were included under the ICD-11 classification of chronic primary pain at the time of guideline development were included within the review population, with the exception of those already covered by existing NICE guidelines. The searches and sifts of the evidence were therefore broad and inclusive of any studies that may fall under the umbrella term of chronic primary pain, rather than limiting to studies that used this specific term. The evidence for sleep hygiene was carefully considered by the group. This

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					was from 1 small study and although the committee noted it reported promising results it was insufficient to inform a recommendation for its use on the NHS. The committee agreed further research was required. Another study demonstrated that sleep hygiene was less effective than CBT for insomnia however. As a research recommendation was included for CBT for insomnia, the committee considered this would include elements of sleep hygiene and a separate research recommendation wasn't required. This is explained briefly in the rationale in the guideline, and in more detail in the committee's discussion of the evidence in chapter F.
The British Pain Society	Guideline	1.3.3 . and 1.3.4 .	General	**Psychological therapies relaxation therapy, mindfulness and psychotherapy**: This isn't something you dish out like a pill – it has to be placed in context of the pain Context is missing from the RCT's . CBT/ACT as applied and developed for chronic pain is missing	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in

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				Again this may be because the diagnosis is too new - there may be enough research out there for all chronic pain and this is what needs including. *", I feel it to be somewhat short-sighted to not recognise the connection between pain and distress, and consequently the benefit which relaxation therapy, mindfulness and psychotherapy provides."*	existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The searches and sifts of the literature for these questions were not restricted to the term 'chronic primary pain'. They were broad and inclusive to include all conditions that were included under the ICD-11 umbrella term of chronic primary pain at the time of development of the guideline. Full details of the search strategies are available in appendix B of each evidence review chapter. Psychological distress was included as a critical outcome for decision making in all reviews, as well as pain reduction amongst other outcomes (detailed in

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					the review protocols in each chapter). The committee's discussion of the evidence for both relaxation and mindfulness, including effects on psychological distress, are detailed in evidence review F. For both of these topics the committee agreed that the evidence was insufficient to inform a recommendation, but promising and so warranted research recommendations to inform future updates of the guideline.
The British Pain Society	Guideline	1.3.5	General	**Acupuncture** : Due to short lived benefits this needs to be conducted in the context of sensitised nervous system and biopsychosocial approach. It is unlikely that a junior physiotherapist would have this level of knowledge and skills and so it may not be cost effective in the real world. A short course only and restricted , in the context of many years lived with pain is not how acupuncture should be approached with this group. Separation is needed between cost effectiveness and effectiveness to explain decision making to the taxpayer.	Thank you for your comment. The guideline recommendations assume that all people delivering the interventions recommended should be appropriately trained to do so. This has been added to the recommendation for clarity. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the

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					recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
The British Pain Society	Guideline	1.3.7 -14		**Pharmacological management for chronic primary pain** There is a risk of throwing baby out with bathwater – as guidance can be applied thoughtlessly to all types of chronic pain rather than chronic primary pain It is unclear what search strategy was used. What did the search cover ? We have significant concerns that to thoughtlessly withdraw drugs could cause huge drops in function and distress .A large group RCT should be	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and

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				supplemented by n of 1 studies - as this reflects clinical practice Also it might be useful to review See Andrew Moore on only small numbers in each group actually benefit Moore A, Derry S, Eccleston C, Kalso E. Expect analgesic failure; pursue analgesic success. Bmj. 2013 May 3;346:f2690.Comments in drugs section are made as if mechanisms fully understood which is not the case *"Overall I would say that I am not a fan of using medication, following early attempts from primary care services (prior to my being accepted to the Glasgow Pain Management Programme) to manage my pain with opioids and various others, which I found to be detrimental to my overall health, pain and mobility. However I do recognise the benefits of medication when used moderately, carefully and in combination with other strategies and techniques. Medication alone will have some impact on pain, but not as much as the incorporation of other tools. "* The part of the guidelines which is of most concern to chronic pain sufferers is the assertion that chronic pain patients not be given analgesia to help them." *I think most people with chronic pain will agree that the side effects of drugs used are horrendous. My concern here is that removing drugs without adequate support during withdrawal is not that helpful. The report mentions that work needs to be done in developing this support. I think that should be in place before just stopping the drugs. My experience when I did*	added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The methods followed in the development of the guideline are consistent with those detailed in Developing NICE Guidelines: The Manual, and the Methods chapter for the guideline. The search strategies for each review question are detailed in appendix B of the relevant chapters. The protocols for each review (in appendix A) detail the study design that is appropriate to answer each review question. For intervention reviews, the best quality evidence

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				decide to reduce drug intake was that I got no advice on how to do it and what to expect from my GP. The pharmacist was my chief source of help. So some thought needs to be put into what is needed here." *"The only medication fully recommended by NICE are antidepressants. Yet they also come with serious side effects in the shape of "serotonin syndrome" and cognitive impairment."*	widely recognised in evidence based medicine is RCTs or high quality systematic reviews of RCTs. When setting the protocol for this review it was agreed that the best quality evidence should be used to inform recommendations on this topic. N of 1 trials, or case studies were agreed as not sufficient quality to include. The committee discussed that the limitations of such evidence include that they are not controlled and have no comparator, therefore are particularly at risk of being impacted by the high placebo response rate observed in pain studies and cannot inform on true effectiveness of an intervention. This evidence is therefore not generalisable to a wider population. The committee agree that mechanisms are not fully understood. They do however agree that the conditions that fall under the umbrella

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					term of chronic primary pain share similar features so there is no reason recommendations cannot be made across this group of painful conditions, unless evidence suggests otherwise. The committee agree that supporting people withdrawing from ineffective and/or harmful medicines can be difficult and further support may be required. They highlight the upcoming NICE guideline on safe prescribing and withdrawal management. The committee do not agree that it is appropriate to continue people on such medicines until there is further support. Healthcare professionals are already having to support people through stopping or reducing medicines, and should do so where it is known that risks outweigh the benefits. The committee agree that the side effects of antidepressants should be

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					considered when making a decision to use these medicines. The recommendation states that this decision should be made after a full discussion of the benefits and harms.
The British Pain Society	Guideline	4	002-017	Section 1.1: The BPS supports treating patients as individuals, as the section on Assessment helpfully makes clear. Having stated that, we cannot understand that after this the rest of the document treats all patients as a homogeneous group which contradicts this initial set of statements and undermines the value of the document as a whole. We are also surprised not to see a single reference to multidisciplinary or multiprofessional working in the assessment and communication of chronic pain conditions.	Thank you for your comment. The committee do not agree that the management recommendations treat everyone as a homogeneous group. They agree that management should take an individualised approach, which is specifically mentioned in some recommendations and detailed in the rationales. The committee agreed that the assessment recommendations apply to all healthcare professionals. They did not consider it necessary to specifically state the need for a multiprofessional assessment. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary

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					to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered
The British Pain Society	Guideline	Economic Report	General	It is noted that the committee did not include the paper by Hedman-Lagerlof, et al., (2018. Cost Effectiveness and Cost-Utility of Internet- delivered Exposure Therapy for Fibromyalgia: Results from a Randomized, Controlled Trial. The Journal of Pain) in their cost-effectiveness analysis, despite including it in their effectiveness analysis.	Thank you for your comment. This paper was selectively excluded after assessment of applicability and methodological limitations as it was judged to have very serious methodological limitations. It is listed in the excluded health economic studies table in Appendix I of Evidence report F.
The British Pain Society	Guideline	Economic report	General	It is noted the committee did not include the study by Luciano et al. (2013. Cost-Utility of a Psychoeducational Intervention in Fibromyalgia Patients Compared With Usual Care. Clinical Journal of Pain. 29: 702-711) in their cost-effectiveness analysis and is not seen in their list of excluded papers. We can see no reason why it was not included.	Thank you for your comment. This RCT was excluded from the clinical and economic review as the intervention did not meet the protocol due to being a combination of types of psychological therapy. It is listed in the

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					excluded clinical studies table in Appendix I, Chapter F.
The British Pain Society	Guideline	General	General	**Question 1: Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why?** 1. The British Pain Society believes that the conflation of 'chronic (secondary) pain' (CP) with 'chronic primary pain' (CPP) in one guidance document is unhelpful, unnecessary and predicted to cause widespread confusion and misinterpretation. First, the new ICD-11 coding is only now being introduced into healthcare education and it is highly unlikely that any healthcare professionals other than pain specialists will have even heard of it yet. It is still being evaluated and we believe it is premature to issue a guidance document on CPP at this stage (we will comment more on this below). Without the education and evaluation, we are very concerned that a document entitled *"Chronic pain in over 16s: assessment and management"*is bound to be applied to all forms of chronic pain – secondary and primary, by all but pain specialists who can understand the nuances. Second, whilst the Assessment section of the guidance helpfully refers to the need for adopting an individualised approach, in the Management section this is lost and everybody who has one of multiple	Thank you for your comment. 1. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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				types of CPP is treated as homogenous group with respect to interventions. Third, we are astounded that there is no recognition in the current draft that many patients – we believe actually form the majority – could have both chronic secondary and primary types of pain. The simplistic approach of the draft guidance betrays a lack of clinical insight into the reality of chronic pain to have missed this, and to offer no guidance on how to manage a new 'diagnosis' of CPP in a patient with existing CP, and vice versa. We will supply numerical and verbal data from our surveys of BPS professionals below to support this view. 2. Moreover, the British Pain Society is gravely concerned that the largest single impact of this Guideline, in its current draft, will be that commissioners could misinterpret the guidance to undertake mass withdrawal of all forms of pharmacological management of chronic primary pain, other than antidepressants. This would clearly be an understandable response by them to reduce spending on pain in community, secondary and tertiary care pain services. We appreciate that the guidance does not specifically recommend mass withdrawal but there is serious risk of this being implied by the combination of recommendation statement 1.3.11 "Do not offer any of the following,	clarifying what populations are covered by each recommendation. The committee agree that an individualised approach is required. The management recommendations should be considered for each person based on the person-centred assessment and according to people's priorities, goals and abilities when developing the care and support plan. The interventions all can be individualised and this is reflected in the recommendations and rationale (for example this is explicitly stated in the exercise recommendation). The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was

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				by any route, to people aged 16 years and over to manage chronic primary pain:", with recommendation 1.3.13 "If a shared decision is made to stop antidepressants, opioids, gabapentinoids or benzodiazepines, be aware of the problems associated with withdrawal." Nowhere does the guidance cover the reality of the hundreds of thousands of patients with ALL forms of chronic pain who are currently on the range of medications no longer recommended. The reference to the forthcoming "guideline on medicines associated with dependence orwithdrawal symptoms: safe prescribing and withdrawal management" does not help this situation at all, because it is not scheduled till much later in 2021, after the current draft will in practice. Moreover, we are concerned that recommendation (1.2.1) for further research about PMPs will also lead commissioners to use this as a rationale for withdrawal of funding for these services. The guidance should rather make it clear that further evidence is needed, but that PMPs could have benefits for specific conditions and patients and should be 'considered'for patients on an individual basis. Again, we will supply numerical and verbal data below to support these concerns. 3. We were pleased to read that the guidance is directed not only to healthcare professionals and	consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggested otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the

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				commissioner, but also to"People with chronic pain, their families and carers". However, we are disappointed by the lack of clarity in how CP and CPP are described, and without recognition that they may co-exist in many patients. We are concerned that many patients with 'purely' CP will believe that recommendations 1.3 onwards will apply to them. We have evidence from our survey of the public which we will share below, that this is one of their main reactions to the draft guidance. We would have expected that such a complex issue as chronic pain and the host of management strategies attached to it should have had a separate Patient and Public version issued to ease comprehension and allay anxieties.	recommendations (for example, separate research recommendations for pharmacological management of CRPS). The committee agree it is important to acknowledge that people can have both primary and secondary pain. Additional recommendations have been added to the assessment section to highlight when a diagnosis of chronic primary pain should be considered, and that chronic primary pain and chronic secondary pain can coexist. Furthermore the recommendations include highlighting that the initial diagnosis may change and should be re-evaluated, particularly if presentation changes. 2. The committee agree that the guideline should not be interpreted to mean all medicines should be withdrawn. The committee agree that the review of people already receiving

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					these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree

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					that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research. The rationale for this topic details that the committee did not make a recommendation for or against pain management programmes. There is also a cross reference in the guideline to other related guidelines for management of other types of chronic pain (other than chronic primary pain). 3. As stated above, the committee have added more explanatory text and headers and rearranged the guideline to aid clarity in which sections are for chronic pain and which for chronic

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					primary pain. This is intended to improve clarity for all users of the guideline, including people with chronic pain. The guideline webpage will also include a short document about the guideline with Information for patients.
The British Pain Society	Guideline	General	General	**Question 2: Would implementation of any of the draft recommendations have significant cost implications?** 1. As noted above the unintended consequences of these draft recommendations will lead to misunderstanding and confusion leading to inappropriate commissioning decisions which would predictably work in the direction of de-commissioning services such as PMPs and mass withdrawal of medications other than antidepressants. Whilst this would give a reduction in primary care drug and service costsfor chronic pain, we foresee that paradoxically there will be an increase in referrals to existing chronic pain services for patients who were previously managed within the primary care setting, as GPs will now have nothing but antidepressants, exercise and community CBT to offer within that environment. The guidance correctly recognises that CP arises in many long-term painful	Thank you for your comments. The committee agree that the guideline should not be interpreted to mean all medicines should be withdrawn. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged

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				conditions (Rec 1.2). Thus we believe the draft guidance is likely to increase referrals to secondary care clinics dealing in long-term conditions, and will add to the burden of service waiting times across many specialties such as rheumatology, orthopaedics and neurology. It will also result in people being sent for inappropriate expensive investigations by GPs and non-pain hospital specialists to exclude any of the multiple forms of CPP. 2. Similarly, we predict that if PMP services are no longer commissioned as a result of not having even a 'Consider' recommendation, any cost savings to commissioners will soon be offset in the same patients being referred back to their original specialties in the case of CP conditions; and increased referrals to the few and already overstretched exercise, psychological and acupuncture services which have been recommended. We also point out respectfully that ironically, all of these modalities are currently an integral part of any well-funded PMPs, which as we have pointed out, are threatened in the currently worded draft guidance.	and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to support people to reduce or stop safely in the absence of this guideline. The rationale for pain management programmes details that the

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					committee did not make a recommendation for or against pain management programmes. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for

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					any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.
The British Pain Society	Guideline	General	General	**Question 3: What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** 1. The BPS is a multiprofessional organisation with strong patient representation, which advocates the MDT approach to assessing, treating and supporting patients with all forms of acute and chronic pain. This philosophy underpins the work of all PMPs. We were saddened to see not one single reference to 'multiprofessional' or 'multidisciplinary' in the whole document. This would be unforgivable in a current document about specialties such as oncology, geriatrics or primary care; or about healthcare scenarios such as end of life care. Its exclusion in a document about chronic pain is inexplicable and	Thank you for your comment. 1. The guideline does not exclude multiprofessional working or a multidisciplinary approach. The evidence reviewed demonstrated effectiveness of interventions as standalone treatments, but that does not preclude multidisciplinary working or a joined up approach to healthcare. The committee agreed that the evidence for pain management programmes did not enable a recommendation to be made for or against their use. The guideline cross references to other NICE guidelines

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				would need to be rectified for the guidance to overcome the challenges it faces. This leads us to reassert that there needs to be a recommendation that existing multiprofessional PMPs should be 'considered' to continue. We also advise that there is further investment in community-based multidisciplinary primary care pain clinics. 2. It is clear to BPS that NICE has also overestimated the capacity for primary care and secondary care specialists such as geriatricians, neurologists etc to make accurate diagnoses of pain condition in compliance with the new ICD-11 coding. Thus we contend that there needs to be a recommendation for enhanced training in chronic pain assessment and management for all clinicians through education, training and practice, as well as for a new cohort of pain clinicians working in the primary care environment. This needs to include specific training in medication management for chronic pain including the management of reduction and withdrawal of medication, <u>if indicated,</u>following a shared decision process. There needs to be a multidisciplinary programme of training in managing chronic pain, going beyond medical professionals, including how to assess and manage specific and 'hard to diagnose' conditions such as CRPS and chronic pelvic pain. Services supporting long-term conditions must be	for recommendations for management of other types of chronic pain. 2. The committee agree that specialist assessment for diagnosis of chronic primary pain is not required for most people. Healthcare professionals in primary care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered. A recommendation has been added to the guideline for when to consider a diagnosis of chronic primary pain. There are areas that may need support and investment, such as training costs, to implement some

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				staffed with workers that hold a strong understanding of contemporary pain management principles, grounded in the biopsychosocial model. Maintaining a broad tool-box approach to care that is carefully applied after specialist assessment, delivered in a supportive environment to facilitate optimal self-management would be a strong model to follow. This of course should exist within an appropriately funded national system that understands the complexities of the persistent pain experience and its impact upon society. In the spirit of taking 'care closer to the patient', we were disappointed not to see any recommendation for improving the capacity and skills of primary care in assessing and managing patients with chronic forms of pain which would normally have been referred by GPs to pain clinics and PMPs.	recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
The British Pain Society	Guideline	General	General	**Question 4: The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.** No group-based therapy can take place currently, for example, PMP group therapy and research into it cannot take place at the moment during COVID-19 restrictions. It is impossible to know when group therapy will recur	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation

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				and there will be consequent increased costs due to delivering the proposed support modalities on an individual basis. Access to what was considered "routine care" is challenged and will remain so for the near future. Many services have limited capacity to deliver planned treatment interventions and are managing huge back-logs (as are most other services). IT infrastructure to support primary care clinicians to effectively support and manage patients remotely is under-resourced and not yet effectively embedded. Costs in creating, delivering and ingraining remote and digital care models are likely to increase substantially before potential savings may occur through more efficient ways of working. Thus we conclude that because of the likely continuing impact of COVID-19 for possibly years, now would be the worst time to implement such radical changes to chronic pain assessment and management in the UK as the draft guidance implies.	and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
The British Pain Society	Guideline	General	General	It was recognised within the initial comments, including from BPS, within the Scoping Consultation Feedback that the topic area is wide, diverse, complex, pan-speciality and age, and often conflicted. It is appreciated that this feedback was incorporated into the review process and the subsequent Draft Guideline production, however our concerns remain that the Draft Guideline as currently presented is open to confused interpretation with	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and

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				concerning unintended clinical application, with poorer outcomes rather than better as a consequence.	added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Pain Society	Guideline	General	General	BPS is concerned that whilst the draft guidance purports to cover assessment and management of ALL chronic pain (Section1.1 Title), it refers to multiple existing NICE guidelines for painful long-term conditions. However in many of these pain is not the primary focus of those guidelines and is thus not adequately covered. The new draft guidance then switches from referring to these very common forms of CP, to focus on CPP which is a single arm of a very new classification of pain (ICD-11). The guidance shows the misunderstanding that a patient's pain can be slotted into one sub-type of CP or CPP, totally missing the fact that in a large proportion of people living with 'chronic pain', they may have elements which cross multiple sub-classes. Specifically, the guidance ignores the possibility that patients may have	Thank you for your comment. In consideration of stakeholder comments the title of the guideline has been amended to clarify that chronic primary pain is also a focus of the guideline. It was agreed that for distinct types of chronic pain, management differs according to condition and therefore the management of these could not all be adequately addressed in one overarching guideline. While the topic specific guidelines in many cases cover

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				both a robustly diagnosed form of CP and CPP at the same time. ***The BPS patient survey quantitative data (n=584), co-designed with our Patient Voice Committee and conducted through our social media group, were analysed by Prof Sam H Ahmedzai and are quoted here and further below to exemplify our Comments regarding patient and public perception of the draft guidance.*** In response to Q9. What kind(s) of pain are you living with? (tick all that apply), there were 771 responses. Chronic secondary pain 31%; chronic primary pain 41%; Mixed 45%; Don't know 3%.	aspects other than pain management, it was still agreed that the management of these conditions was best covered in this separate guidance. However, it was considered that the approaches to assessment would apply to all types of chronic pain and are not addressed in the separate guidance. Chronic primary pain was agreed as a subgroup of chronic pain where the management strategies would align, aren't fully covered elsewhere in NICE guidance and therefore could be covered within this guideline. The committee agree that it is important to acknowledge that types of chronic pain can coexist. A recommendation has been added to highlight this and this is included in the definitions at the start of each section.
The British Pain Society	Guideline	General	General	All patients require individual assessment and management and therefore cannot be optimally managed by a broad-brush document which simply ignores those with a multiplicity of overlapping and co-existing	Thank you for your comment. The committee agree that a person centred, individualised approach is

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				conditions. This deficiency needs to be noted and it must be emphasised that all patients with persistent pain need to be individually assessed and reviewed by clinicians with expertise in pain management to allow appropriate management or triage into the multidisciplinary arms of pain management as per General Medical Council guidelines. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice	required. This is emphasised in the assessment recommendations. All of the management options can be considered in an individualised manner, with people being actively involved in a shared development of a care and support plan, but also in tailoring the interventions to the person, which is also highlighted in some recommendations for management.
The British Pain Society	Guideline	General	General	It is important that it is emphasised that those patients with CPP alongside further painful CP diagnoses are not treated at the level of the lowest common denominator of care. Chronic pain with an identified cause (e.g. significant osteoarthritis, spinal stenosis, degenerative disc disease, endometriosis and musculoskeletal pain such as shoulder capsulitis) may co-exist in the same patients as CPP. The current approach taken appears to move care towards a one-size-fits-all model which shrinks care options and inconsistently applies logic and evidence evaluation.	Thank you for your comment. A recommendation has been included to highlight that chronic primary pain and chronic secondary pain can coexist. The guideline cross refers to other relevant NICE guidelines for management of chronic secondary pain. In these cases clinical judgement should be used to determine appropriate management for the type of pain being treated, according to the relevant NICE guideline.
The British Pain Society	Guideline	General	General	The lack of existing double-blind randomised trials in 'chronic pain' as a whole, and CPP in particular is NOT equal to absence of therapeutic value. In all forms of	Thank you for your comment. The evidence reviews and subsequent

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				chronic pain, acceptance of consensus-guided good clinical practice could have been taken into consideration. The reasoning behind this, as noted again in the Scoping Consultation feedback, is due to the complex biopsychosocial system/ organic model that is 'chronic pain'. When considering this complex model it has to be appreciated that treatment effect may be modulated by a synergistic effect of multiple interventions; whereas when each individual treatment element is analysed alone they may fail to meet a predefined statistically significant level.	decision making on recommendations from these follow the processes set out in the methods chapter of this guideline and Developing NICE guidelines: The manual. Decision making is not based on statistical significance. Further details on the factors that are taken into account are detailed in the methods chapter for the guideline. Recommendations should be based on the best available evidence. Protocols are agreed for each review question detailing the appropriate study design required to answer the question. Expert committee opinion also informs the recommendation with their interpretation of the evidence. The committee consider the limitations of the evidence and its generalisability in their interpretation of the evidence alongside their experience as either healthcare professionals or lay members. This deliberation is detailed in their

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					discussion of the evidence in each review chapter.
The British Pain Society	Guideline	General	General	The highly selective and artificial nature of research and randomised control trials can only provide an approximation of routine practice and is not designed to reflect the heterogeneous nature of the patients involved and the complex inter-relationships that are taking place.	Thank you for your comment. The committee consider the limitations of the evidence and its generalisability in their interpretation of the evidence. This is detailed in their discussion of the evidence in each review chapter.
The British Pain Society	Guideline	General	General	There have been many individual concerns raised to us about the formatting of the guidance. Part of it applies to CP, generally, and the majority to CPP. This is a recipe for confusion. There is a strong possibility that patients, clinicians, managers and commissioners may not read or understand the classification detail and are likely to apply the guidance across multiple pain classes, rather than just the specific diagnostic class it was intended for. This may be particularly likely to happen within non-pain specialist services. The British Pain Society would strongly urge the division of the guidance into multiple separate guidelines, issued separately, with a more detailed and 'patient-friendly' way of describing the classification. In this context, we advocate the publication of parallel 'Patient and Public' versions as NICE has done elsewhere.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline,

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					and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Pain Society	Guideline	General	General	The ICD-11 system is designed for coding and monitoring of the prevalence of conditions. The authors of the official IASP publication announcing the new classification of chronic pain (Treede et al, 2015) wrote: *"This is a new phenomenologicaldefinition, created because the etiology is unknown for many forms of chronic pain."* (Our underlining). It is based more on phenotypic expressions of pain than biomarkers or genetics, as compared say with a histological classification of cancer. Therefore it cannot be used to describe a whole group of individuals expressing a set of pain parameters as if they were a biological homogeneous cohort. The original concept of creating the classification of CPP was to allow patients with these diverse pain expressions to be better served as they didn't fit into more classical pain diagnoses. This is in keeping with the holistic nature of the biopsychosocial model of pain. The classification of a CPP condition can only reflect the current understanding of its putative mechanisms. If a biological mechanism is presently ill-defined, that should not lead to the conclusion that the pain is 'psychological'.	Thank you for your comment. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggested otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was

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				This is reflected in the detailed sub-classification of CPP, as follows *[Treede et al, 2018, A classification of chronic pain for ICD-11]* 1. Chronic primary pain 1.1. Widespread chronic primary pain (including fibromyalgia syndrome) 1.2. Localized chronic primary pain (including nonspecific back pain, chronic pelvic pain) 1.x. Other chronic primary pain 1.z. Chronic primary pain not otherwise specified Thus even the main diagnosis of CPP is subdivided into 'widespread CPP' and 'localised CPP'. This is not mentioned in the draft guidance and would have been helpful to primary care and non-pain specialists to understand the new classification better. Second, the presence of 'Other' CPPs shows that even the ICD-11 committee was not totally confident about delineating how CPP differs or overlaps with secondary forms of CP. This is highlighted by the consideration of CRPS within the CPP group, in that there is recent evidence of several immunological mechanisms involved in its pathophysiology. This shows CPP is multifactorial and complex. Indeed, CRPS also appears in the ICD-11 as a form of neuropathic CP.	present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to

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				The BPS understands the weak nature of research evidence for all types of chronic pain (including chronic secondary pains and CPP), but this is due to the heterogeneous nature of patients with persistent pain and would highlight the guidance's initial statement that patients should be viewed on an individual basis and their treatment based upon that individual assessment, rather than being treated as a simplistic homogeneous entity.. Again citing Treede et al (2015): *"With the introduction of chronic primary pain as a new diagnostic entity, the classification recognizes conditions that affect a broad group of patientswith pain and would be neglected in etiologically defined categories."* (Our underlining).	where CRPS should be categorised, but it is their view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there is no reason not to consider this with other types of chronic primary pain.
The British Pain Society	Guideline	General	General	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines. The quotes included in this feedback are verbatim,but some have had minor corrections to obvious typographical errors for clarity but where ever possible quotes are not edited.*** Respondents were asked for comments with regards the classification used within the guideline and here is one response: *"The proposed ICD-11 classification of chronic primary pain is not yet well understood among pain specialists and is little known in primary care. Official implementation is not until January 2022 and field testing is ongoing. While laudable*	Thank you for your comment. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The committee are also aware there is current debate as to

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				that NICE have been mindful of emerging concepts, implementation will be tricky given the lack of practitioner and public awareness, let alone lack of understanding of severity codes (intensity / distress / disability codes). *NICE has skimmed across these. Where is the rigorous evidence to underpin whether or not a treatment has merit at the different levels of severity?* *How long will Primary Care and Specialist / Specialised Pain Services be given to test the guidance against the ICD-11 before CCGs reduce or remove funding for treatments that may have worth at one level, but not at another. Currently, we simply do not have a sound enough evidence base to make the decisions NICE has done using ICD-11."* To confirm this BPS member's comment, we quote the WHO which oversees ICD, which has a timeline for ICD-11 which states: "***January 2022.*** *Following endorsement, Member States will begin reporting health data using ICD-11.* (https://www.who.int/classifications/icd/revision/timeline/en/, last accessed 13.09.20). So far only one paper has been published, to our knowledge, covering the evaluation of the new ICD-11 chronic pain classification. *[Barke 2018 - Pilot field testing of the chronic pain classification for ICD-11 the results of ecological coding]*In this study, 5 independent pain centres in three continents	where CRPS should be categorised, but it is their view that it was appropriately categorised under chronic primary pain as although the mechanisms aren't fully understood, the similarities are such that there was no reason not to consider this with other types of chronic primary pain. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline.

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				coded 507 consecutive patients. The raters received the definitions for the main diagnostic categories of the proposed classification and were asked to allocate diagnostic categories to each patient. In addition, they were asked to indicate how useful they judged the diagnosis to be from 0 (not at all) to 3 (completely) and how confident they were in their category allocation. Results showed that "Of the 507 patients coded, 102 patients (20.1%) were classified as belonging to more than one category." This confirms the BPS view that the ICD-11 coding is not 'water-tight' and patients will indeed have multiple pain conditions. Barke et al quantified this as: *"36 (7.1%) were due to co-existence of two separate pain conditions"*. And further, *"In 33 (6.5%) cases, it appears that chronic primary pain was given as an additional comorbid diagnosis in order to express the presence of psychosocial factors influencing a diagnosis of secondary pain.*". Thus it would appear that even trained field researchers were adding a diagnosis of CPP, just because the patient had additional 'psychosocial factors' on top of a clear secondary pain. We would find it hard to find a patient with long established chronic secondary pain who did not have additional psychosocial factors in their lives, which leads us to fear that it would easy for untrained practitioners to label a patient as having CPP for no other good reason.	

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				Finally Barke et al found that the level of confidence in their trained field-testers in allocating an ICD-11 code was lowest for CPP for 'perceived utility', and equal lowest with 'chronic secondary visceral pain; for 'subjective confidence'. Thus, we assert that the move to adopting the ICD-11 coding prematurely could lead to some patients having the label of CPP erroneously given, leading potentially to withdrawal of several management strategies. In any case, this study confirms our view that patients in real life do have multiple types of pain and this is nowhere addressed in the draft guidance. It would appear therefore, that NICE is 'jumping the gun' in implementing a healthcare innovation before it has been thoroughly evaluated and researched, never mind officially launched by its own originating body. This would seem to cut across NICE's respected approach of basing guidelines on only evidence-based innovations.	
The British Pain Society	Guideline	General	General	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked for comments with regards the classification used within the guideline:	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of

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				"NICE conflates CP and CPP in many parts of the document. The concept of CPP is useful for an overarching approach to terminology as presented in ICD-11 but does not relate to the clinical reality of managing a breadth of disparate conditions which fall under this umbrella"	the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was

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					consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there was no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations

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					for pharmacological management of CRPS).
The British Pain Society	Guideline	General	General	Within the draft guidance the definition and scope of CPP needs further clarification. It is noted there is a separate guideline for the management of headache and yet further in this draft, chronic primary headache is stated to be covered by this document. This is very confusing, especially to non-pain specialist or in this case, neurologists treating specific forms of headache. The document needs to be more specific, and better formatted so that it is clear which individual diagnoses sit within which classification and the biological reasoning for that placement.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Pain Society	Guideline	General	General	It has already been seen by the general media response following the release of the draft guidelines that the lines between chronic pain and CPP have been blurred with reports on TV, Press, radio and social media, stating or	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled;

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				implying the CPP recommendations apply to Chronic pain, frightening already psychologically depleted individuals with the range of persistent pain. There needs to be clearer documentation of the lines between each section and a more appropriate communication strategy to ensure these lines are obvious to clinicians, commissioners and the general population alike.	definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. It is hoped this will improve clarity for all guideline users, including the media.
The British Pain Society	Guideline	General	General	It is noted there was no reference to education about pain mechanisms in the guidelines.	Thank you for your comment. Pain education was considered within the psychological therapies review. There is a brief discussion in the rationale for the recommendations and more detail in the discussion of evidence review F.

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The British Pain Society	Guideline	General	General	Our review of the Guideline Development Group BPS has raised concerns there may be conflicts of interest (COI) for individual members with respect to specific aspects of the guidance. We would ask NICE to ensure that there has been full disclosure of COI's and this has been fully assessed and evaluated by NICE.	Thank you for your comment. The NICE conflict of interests policy was followed throughout development of this guideline. All committee members abided by this policy and declarations were included on a register and reviewed in accordance with the policy. The declaration of interests register is publicly available with the guideline documents and states what action was taken for each declaration. The minutes of each meeting state where committee members withdrew from discussions.
The British Pain Society	Guideline	General	General	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines. The quotes included in this feedback are verbatim,but some have had minor corrections to obvious typographical errors for clarity but where ever possible quotes are not edited.*** The BPS patient survey identified that some respondents felt that the guidelines were treating all patient as a homogenous group and that the guidance was generic.	Thank you for your comment. The assessment section of the guideline covers all types of chronic pain, but the recommendations for specific management options are for chronic primary pain only. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. Further clarification has been provided in the headers of each section in the

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				"Each person with pain is different. You can't make one document to generalise treatment for chronic pain. This document is too general for the massive variety of chronic pain conditions" "*A one size fits all approach is short-sighted. Some people respond to different types of treatment"*. The feeling conveyed by the many comments about this was that of fear, anger and frustration. Having fought for many years with individual health practitioners to access assessment and treatment, the guidelines are perceived to threaten individualisation and range of treatment options (and as will be seen in later comments, removal of currently effective strategies). "*Taking away the option for certain pain management treatment is a dreadful thing to do. Pain management is that, management."* "*Don't take away any options as different things work for different people. Give as many tools as we can use"*. "*Only secondary pain sufferers can know what they need - their condition is hard enough without removing choice"*	guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with

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					subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). The committee agree that there should be an individualised approach and people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain.

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The British Pain Society	Guideline	General	General	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** The mood of the BPS patient survey respondents was angry, frightened, and frustrated. The respondents talked in heated language about the panel not understanding the situation they were in. Some pointed out how ironic this was given that parts of the document helpfully supported their rights to be respected partners in care and decision-making. ''*These NICE guidelines are like a kick in the teeth"* *"I think this guidance sums up the 'expert's approach', dismissive, uninterested and only looking at the bottom line"* *"The people making up these rules have clearly never suffered constant debilitating pain! They care only about money!"*	Thank you for your comment. The committee do agree it is important that people with chronic pain are respected partners in care and decision making. The guideline recommendations intend to highlight that. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain. The recommendations are made on the basis of the clinical effectiveness. Cost effectiveness is taken into account for all recommendations as is the resource impact to the NHS, but there has to be evidence of clinical effectiveness. There are no

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					treatments that have been recommended against in this guideline on the basis of cost alone. The committee includes two lay members with personal experience of chronic pain who are equal members of the committee and are actively involved in all stages of the guideline development alongside healthcare professional members and their views are an important consideration when making recommendations. Stakeholder views received during consultation are also all taken into account and recommendations have been revised in consideration of these comments.
The British Pain Society	Guideline	General	General	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** The BPS patient survey raised the idea that economic factors were driving the proposals. *"Pain management is very specific to the individual, and to*	Thank you for your comment. The recommendations were made by a committee of healthcare professionals and lay representatives after careful consideration of the evidence of effectiveness and cost effectiveness. Cost effectiveness analysis quantifies both costs and health effects of

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				my mind the current draft guidelines from NICE do not reflect this and appear to be very narrow and financially driven." Some felt that chronic lack of funding had led to poor service availability because chronic pain "*is not an illness that can kill you"*. The guidelines were perceived to increase the risk of further reduction in services because commissioners and GPs would use them to reduce services and restrict referrals. "*I understand there are financial implications in this but the grass roots are important for any condition be it chronic pain or otherwise. Also there should be more pain management clinics as the waiting list for these are immense and to my mind everyone is different but should be looked at according to their individual health issues not labelled as I said before."* *"I think there needs to be more support not less, stop taking away support that's needed just to save money"*, *"The authors of this policy are the ones who need psychological interventions, not the harassed patients trying to get on with their lives. And the GPs who will have to send patients away to misery when their pain could be perfectly well managed will suffer almost as badly."*	different courses of action and aims to maximise population health within the limited NHS budget. Interventions are recommended if there is good evidence they are effective and cost effective whether they will increase or decrease costs within the NHS. Interventions that were not recommended within the guideline generally did not have good evidence they benefited patients, and some were also associated with harms.
The British Pain Society	Guideline	General	General	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line***	Thank you for your comment. It is important to note that the reviews for

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				by line coding guided by the framework of the NICE guidelines. The BPS patient survey revealed that many respondents were distressed by the suggestion that some therapies and treatments might be restricted or stopped. There are further comments about specific aspects of the guidelines later in this feedback, but these reflect some more general feelings expressed by the respondents. "*The NICE guidelines are wrong and many will die because of them!"* "*I have online friends with chronic pain like mine. They have said they will commit suicide if their painkillers are removed as the pain was so bad. The NHS will kill those people plus many more"* "*To take away a treatment that helps people, to be put on waiting lists to see psychologists when you can't even get out of bed is devastating. People need treatment. You should never take that away from them. If you do, you end up with people being even more suicidal than they already are because of the pain. 10.5% of chronic pain patients committed suicide in 2014. That was an increase from 7.4% in 2003. The figure is most likely even higher in 2020. Taking away treatment from me and many who live with chronic pain will make this figure even higher. Our quality of life*	specific interventions included in this guideline, and related recommendations, are all for the chronic primary pain population only, rather than all types of pain. This includes the recommendations for pharmacological management. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more

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				needs to be considered. You put down an animal when they have a long term condition, due to quality of life. So why don't we help humans and give them as much treatment and resources as they need to have a life worth living."	easy navigation between the recommendations for different topics. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The assessment recommendations in the guideline include the importance of considering people's physical and

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					psychological wellbeing as well as recognising how distressing living with pain can be.
The British Pain Society	Guideline	General	General	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** One of the major themes emerging from the BPS patient survey was that of a sense of abandonment. Patients described varying degrees of effort to diagnose from zero to extensive testing and repeated efforts over many years before being told that there was nothing that could be offered. "*I have no care, I have no help, I'm left to rot, my GP isn't interested"* "*I've been told to "live with it"; feel I've been left alone / written off"* *"The doctors made sure it was nothing serious like cancer. Then they let me to live with the pain. My pain is 10 out of 10 on a scale"* "*The medical profession is appalling. They don't check you understand you or even want to try to understand. There is no support. No therapy or treatments. You are told to go*	Thank you for your comment. The committee agree that the evidence demonstrated there were shortcomings in people's experience of communications with healthcare professionals. They agreed it was important to include within the recommendations on the assessment of chronic pain the importance of a person centred assessment, knowing the person as an individual, and developing a shared understanding of how chronic pain affects their life and how aspects of their life may affect their chronic pain. The assessment section has been reworded in response to stakeholder feedback to strengthen these elements. The committee agree it is important that all people with chronic pain can discuss all available treatment options including their risks, benefits and

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				away and manage" A recurrent theme was that patients with co-morbid mental health issues were told that they could not be offered pain management *because*of a mental health condition. "*I've had none really. The local team refused my referral because I was being treated for a mental health condition. This made my NHS psychotherapist very angry.*"	evidence for them as part of developing a shared care and support plan. The committee hope that inclusion of these recommendations in the guideline will help address some of these issues.
The British Pain Society	Guideline	General	General	***The BPS patient survey free text comments (n=584), were analysed by Dr Amelia Swift in NViVO version 12 using line by line coding guided by the framework of the NICE guidelines.*** Pharmacological therapy was a dominant topic for the BPS patient survey respondents. Overall their comments expressed that pharmacological management had been a useful component of their pain management and many were very fearful that this might be withdrawn. Fewer commented that pharmacological therapy had not been helpful in pain management and many experienced intolerable side effects. "*Without pain medication I would struggle to hold down my job, look after my child, run my home and get up in the morning. Living with chronic pain is horrendous and I fear*	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are

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				somebody taking away the thing that can actually work in giving me some relief. How can I give my child a good quality of life if I don't have one? Being medicated is nobody's choice but if it works, why change it? It causes me more anxiety and stress worrying about doctors taking it all away and leaving me not able to cope as the pain gets so bad. How will I provide for my family? How will I manage my pain? I can't! It goes beyond physical pain and into mental anguish."	receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
The British Pain Society	Guideline	General	General	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards to General comments: "Pain therapy must always be multi-disciplinary I using a multitude of techniques that include drug therapy, psychology, Physiotherapy (Exercise), acupuncture, all of which should be combined together. No single treatment will work - there is no single magic bullet, but multi-disciplinary treatments combined in a sensible way."	Thank you for your comment. The evidence for this guideline demonstrated effectiveness of exercise, acupuncture and CBT or ACT as standalone interventions for chronic primary pain.

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The British Pain Society	Guideline	General	General	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards to General comments: "It brings us back to pre-Cartesian days, assuming that the brain and the body are separate, which they are not. A much broader and multi-disciplinary approach needs to be used and data from this combined approach needs to be sought, rather than single modalities."	Thank you for your comment. The committee agree that in the assessment of chronic pain a holistic approach is required. However the evidence for chronic primary pain demonstrated effectiveness of exercise, acupuncture and CBT or ACT as standalone interventions.
The British Pain Society	Guideline	General	General	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines. The quotes included in this feedback are verbatim,but some have had minor corrections to obvious typographical errors for clarity but where ever possible quotes are not edited.*** Respondents were asked about the recommendations with regards General comments: "The guidance is appropriate for the small subgroup with "pure" CPP. However, most patients have mixed aetiology with traumatic / degenerative / inflammatory components amplified by psychological / social factors resulting in limbic upregulation. It is very unclear how the	Thank you for your comment. A recommendation has been included to highlight that chronic primary pain and chronic secondary pain can coexist. The guideline cross refers to other relevant NICE guidelines for management of chronic secondary pain. In these cases clinical judgement should be used to determine appropriate management for the type of pain being treated, according to the relevant NICE guideline.

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				guidance applies in this situation and I am concerned that the guidance can be readily misinterpreted to decommission pain services"	
The British Pain Society	Guideline	General	General	We are deeply concerned by this guidance, by the use of a barely out of the blocks definition of chronic primary pain on which evidence has not been developed with its use as yet , the conflation of all types of chronic pain together with this new definition, the lukewarm support for pain management programmes, the lack of balance on pharmacological advice, the poor statement on acupuncture and the confusion with self management. In what is a difficult and complex area overall we feel there is too much reliance on papers and not enough interpretation by experts We feel this statement from one of our members sums it up : "*In effect the NICE guidelines just encourage advisors and some health professionals to say there is nothing they can do to help the sufferers and leave them on their own to get through their excruciating pitiful lives which often lead to suicidal thoughts and attempts. Surely the best thing to be done is to fully inform chronic pain sufferers of all the risks any medication comes with and let the patient decide what is best for them. The health professionals say they 'must do no harm' yet*	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added

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				by the current blanket policies they harm the patients more in allowing the intractable pain to take over the sufferers' lives causing them so much despair that suicide seems the only option of escape."	clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with

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					subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). Recommendations were made in accordance with Developing NICE guidelines: The manual as well as the methods chapter for this guideline. The committee agree they reflect best practice and recommend the treatments that demonstrate benefit for people with chronic primary pain.
The British Pain Society	Guideline	General	General	The Guidance is better separated into two documents - Chronic Pain and Chronic Primary pain. Otherwise commissioners and managers will conflate two which is too risky.	Thank you for your comment. The guidance needs to reflect the areas that were agreed to be covered as set out in the scope. The committee agree that it is important this guideline is

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				"*Without the strong and systematic underlying knowledge base, Chronic Pain: assessment and management as a document, will only serve to confuse and distress the medical community at large causing more, not fewer, problems than are presently plaguing people suffering with chronic pain, and those that care for them.*"	clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Pain Society	Guideline	General	General	"On the one hand NICE say analgesia isn't allowed – only self-management is, but there is no evidence it actually works. The 28 page guidelines just confirm the complete disarray and understanding of chronic pain conditions."	Thank you for your comment. The committee recommend those treatments for chronic primary pain where there is evidence of benefit; exercise, CBT or ACT, acupuncture or antidepressants for their effects on the symptoms of chronic primary pain.

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The British Pain Society	Guideline	General	General	COVID: " Overall I think the guidelines are very sensible and should improve matters. I am concerned with the lack of resources that are likely to be available and the document makes really passing reference to this saying as I read it that it will take more! If Chronic pain is as widespread as even the pooled mean then it is going to require A LOT. In the middle (or the beginning) of a pandemic which is increasing the size of waiting lists daily I fear the resources will not be there. Pain management NEEDS face to face contact I think to work most effectively (although I could be wrong). Now that most of the consultations we have are by telephone how will this affect effective treatment for pain? Perhaps NICE needs a wee appendix to tell us what it thinks?"	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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					that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The British Pain Society	Guideline	Page 1	Box	The introduction states "**This guideline covers** assessing and managing chronic pain…." BPS believes this is deceptive as there is no mention that the majority of the guidance refers to management of CPP rather than chronic pain as a whole.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now

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					placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Pain Society	Guideline	Page 1	Box	The guidance states that it is for 'people with chronic pain, their families and carers'. The BPS feels that the document, in its current form, provides no real guidance for patients and their families, and indeed is more likely to foster confusion and anxiety. There is disappointingly little in this guidance from a patient perspective. This is supported by a significant level concern in the patient conducted by BPS. In response to our BPS patient survey, Q 7. Did you understand the ways that NICE has explained the different types of chronic pain? There were 800 responses: 17% replied 'No, very little understood' and 'No, quite confused'.	Thank you for your comment. The guideline has been edited following stakeholder consultation to improve clarity. Further definitions have been included and a visual summary to clarify which recommendations apply to which populations. Patient members on the committee have been involved in the editing to get ensure their perspective is included.
The British Pain Society	Rationale	006	002-004	These patients are complex and consume a disproportionate amount of resources by accessing the healthcare system multiply over time. PMP may at least reduce that and offer a better quality of life. Experienced clinicians need to weigh the balance of how much is CPP, CP, or mixed and draw upon the services required for all	Thank you for your comment. The committee agreed that the evidence reviewed in the guideline did not enable a recommendation to be made for or against the use of pain management programmes. The committee agree that healthcare professionals need to consider if there

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					is an underlying cause for the pain, and also acknowledge that chronic primary pain and chronic secondary pain can coexist. Clinical judgement should be used to determine appropriate management according to the relevant NICE guideline in those cases.
The British Pain Society	Rationale	006	002-004	Section 1.2.1: These variations noted in the literature assessed lead the BPS to ask for consideration of a 'consider' statement whilst further research is funded and supported.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a

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					recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The rationale has been updated accordingly.
The British Pain Society	Rationale	007	002-006	Section 1.3.5: Regarding acupuncture, on review of the committee rationale there has been a significant application of research and financial indicators to provide a treatment the committee agrees would only deliver short term benefit. Is the committee advocating the consistent delivery of this 3 monthly for all patients with chronic primary pain? The cost implications of this would be extraordinary. If this is so, this would require the	Thank you for your comment. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the

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03/08/2020 – 14/08/2020

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				reassessment of all previous guidelines for the recurrent delivery of other treatments which have been declined due to only giving short term benefit in what is known to be a long term condition. If this is not what the committee is advocating can they explain the rationale for offering this treatment for short term effect and disallow other treatments within this guideline?	recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
The British Pain Society	Recommendation	011-013	004-003	Recommendations for Research: It is noted there are multiple recommendations for research priorities and the BPS welcome funding and support to allow further investigation into a multidimensional and complicated speciality.	Thank you for your comment. All NICE research recommendations are reviewed by the NIHR to consider for their funding streams. Other research funders also consider NICE research recommendations.
The British Pain Society	Recommendation	011-013	004-003	Recommendations for Research: There are concerns the nature of the widespread causation inherent on chronic pain occurrence needs to be accepted within research	Thank you for your comment. Where research recommendations have been

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				guidance and that research needs to be directed at specific sub-groups and not aimed at a broader classification which will inevitably return poor results. There is sufficient knowledge of the subgroups within CPP that they cannot all be considered to have the same pathological basis and this should be acknowledged by the committee and whilst this would cause widespread changes to the current document it would help the forward movement of how we treat our patient cohort appropriately in the future.	made this is because of a lack of evidence for all types of chronic primary pain, and therefore specific subgroups have not been specified to focus on within the research, although the templates provided do not preclude that as an option.
The British Pain Society	Recommendation	011-013	004-003	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Research: There is a great need for high quality research in these fields however as our experience of managing COVID 19 has proven these must be inclusive of all our population. We lack inclusion and consultation with the diverse communities that we treat. This is a rich seam for research and vital to make sure we are meeting the needs of all our patients. I think all the interventions they are trying to cut out need more research but perhaps accepting large (many thousand) case series as there is no possible way of getting RCT data. No 2 pain journeys are the same and no 2 people have the same desired outcomes"	Thank you for your comment. The committee agree that research should aim to be inclusive and representative of the whole population wherever possible.

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The British Pain Society	Recommendation	011-013	004-003	***The BPS Healthcare Professional members survey free text comments (n=151), were analysed guided by the framework of the NICE guidelines.*** Respondents were asked about the recommendations with regards Research: "Generally happy with these - the difficulty is in initiating / coordinating any useful research - will need a level of clinical / academic cooperation (and management support) that doesn't seem to exist at the moment. Could the BPS play a role in initiating and coordinating research programmes for the complex clinical interventions like PMP and mindfulness?"	Thank you for your comment. All NICE research recommendations are reviewed by the NIHR and help inform their future funding streams. Highlighting areas where research is required also helps inform other research funders of priority areas. Coordination of research programmes on these topics is welcomed.
The British Polio Fellowship	guideline	004	015	We welcome the recommendation to be sensitive to the risk of invalidation the persons experience of pain.	Thank you for your comment.
The British Polio Fellowship	guideline	004	002	We welcome the recommendations in this section, eg for knowing the patient as an individual, shared decision making. We are concerned however, that the government plans for long-term reductions in doctor/patient direct contact will make this ideal interaction impossible to deliver. We feel the use of e-doctor triage is an extra barrier to communication, particularly of complex issues, for older patients with long term painful conditions.	Thank you for your comment. The committee cannot comment on e-doctor triage as location/means of the assessment was not reviewed within the guideline. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions

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					relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
The British Polio Fellowship	guideline	006	011	We are concerned that exercise programmes may not be managed by sufficiently experienced professionals, for example if contracted out to non-NHS organisations. For those with prior polio, such programmes need to be supervised by a professional experienced in neuromuscular conditions; inappropriate exercise can cause damage to already vulnerable systems. We suggest that 1.3.1 should read 'offer an appropriately supervised...'	Thank you for your comment. This recommendation is for people with chronic primary pain only. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation

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					between the recommendations for different topics. All recommendations in the guideline assume that they are delivered by a person who is appropriately trained to do so.
The British Polio Fellowship	guideline	007	012	We are concerned that the limit on band level will mean inadequate experience of the acupuncturist	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for the same cost. This allows for local commissioning to structure services differently and aid implementation.
The British Polio Fellowship	guideline	007	013	The limit to 5 hours of treatment is wholly inadequate for those with very long term conditions spanning decades	Thank you for your comment. The recommendation has been reworded slightly following consideration of stakeholder comments to include specifying that alternative service configurations for delivering acupuncture can be considered, provided that it can be delivered for

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					the same cost. This allows for local commissioning to structure services differently and aid implementation.
The British Polio Fellowship	guideline	008	014	We are concerned that the first drugs recommended are antidepressants and that this will lead to even more over prescription of these in lieu of more appropriate treatments. Because of the many decades that polio survivors have lived with this disease and also because of the original advice to push themselves hard with no support, survivors can find it extremely hard and emotional to discuss their needs resulting in being offered antidepressants rather than a full multidisciplinary assessment/referral	Thank you for your comment. The guideline does not recommend a sequence of interventions. All of the treatment options should be considered when developing the care and support plan with the person with pain. This should consider both pharmacological and pharmacological options and a shared decision should be made on which to consider. This approach is detailed in the recommendations in section 1.1 of the guideline. These recommendations also highlight the importance of fostering a collaborative and supportive relationship, and taking into account people's experiences in the assessment to aid these discussions.
The British Polio Fellowship	guideline	008	002	We are concerned about the removal of these as an option for pain management	Thank you for your comment. It is important to note the reviews for specific interventions included in this

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					guideline, and related recommendations, are all for the chronic primary pain population only, rather than all types of chronic pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The committee also agree that the review of people with chronic primary pain already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people

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					who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
The British Polio Fellowship	guideline	023	016	Question 1: Where is the evidence that efficacy demonstrated for women with fibromylagia can be expanded to all other pain conditions?	Thank you for your comment. The evidence base varied across reviews. For some there was a predominance of females with fibromyalgia, and in some cases a large number with chronic neck pain, but evidence for other types of chronic primary pain was available. The committee have detailed in each relevant rationale and discussion of the evidence in the evidence reviews where they believe evidence can apply to all types of chronic primary pain, and why, or

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					where separate considerations are required.
The British Polio Fellowship	guideline	025	020	We welcome that gabapentinoids are recommended for neuropathic pain and is included in the NICE guideline CG173. We feel that this should be made clear in section 1.3.11 in order to avoid removal of this drug from polio survivors.	Thank you for your comment. The NICE pathway for this guideline will directly link to other related NICE guidance, including CG173 and a visual summary has been added clarifying what populations are covered by each recommendation.
The British Polio Fellowship	guideline	027	026	While we understand the possible benefits of reducing drug use where it is ineffective or risky, benefits to the individual will only be realised if some other treatment is actually available and accessible to help manage chronic pain. We are concerned that the removal of some of these therapies will cause stress as there is little capacity for psychological or other therapies.	The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.

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The British Polio Fellowship	guideline	009	010	We are very strongly concerned that the impact of this recommendation will be to remove the only pain relief available to many polio survivors living with neuromuscular pain on a daily basis and that this will cause enormous distress to our community. We offer to consult with our members about the potential impact of these recommendations as further input to the consultation process. Given COVID-19 and the reliance on using electronic communications with a largely elderly membership this would need several weeks.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, not chronic secondary pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.
The British Polio Fellowship	guideline	general	general	The British Polio Fellowship supports people who had polio and are living with its widespread neuromuscular impact. Most have been living with the condition since the 1950's UK epidemics, but increasingly there are	Thank you for your comment. The recommendations on assessment in this guideline are for all types of

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				younger people seeking help who contracted polio abroad and will have many decades ahead of them requiring help to manage the condition. There are no NICE guidelines covering management of prior polio or Post Polio Syndrome, so guidelines covering the individual symptoms are very important to this community. Many live with chronic pain because of the neuromuscular damage, skeletal deformity (scoliosis, kyphosis, different leg lengths) and long term injury due to overuse of less damaged muscle groups. The condition requires multidisciplinary care and a good treatment plan would include exercise supervised by an experienced neurophysiotherapist, psychological support, electrical and physical therapies and pharmacological pain management. Other care is required from services outside the remit of this guideline such as assistive aids and orthotics. We are concerned that this guideline recommends not offering many modalities, in particular not offering a long list of drugs, some of which are the only relief from pain available to many people living with prior polio and Post Polio Syndrome and could cause considerable pain and distress. We also are concerned about the timing of this guideline during the COVID-19 pandemic. Many of the people we support are shielding, and are finding it difficult to get any of their usual support from GPs and specialists, and the	chronic pain, but the reviews for specific interventions, and the related recommendations are all for the chronic primary pain population only, rather than all types of pain. Further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. We acknowledge that NICE guidelines do not cover all topics that may cause pain. Clinical judgement must be used in these cases. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions

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				impact of some of these recommendations will make a difficult situation even worse. We appreciate that the committee aims to reduce ineffective or potentially dangerous treatments and aims that treatments with more evidence of efficacy are used such as good exercise programmes or psychological therapies. We are concerned that there is presently little appropriate capacity in these areas and therefore are not available as an alternative treatment.	relating to COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in

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					other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The Ehlers-Danlos Support UK	Evidence Review Social Interventions	General		The term 'social prescribing' appears to have been used in the evidence review in place of the more common term 'peer support', therefore there does not seem to have been any review of the effectiveness of peer support, which is widely recognised to be valuable in supporting people to manage pain (e.g. Lorig K. and Holman H (1993). 'Arthritis self management studies: A twelve year review.' Health Ed Quart 20: 17–28; Warsi A, LaValley MP, Wang PS, Avorn J, Solomon DH (2003). 'Arthritis self management education programs: a meta-analysis of the effect on pain and disability.' Arthritis Rheum 48(8): 2207–13; Ersek M, Turner JA, McCurry SM, Gibbons L, Kraybill BM (2003). 'Efficacy of a self-management group intervention for elderly persons with chronic pain.' Clin J Pain 19(3): 156–67. This seems an omission from the evidence review.	Thank you for your comment. The protocol definition of social interventions was deliberately not restrictive, so that any intervention relevant could be included. Examples were provided in the protocol, including: Social interventions aimed at improving quality of life, for example: • Social prescribing • Cultural commissioning • Health training and coaching • Case management • Vocational rehabilitation • Befriending • Advocacy • Combinations of these. However these were noted not to be all inclusive. The search terms were also broad to ensure evidence on relevant programmes would be

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					identified (provided in Appendix B of the evidence report). Peer support would have been included where it met the above criteria (for example befriending) however peer led pain management programmes were considered in the pain management programme review, and pain education as a specific intervention was considered within the review of psychological therapies for chronic primary pain. The references you provide have been checked, however no additional studies were identified that would be relevant to the social interventions review. One study was identified that has now been added to pain management in the psychological therapies review however.
The Ehlers-Danlos Support UK	Guideline	005	018	We would like it to be acknowledged here that there are other conditions known to be associated with chronic pain but for which there are currently no NICE guidelines. For example, wording could be 'For guidance on specific conditions that cause pain, see..... Other conditions are	Thank you for your comment. This list is not intended to be inclusive of all causes of chronic pain and we acknowledge that NICE guidelines do

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				known to cause chronic pain but guidance does not currently exist for them. These include but are not limited to hypermobility-related conditions, connective tissue disorders….'	not cover all topics that may cause pain. Clinical judgement must be used in these cases.
The Ehlers-Danlos Support UK	Guideline	006	001	Pain management programmes are already extremely difficult for patients to access and we are concerned this guidance will make this worse. While the evidence of benefit may be inconsistent many individuals derive huge benefit from these programmes and we are concerned a further reduction in access will worsen the quality of life for the many patients who are already waiting for a programme. We would be pleased to provide case studies of patients with EDS who have gained benefit from pain management programmes.	Thank you for your comment. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of

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					life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may

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					be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline.
The Ehlers-Danlos Support UK	Guideline	006	011	This recommendation will be challenging in practice due to the number of people severely disabled by their pain-associated condition and who find travel impossible, unless it becomes the norm to offer these sessions virtually. It is noted that the programmes should be tailored to the preferences, needs and abilities of individuals but the scale of the need for adaptations to make sessions truly accessible to all who need them is likely to have been underestimated.	Thank you for your comment. The committee do agree that the programmes should be tailored to the needs of the person, evidence for virtual exercise programmes was not identified however. The recommendations for developing a care and support plan also include the importance of discussing the risks and benefits of all treatments with people with chronic primary pain when determining the most appropriate management plan according to their needs and preferences.
The Ehlers-Danlos Support UK	Guideline	006	015	This guidance assumes that all patients with chronic primary pain are given exercise advice to help manage their pain. We have over 13,000 members, the majority	Thank you for your comment. The guideline reflects the evidence for

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				of whom are patients with Ehlers-Danlos syndrome or symptomatic hypermobility, many of whom will have been diagnosed with chronic pain or chronic primary pain and regular and consistent feedback from them indicates this is rarely the case. What provision will be made for targeted exercise advice to be routinely available for all chronic pain patients, especially in primary care?	best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The Ehlers-Danlos Support UK	Guideline	009	010-024	We are concerned that this recommendation could leave patients with increased, unmanageable pain especially where access to non-pharmacological management options are severely limited or delayed. This could put pressure on other services such as A&E and mental health services. Short term pharmacological pain relief can be helpful to maintain quality of life during flare-ups of EDS and hypermobility-related problems alongside self-management practices and peer support.	Thank you for your comment. The committee do not agree that there is evidence that the interventions recommended against for chronic primary pain, are any more effective for short term use for a flare up of the same painful condition. The evidence reviewed included short and longer

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					term follow up and for these interventions benefit wasn't seen in the short term either. The committee did agree it is important to add recommendations for flare up of pain however and have now added a recommendation including considering investigate new symptoms and any factors contributing to the flare-up (for example, stressful life events).
The Ehlers-Danlos Support UK	Guideline	General	General	The guideline says it aims to reduce distress and improve quality of life but we are concerned it will actually negatively affect both. The Ehlers-Danlos syndromes (EDS) and other conditions which include symptomatic hypermobility are difficult to diagnose and many people with them are initially diagnosed with chronic primary pain in line with the ICD-11 definition. Until there are NICE guidelines for the diagnosis and management of symptomatic hypermobility and/or EDS, this will continue to be the case. We are about to commission a health needs assessment for people with hypermobile EDS and hypermobility spectrum disorder and would be pleased to share the outcomes. In the meantime, we believe some sections in the guidelines have the potential to worsen the quality of life of those living with chronic pain and/or chronic primary pain, e.g. those with EDS or related	Thank you for your comment. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert

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				conditions. The specific sections of concern are those on pain management programmes, electrical physical modalities, manual therapy and pharmacological management. The guidance is likely to lead to some of these approaches being withdrawn, possibly with no alternatives offered or none being available without a long wait. Especially where the underlying cause of pain is not recognised and therefore not appropriately treated (e.g. in pain related to hypermobility), approaches which could work for individuals despite inconsistent evidence will not be tried. We believe that the implementation of the guidelines as they stand are likely to put pressure on other services such as A&E and mental health services.	consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.

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The Ehlers-Danlos Support UK	Guideline	General	General	The guideline is confusing as written in terms of the recommendations for chronic primary pain versus those for all forms of chronic pain. Some of the communication from NICE itself seems to have used 'chronic pain' and 'chronic primary pain' interchangeably, leading to media coverage doing the same. This has added to the confusion.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The EMDR Association UK & Ireland	Evidence review F	456	J2.28	You state that 'Current evidence base: All studies in the guidelines review were in people with fibromyalgia but no other chronic primary pain conditions'. That this is the primary focus of the guidelines is not clear from the title of the Guidance. We speculate that this will not be clear to the Caring Professions and that there is the danger	Thank you for your comment. This statement relates to the evidence base in the guideline for CBT for insomnia, where the only available evidence was for people with

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				that the recommendations will be applied indiscriminately to all varieties of Chronic Pain. This, should it happen, could cause immense suffering. The use of the words 'primary chronic pain' throughout the document when you mean fibromyalgia, or similar, adds to the illusion that the Guidance applies to all Chronic Pain. We cannot support this as it stands.	fibromyalgia. The psychological therapies review (as for all specific interventions included in this guideline) is for the chronic primary pain population only, rather than all types of chronic pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title of the guideline has also been amended to clearly state that chronic primary pain is included as a focus of the guideline.
The EMDR Association UK & Ireland	Guidance	018	012	We note and support the finding that improving sleep can improve quality of life and reduce pain by whatever Psychotherapeutic modality is used. Recent research from EMDR practitioners has focussed on this and it promises to be an extremely fruitful line of research, to which we would be happy to contribute.	Thank you for your comment.

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The EMDR Association UK & Ireland	Guidance	019	007	The cost implications for implementing EMDR would be no more than for CBT or ACT and could be less.	Thank you for your comment. No evidence for EMDR for chronic primary pain was identified to include within the review, the committee agreed not to make a recommendation on this topic.
The EMDR Association UK & Ireland	Guidance	General	General	While EMDR (Eye Movement Desensitisation and Reprocessing) is mentioned as a potential intervention (Evidence base F, 1.3.33) No further mention is made or evidence discussed. We consider this 'absence of evidence' should not be taken to imply 'evidence of absence'. We have much to contribute.	Thank you for your comment. EMDR was included as an intervention of interest, and literature was searched for evidence of this in chronic primary pain, but none was identified. This is detailed in the discussion of the evidence section in evidence report F.
The EMDR Association UK & Ireland	Guidance	General	General	We acknowledge that we, as an organisation, became involved in the NICE consultation process for this Guidance too late to be able to provide suitable evidence. EMDR Is young but growing exponentially. There is now substantial Clinical as well as Research Experience to make it at very least a contender equivalent to CBT or ACT in practice, especially as the research evidence for them is weak. EMDR includes Mindfulness practice at the heart of the technique and can incorporate many other Eastern and Western approaches to pain. Dr Zeynep Zat has been awarded $25,000 by EMDRIA Research Awards to conduct research into Migraine and Fibromyalgia. We would request that a note be included in the Guidance that EMDR be included as a worthy candidate for further	Thank you for your comment. There was no evidence identified for EMDR, the committee therefore agreed not to include a research recommendation as it was unclear whether this would add value for this population.

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				research and would be happy to add our experience to the NICE shared learning database.	
The EMDR Association UK & Ireland	Guideline	013	013	We fully support the Guidelines emphasis on a 'comprehensive biopsychosocial approach to assessment and management'. We consider that the hypothesis that the extension of assessment to unresolved trauma in the history is well worth investigating, especially in the light of new successful Clinical results using EMDR to resolve such trauma and so reduce pain and its impact. EMDR's unique contribution is the ability to tackle and resolve the chaos and horror that underlies many health conditions but is blocked from awareness and so is not amenable to CBT or ACT.	Thank you for your comment. The committee agree this is important. Consideration of previous physical or emotional trauma has now been added to the recommendations.
The Good Thinking Society	Evidence review G	006	001 - 037	The Introduction to the Evidence Review discusses acupuncture in some detail but makes no reference to risk. Safety considerations must be paramount when making recommendations relating to treatment decisions. Even where clinical effectiveness has been established, treatment decisions should also take into account any associated risks of harm. As stated above, commonly reported adverse effects relating to acupuncture include dizziness, temporary loss of consciousness and needles being left in the patient. More serious but rarer events have also been observed, such as collapsed lung (pneumothorax). There is therefore no clinical or economic justification for the use of acupuncture to treat chronic primary pain or associated conditions.	Thank you for your comment. The committee discuss possible harms of acupuncture in their discussion of the evidence. This was detailed in 'other factors the committee took into account' but has now been moved to the 'benefits and harms' section of the evidence report for clarity. This was considered in their interpretation of the evidence. The introduction to the evidence review provides some background and

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				The Introduction describes concepts and beliefs associated with TCM: "*Therapists trained in traditional Chinese medicine operate under the assumption of optimising the flow of the vital energy "Qi" in the body*" "*In contrast protagonists of traditional Chinese medicine (TCM) choose distant points in their attempts to harmonise the perceived misbalance of body functions and emotions*." It should be clarified alongside these statements that the beliefs described are at odds with modern understanding of medical science and basic physiology. It would not be unreasonable for a member of the public to mistake the NHS providing a treatment based on the notion of "vital energy flow" with the NHS actively promoting the idea that the body has "vital energy" flowing through it, blockages in which cause disease. The NHS should not be party to spreading incorrect information on physiology. It should also be noted that TCM practitioners are generally unregulated (although many do use the title "Dr") and that where treatments are based on belief systems rather than on good clinical evidence, patients are likely to be misled and to be offered treatments for which there is no clinical justification. These risks should	discusses different approaches. The paragraph which acknowledges traditional Chinese medicine starts by acknowledging that there are wide variations in what people associate with the term acupuncture. It includes both TCM and western acupuncture as well as explaining what dry needling is. The committee agree that the mechanisms by which acupuncture produces effects are not understood, and may include the non-specific effects of the therapist, but they agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were

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				have been identified and considered before making recommendations regarding acupuncture. Even if NHS treatments would not necessarily follow TCM concepts, the use of acupuncture within the NHS for chronic primary pain would nevertheless lend legitimacy to acupuncture in general.	also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. These recommendations are for the NHS. The committee agree that the risks of how recommendations may be applied beyond the NHS should not be a reason to avoid recommending a treatment that has been demonstrated to be clinically and cost effective for chronic primary pain.
The Good Thinking Society	Evidence review G	043 044	031 - 045 001 - 005	The Evidence review states: "*The majority of the evidence identified was of low to very low quality, with only a small amount of moderate quality evidence. The evidence was mainly downgraded due to risk of bias and imprecision. Risk of bias was often high due to attrition and selection bias. In the usual care comparisons there was a lack of blinding in*	Thank you for your comment. We do not exclude low or very low quality evidence from the systematic review. When making recommendations, the committee consider the whole body of

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				the studies due to the nature of the intervention; this combined with the mostly subjective outcomes resulted in a high risk of performance bias. The committee took into account the low quality in their interpretation of the evidence, particularly when considering the small amount of evidence for comparisons of different types of acupuncture" Very low or low quality evidence should not be used as a basis on which to make clinical recommendations and should therefore have been excluded. Furthermore, moderate quality evidence should be interpreted critically and treated with caution. Although we note that risks of bias were identified and that the committee acknowledged the low quality of the evidence, we do not consider that the evidence was sufficiently robust to support the conclusions drawn by the committee.	evidence available considering the evidence quality alongside factors contributing to the rating, amount of evidence and magnitude of the effect. Taking all of these factors into account, we do believe there is sufficiently robust evidence to support this recommendation, which is also supported by evidence of health economic effectiveness.
The Good Thinking Society	Evidence review G	044 045	006 – 051 001 - 047	This section is headed "Benefits and harms". It includes substantial and detailed discussion of perceived benefits of acupuncture, but no discussion of the risks of harm. This is an extremely important oversight. There is no good evidence that acupuncture is of benefit to treat chronic primary pain or associated conditions. We do not agree that evidence reviewed by the committee was sufficiently robust to support their conclusions in relation to benefit. The only reference to harm within this section appears in lines 29-31 of page 45:	Thank you for your comment. The evidence review did not inform on the potential harms of acupuncture. The committee were aware of risks of harms however, and did discuss these in their interpretation of the evidence. This was detailed in 'other factors the committee took into account' but has

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				"*The committee considered the overall benefit of acupuncture, particularly for reducing pain and improving quality of life, in combination with the lack of harm, other than discontinuation from the therapy*" It is deeply worrying that the committee failed to recognise any of the risks associated with acupuncture. As stated above, commonly reported adverse effects include dizziness, temporary loss of consciousness and needles being left in the patient. More serious but rarer events have also been observed, such as collapsed lung (pneumothorax). There is therefore no justification for the use of acupuncture to treat chronic primary pain or associated conditions.	now been moved to the benefits and harms section for clarity. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.

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The Good Thinking Society	Evidence review G	045 - 048		The trials used for the economic analysis compared acupuncture in addition to usual care with usual care. There was no sham acupuncture control group. The trials therefore failed to account for non-specific effects. Furthermore, the confidence intervals for the UK trial were very large. We therefore do not consider the evidence reviewed sufficiently robust to conclude that the treatment is of benefit. The Evidence review states (page 46, lines 40-42): "*Overall, although both studies had outcomes favouring acupuncture, the committee noted that there still remained uncertainties about the cost effectiveness of acupuncture, as it is a limited evidence base and there are uncertainties around the cost of the intervention.*" There is no good evidence that acupuncture is of benefit for chronic primary pain, or associated conditions. We therefore do not consider that there is any clinical or economic justification for recommending the treatment.	Thank you for your comment. While sham evidence was considered important for assessing whether there are treatment-specific effects from acupuncture (and was included in the clinical evidence review), it was agreed that the data comparing acupuncture as an adjunct to usual care with usual care alone should be used in the economic evaluation as sham is not a real-world comparator. A detailed discussion of the rationale for this decision is included in Section 2.1.1.1 of the acupuncture modelling report. The text you quote relates to the two published economic studies included in the evidence review. New economic modelling was also undertaken and this was considered to reduce the uncertainty regarding the cost effectiveness of acupuncture. This is discussed in the following paragraph in this section.

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					The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.
The Good Thinking Society	Evidence review G	048	033 - 039	The committee noted that they could not assume repeated courses would have same effectiveness and therefore agreed that a research recommendation should	Thank you for your comment. The committee agreed that overall the

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				be drafted to determine the clinical and cost-effectiveness of repeat courses of acupuncture. We do not consider that there is good evidence that even a single course would be of benefit, and we are therefore not convinced that further research can be justified.	large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.
The Good Thinking Society	Evidence review G	048	040 - 046	The Evidence review states: "*The committee considered the potential harms related to the use of acupuncture. One of the most serious possible harms of acupuncture is organ puncture, although there were no reports of this within the evidence. The committee noted that guidance on*	Thank you for your comment. As detailed in response to your previous comments, the committee disagree. They consider that the evidence

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				acupuncture techniques should establish a depth of needle injection based on the target body area and other factors such as the physique or build of individuals with chronic pain. The committee also noted the importance of demonstrated competence of the person delivering acupuncture, and that single use sterile needles should be used to prevent infection". As there is no good evidence that acupuncture would be of benefit for chronic primary pain, no level of risk would be acceptable, and the treatment would therefore not be justified. Furthermore, before a decision can made to recommend a treatment, the risk of harm must be considered adequately. The committee were aware that there is a risk of organ puncture and infection, but do not appear to have referred to relevant studies of acupuncture risks, which indicate that mild adverse events are common and that serious adverse events, while relatively rare, continue to be reported.	review does demonstrate consistent benefit of acupuncture for chronic primary pain. They considered that the risks of harms are minimal and can be mitigated against with safe delivery of acupuncture. The evidence report considered discontinuation due to adverse events as an outcome. For the majority of comparisons there was no greater discontinuation in the acupuncture groups than sham or usual care.
The Good Thinking Society	Evidence review G	049	001 - 011	The Evidence review states "*The committee discussed and compared the evidence within this guideline to the low back pain guideline and agreed there was a difference in the available evidence base between the two guidelines, with less consistent results demonstrated in NG59, and the current review demonstrating more favourable results when compared to sham acupuncture*"	Thank you for your comment. The committee disagree. Consistent benefits were observed for quality of life and pain compared to sham acupuncture from a large evidence base. Benefits were also observed in function and psychological distress.

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				The evidence included in the review is not of sufficient quality to conclude that it shows favourable results when compared to sham acupuncture	
The Good Thinking Society	Evidence review G: Appendix J: Research recommendations	208	011 - 012	The recommendations state: "*Evidence from this guideline has demonstrated that acupuncture is a clinically and cost effective treatment option for the management of chronic primary pain*" The evidence reviewed was not of adequate quality to be meaningful. Acupuncture has not been demonstrated to be clinically effective to treat chronic primary pain. Furthermore, it carries a risk of harm. There is therefore no clinical or economic justification for recommending acupuncture.	Thank you for your comment. As stated in response to your previous comments, the committee disagree and have detailed the evidence of benefit for both clinical and cost effectiveness and their rationale for the recommendation and in the discussion of the evidence in Evidence report G.
The Good Thinking Society	Guideline	019	020 - 029	The Guideline states: "*Many studies (27 in total) showed that acupuncture reduced pain and improved quality of life in the short term (3 months) compared with usual care or sham acupuncture. There was not enough evidence to determine longer term benefits. The committee acknowledged the difficulty in blinding for sham procedures, but agreed that the benefit compared with a sham procedure indicated a specific treatment effect of acupuncture*." The studies were not sufficiently robust to draw the conclusion that acupuncture reduces pain and improves quality of life, either in the short or long term, nor were they sufficiently robust to reliably indicate a specific	Thank you for your comment. All evidence included in the review is critically appraised. The risk of bias of each study is assessed and accounted for in the quality of evidence rating for each outcome as detailed in the methods chapter of the guideline. Recommendations are made following processes set out in Developing NICE guidelines: The Manual. The quality of evidence across the whole body of evidence in the review is considered

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				treatment effect. Recommendations should not be made based on "very low" or "low" quality evidence, and "moderate" evidence should be evaluated critically and treated with caution, particularly where there are significant risks of harm and significant cost implications.	when making recommendations, in accordance with these processes.
The Good Thinking Society	Guideline	020	009 – 017	The economic model developed compares acupuncture with "usual care comparisons" rather than with sham acupuncture. There was no control for non-specific effects. The model is therefore inadequate to draw any reliable conclusion.	Thank you for your comment. While sham evidence was considered important for assessing whether there are treatment-specific effects from acupuncture (and was included in the clinical evidence review), it was agreed that the data comparing acupuncture as an adjunct to usual care with usual care alone should be used in the economic evaluation as sham is not a real-world comparator. A detailed discussion of the rationale for this decision is included in Section 2.1.1.1 of the acupuncture modelling report.
The Good Thinking Society	Guideline	020	018 - 030	The Guideline states: "*Overall, the committee agreed that there was a large evidence base showing acupuncture to be clinically effective in the short term (3 months); the original economic modelling also showed that it is likely to be cost effective. However, they were uncertain whether the beneficial effects would be sustained long term and were aware of the high resource impact of implementation*"	Thank you for your comment. As stated in response to your previous comments, the committee disagree and have detailed the evidence of benefit for both clinical and cost effectiveness and their rationale for

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				The committee's recommendations do not reflect the evidence. There is not a large evidence base showing acupuncture to be effective, either in the short or the long term. The evidence reviewed by the committee was not sufficiently robust to support their conclusions. Similarly, the economic modelling is flawed, as it is reliant on poor quality studies, which did not take non-specific effects into account. There is no clinical or economic justification for offering acupuncture for chronic pain, either in the short term or the long term. Furthermore, in addition to the economic cost, the recommendations do not adequately consider the risk of adverse events, or the indirect risk of lending legitimacy to non-evidence based practices.	the recommendation and in the discussion of the evidence in Evidence report G. More details about the economic modelling methods including a detailed discussion of the rationale for using studies comparing acupuncture to usual care in the analysis can be found in the acupuncture modelling report.
The Good Thinking Society	Guideline	021	001 - 003	The Guideline states: "*No evidence was found to inform a recommendation for repeat courses of acupuncture*." We agree with this statement. However, we do not agree that there is any good evidence to inform a recommendation even for a single course of acupuncture. The committee agreed that further research would help to inform future practice and made a research recommendation. If further research is carried out, it is crucial that it is well designed and that adequate controls are in place. However, we are not convinced there is sufficient justification for further research. When existing	Thank you for your comment. Please see our responses to your comments above regarding the evidence for a single course of acupuncture. In relation to the research recommendation, the committee agree that this should be well designed and appropriately controlled. A suggested protocol for the research is included in appendix J

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				research is critically reviewed (with poor quality studies either excluded or flaws taken into account), the evidence overwhelmingly indicates that any perceived benefits of acupuncture are mild, temporary and result from non-specific effects.	of Evidence review G setting out the key criteria.
The Good Thinking Society	Guideline	021	004 - 011	The Guideline states: "*The recommendation is expected to lead to increased use and need for acupuncture services and therefore to have a resource impact. This is due to the number of people with chronic primary pain, and acupuncture being an individual patient intervention and so staff intensive*" There is no good evidence of benefit. There is therefore no justification of the use of resource. Furthermore, any recommendation by NICE should also take adequate, detailed consideration of risk. The draft guideline does not take adequate consideration of the risks of direct harm to patients (ie from adverse events), or more general risks (potentially lending credibility and legitimacy to non-evidence based treatments and unregulated private acupuncture and TCM practices).	Thank you for your comment. Please see responses above to your comments about the evidence of benefit and discussion of risks. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also

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					be considered by NICE where relevant support activity is being planned.
The Good Thinking Society	Guideline	20	3-8	The Guideline states: "*Two economic evaluations (1 in the UK) showed that acupuncture offered a good balance of benefits and costs for people with chronic neck pain. However, both studies had limitations; a notable limitation being that the costs of acupuncture seemed low. Threshold analysis based on these studies indicated the maximum number of hours of a band 6 and 7 healthcare professional's time that would make the intervention cost effective*." The economic evaluations are flawed as they are based on poor quality evidence, lacking any control for non-specific effects. There is no good evidence that acupuncture is of benefit for chronic neck pain, or any other chronic pain condition. There is therefore no clinical or economic justification for treatment. This would not be an appropriate use of healthcare professionals' time, particularly if there is competition for resources.	Thank you for your comment. Please note that in addition to these two published economic evaluations, new economic modelling was also undertaken in this area. This pooled data from a number of clinical studies and was considered to reduce uncertainty about the cost effectiveness of acupuncture. While sham evidence was considered important for assessing whether there are treatment-specific effects from acupuncture (and was included in the clinical evidence review), it was agreed that the data comparing acupuncture as an adjunct to usual care with usual care alone should be used in the economic evaluation as sham is not a real-world comparator. A detailed discussion of the rationale for this decision is included in Section 2.1.1.1 of the acupuncture modelling report.

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The Good Thinking Society	Guideline	7	7-15	The recommendation "Acupuncture for chronic primary pain" should be removed. There is no good evidence that acupuncture is of benefit to treat chronic primary pain, or to treat any condition associated with chronic pain, either within a traditional Chinese (TCM) or Western acupuncture system. We do not consider that the clinical evidence reviewed by the committee was sufficiently robust to support the conclusions drawn. Furthermore, there are risks of harm associated with acupuncture. Commonly reported adverse effects include dizziness, temporary loss of consciousness and needles being left in the patient. More serious but rarer events have also been observed, such as collapsed lung (pneumothorax). There is therefore no clinical justification for the use of acupuncture to treat chronic primary pain or associated conditions. Similarly, there is no economic justification for the NHS offering acupuncture to treat chronic primary pain. The recommendation could have a significant resource impact to the NHS given the large size of the population living with current pain (even taking into account the caveats that the course would be delivered in a community setting, by a band 7 or lower healthcare professional and would be made up of no more than 5 hours of healthcare professional time). Resources would be better used elsewhere.	Thank you for your comment. As stated in response to your previous comments, the committee disagree. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. No evidence of harm was demonstrated from the review, but the committee considered their knowledge of rare potential harms in their interpretation of the evidence. De novo economic modelling also supported the recommendation for chronic primary

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				As part of our work investigating misleading health claims, we are also aware that misleading and potentially harmful claims are widespread across the largely unregulated private acupuncture and TCM sectors. If acupuncture were available on the NHS for chronic pain, this would lend undeserved legitimacy to acupuncture in general, and to other non-evidence based treatments offered by private acupuncturists and TCM practitioners. Furthermore, if NHS resources are limited and patients are limited to 5 hours of healthcare professional time, it is likely that patients would view unregulated private clinics as an appropriate alternative or follow-up, exposing them to misleading and unregulated health claims that the patient may be more likely to listen to given that their acupuncture experience started with an NHS service. In addition to the risks outlined above, there are further risks associated with unregulated private practice - for example, complications have arisen from the use of nonsterile needles, and insufficient hygiene regarding the washing of hands and wearing of gloves before puncturing the skin. Furthermore, unregulated TCM practitioners frequently use the title "Dr" and offer acupuncture and unlicensed herbal medicines to treat a wide range of conditions, including several for which medical supervision should be sought (eg diabetes, depression, infertility). Patients could be at risk of harm if they were to view TCM as a legitimate alternative to	pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee agree there is sufficient evidence of benefit to recommend that acupuncture is considered for use within NHS settings. Regulation of private practice is beyond the remit of NICE guidance.

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				conventional medicine – a view that could be inadvertently supported by NICE recommending acupuncture.	
The Good Thinking Society	Guideline appendices – Acupuncture cost effectiveness report	006	004 - 005	The clinical evidence reviewed was not of adequate quality to draw any reliable conclusion. We therefore do not agree that the clinical evidence showed a benefit of acupuncture compared to either sham acupuncture or usual care, either in reducing pain or improving quality of life.	Thank you for your comment. As stated in response to your previous comments, the committee disagree and have detailed the evidence of benefit for both clinical and cost effectiveness and their rationale for the recommendation and in the discussion of the evidence in Evidence report G.
The Good Thinking Society	Guideline appendices – Acupuncture cost effectiveness report	006	General	The trials used for the economic analysis compared acupuncture in addition to usual care with usual care. There was no sham acupuncture control group. The trials therefore failed to account for non-specific effects. Furthermore, the confidence intervals for the UK trial were very large. We therefore do not consider the evidence sufficiently robust to support the conclusions drawn. There is no good evidence that acupuncture is of benefit for chronic pain. There is therefore no clinical or economic justification. The report notes that both studies had limitations regarding intervention costs potentially being underestimated and that uncertainty remained around cost effectiveness. The report also notes that a	Thank you for your comment. Please note that in addition to the two published economic evaluations your comment relates to, new economic modelling was also undertaken in this area. This pooled data from a number of clinical studies and was considered to reduce uncertainty about the cost effectiveness of acupuncture. While sham evidence was considered important for assessing whether there are treatment-specific effects from acupuncture (and was included in the

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				recommendation could have a resource impact to the NHS in England given the large size of the population living with current pain. There would therefore be no economic justification for recommending acupuncture for chronic pain in the NHS, even if poor quality studies were accepted and it were considered that there is some clinical justification for the intervention.	clinical evidence review), it was agreed that the data comparing acupuncture as an adjunct to usual care with usual care alone should be used in the economic evaluation as sham is not a real-world comparator. A detailed discussion of the rationale for this decision is included in Section 2.1.1.1 of the acupuncture modelling report. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported

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					the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence quality, and uncertainty in the maintenance of the effects long term.
the Royal College of Chiropractors	Evidence review I – Manual therapy	033-034		The guideline recommends a course of acupuncture or dry needling to manage chronic primary pain, with which we agree, but does not recommend manual therapy. However, for psychological distress (a critical outcome), the evidence shows that both soft tissue technique (p33, line 27) and manipulation/mobilisation(p34, line 15) have clinically important benefits over acupuncture/dry needling in the short term. We suggest this is adequate justification to recommend manipulation/mobilisation for which the evidence was of moderate quality.	Thank you for your comment. The committee noted the promising results in some of the evidence for manual therapies, however it was noted that these were inconsistent between studies for soft tissue technique and only from two studies with very small sample sizes for manipulation/mobilisation. In terms of the comparison with acupuncture/dry needling, although improvements in psychological distress favoured manual therapy, acupuncture/dry needling led to better effects in pain and function for soft tissue technique and no difference for other outcomes

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					with manipulation/mobilisation. The committee agreed that the evidence was not sufficient to inform a recommendation but recommended further research should be carried out on this topic to inform updates of this guideline.
the Royal College of Chiropractors	Guideline – just the recommendations	General	General	The recommendations place an increased emphasis on acupuncture and a decreased emphasis on manual therapy for chronic pain, whereas the recommendations in the NICE guideline on Back Pain and Sciatica recommend manual therapy and do not recommend acupuncture. How is this inconsistency explained?	Thank you for your comment. Evidence for low back pain (and some other topics) was excluded from the reviews for specific treatments for chronic pain, as stated in the scope and relevant review protocols. This was because there was already existing NICE guidance and recommendations on these topics. Consequently, different evidence bases informed each guideline recommendation. In low back pain there was not good evidence of effectiveness of acupuncture compared to sham, however in this guideline the evidence compared to sham was in favour of acupuncture, as

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					was the majority of evidence for acupuncture compared to usual care.
the Royal College of Chiropractors	Guideline–just the recommendations	General	General	The guideline places emphasis on patient-centred care and shared decision making (multiple references in Recommendations), but there is no apparent possibility of patients being able to choose options outside a very limited set of recommendations despite (in the case of manual therapy) "… the committee agree that the benefits compared with usual care were promising and there was no evidence of harm …" (Recommendations, page 23 line 2). NICE has, in the past, suggested options driven by patient choice and we propose that consideration of this is applied to the chronic pain guideline.	Thank you for your comment. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits.
the Royal College of Chiropractors	Guideline–just the recommendations	016-017		Whilst we understand the economic advantages of supervised group exercise, we suggest the recommendations should make it clear that no clinical advantages of recommending group as opposed to individual exercise have been confirmed by the evidence.	Thank you for your comment. The evidence reviewed was largely for group exercise. This was therefore also what informed the economic

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				Indeed, we suggest that individual supervised exercise has greater face value in the context of addressing people's specific health needs, abilities and preferences (and individual care plans) and should be recommended for some patients.	model and this is reflected in the recommendation. The committee agreed there wasn't enough evidence to comment on the clinical or cost-effectiveness of individual exercise.
The Scottish Government	Guideline	006	01	**Pain management programmes:** • The guideline states there was inconsistent evidence for pain management programmes and made a recommendation for research. • Whilst we acknowledge that the evidence threshold may not have been met by existing studies, it should be noted that in order to be considered a 'pain management programme', these interventions must include both exercise- and psychological therapy-based components, which themselves are recommended elsewhere in the guideline (p.6, line 10; p.7, line 1 respectively). The committee should therefore consider how it this is reflected in the guideline to ensure existing, effective pain management programmes remain an option for clinicians and patients alike.	Thank you for your comment. The committee agreed there was insufficient evidence to make a recommendation for or against pain management programmes. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may

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					be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research.
The Scottish Government	Guideline	008	013	**Pharmacological management of chronic primary pain:** • We are concerned that the recommendations in this section are both unrealistic and potentially harmful for patient health and wellbeing (see Comments 5, 6). • Furthermore, it is well established that across most health systems there is currently poor access and few defined referral pathways for non-pharmacological support and management for chronic pain. Therefore these recommendations could lead to increased strain on existing pain management services and	Thank you for your comment. The committee agreed that the review of evidence in this guideline, and their expert consensus opinion, demonstrated that the majority of the medicines reviewed are not beneficial for the management of chronic primary pain.

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				raised anxiety and distress amongst chronic pain patients whose existing treatment regime includes analgesic medication. • We would urge the committee to ensure the guideline acknowledges the role of pharmacological management as a component of many existing treatment strategies for chronic primary pain. Furthermore, whilst perhaps not within the remit of this Committee, there is a clear need for greater education and signposting to resources on pharmacological management of chronic pain, including withdrawal of medication, amongst both clinical and patient communities. NICE should urgently consider how it will support the dissemination and implementation of the finalised recommendations within this guideline.	The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For

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					people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee agree that there should be clear signposting within the guideline to other relevant guidelines where necessary. Links have been added where appropriate. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. Your comments regarding implementation will be considered by NICE where relevant support activity is being planned.
The Scottish Government	Guideline	008	014	**1.3.8 Antidepressants:** • While the links between chronic pain and poor mental health are well described, we are concerned	Thank you for your comment. Antidepressants have been

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				that this recommendation could lead to inappropriate prescribing of antidepressants for people reporting primary chronic pain. • While these conditions are interlinked, and an improvement in one may lead to better outcomes in the other, we feel that the guideline conflates, rather than addresses, this issue. • The committee should consider reviewing this recommendation so that it better explains: i) depression is a common comorbidity with chronic pain and that patients' mental health should be monitored and ii) treatment using antidepressants should only be considered when necessary (e.g. in patients with chronic pain with moderate/severe depression) and after clear assessment. • Furthermore, despite acknowledging the limitations in the quality and quantity of evidence for the use of antidepressants for chronic primary pain, the guideline states: 'However, the committee agreed that for most medicines, response to treatment would be sufficiently similar to allow recommendations to be made across all chronic primary pain conditions, even when evidence was available for only one condition.' (page 23, line 16). • We disagree with this approach and would encourage the committee to consider including much more specific guidance for those medications for which evidence is available for the treatment of conditions	recommended specifically for the management of chronic primary pain in this guideline as a result of evidence of their effects on patient reported outcomes such as quality of life and pain. This recommendation is not based on their antidepressant effects. A recommendation has been added to highlight these are not recommended for depression but because they may help with quality of life, pain, sleep and psychological distress. Many of the studies included in the review excluded people with depression, supporting that these effects are independent of any effects on depression. The committee note that there are some limitations in the evidence and have therefore recommended to consider antidepressants, rather than making a stronger recommendation to offer them for chronic primary pain. Whilst it is true that a number of

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				of primary chronic pain (e.g. fibromyalgia). This approach would ensure more appropriate prescribing of antidepressants and help to manage the expectations of patients for whom these medications are not appropriate. • Whilst not the specific focus of this guideline we also wish to highlight concerns about the advice therein on stopping or reducing antidepressants, which simply refers to the NICE guideline on depression in adults. This guideline itself has not been updated recently. The committee should consider including more suitable information or signposting to more appropriate resources. Overall, greater clarification of this recommendation in-line with the suggestions above would support clinicians to explore other, pharmacological and non-pharmacological, interventions for primary chronic pain including those recommended elsewhere in the guideline which may lead to improved mood.	studies included in the review were in women with fibromyalgia, the evidence for antidepressants included other chronic primary pain populations such as chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Heterogeneity was not observed between types of chronic primary pain, so the committee agreed it provided no evidence against making this recommendation to be for all people with chronic primary pain. The evidence for stopping or reducing antidepressants has not been reviewed by this guideline. The section in the NICE guideline for depression on stopping or reducing antidepressants was updated in 2019. The committee therefore agreed it was appropriate to cross refer to this and also highlight the upcoming NICE guideline for safe prescribing and withdrawal management.

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The Scottish Government	Guideline	009	010	**1.3.11 Medication not recommended for use for chronic primary pain:** • We acknowledge that there is at best mixed evidence for the efficacy of many medicines currently prescribed for primary chronic pain. Furthermore, feedback from patient groups and their representatives has highlighted that many feel medication-led approaches to chronic pain are not always desirable. • However, we are concerned that the guideline's blanket recommendation against the use of a range of analgesic drugs will restrict treatment options considered for the most severely affected chronic primary pain patients. • The draft guideline recommendation is therefore not in line with the approach being advocated in NHS Scotland as per SIGN 136 and the NHS Scotland Quality Prescribing for Chronic Pain strategy.[1]As stated in these publications, despite the variation in patient responses to analgesia, both in terms of efficacy and side effects, there can be a role for the safe and monitored use of analgesic drugs for individual patients, especially those for whom other interventions have proven insufficient.	Thank you for your comment. The committee agree that there should be a shared care and support plan developed with the person, where benefits and harms of all treatment options should be discussed. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits. They do however also agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who

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				We therefore recommend the Committee consider how the guideline can better reflect the role of analgesia in supporting clinicians and patients alike to develop pain management strategies.	are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
The Scottish Government	Guideline	General	General	**Clarity of language:** • The guideline is focused on 'chronic primary pain', and provides only brief mention or signposting to existing NICE guidelines for conditions which cause pain e.g. osteoarthritis etc. • This should be clarified in the guideline title and references throughout in order to ensure clinical and patient stakeholders alike refer to the most appropriate information and advice for their needs. The Committee should also consider the health literacy needs of the chronic pain patient population and ensure the final guideline enhances patient knowledge, understanding, skills and confidence to be active partners in their care and management of their condition.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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					included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The Scottish Government	Guideline	General	General	**Interplay between chronic primary and chronic secondary pain:** • Despite the title of the guideline, it is primarily concerned with management of conditions associated with chronic primary pain as per ICD-11.[2] • The guideline should note that chronic primary pain can *either*be a diagnosis of exclusion (after investigating secondary causes of pain), *or*a temporary diagnosis, pending investigation. Treatment outcomes, and therefore guidelines, will be very different in these two groups. Indeed, the former group is itself very heterogeneous, and will therefore experience different outcomes from different treatments, and this has not been fully recognized in the draft guideline. • The guideline should also better reflect the potential for a change in diagnosis over time (in either direction) between chronic primary and chronic secondary pain to ensure the most appropriate	Thank you for your comment. Additional recommendations have been added to the assessment recommendations including when to consider a diagnosis of chronic primary pain, and to highlight that the initial diagnosis may change with time and should be re-evaluated, particularly if presentation changes. The guideline covers the areas that were agreed during the scoping process. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder

[2] Nicholas M et al. The IASP classification of chronic pain for ICD-11: chronic primary pain. Pain. 2019;160(1):28-37

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				guideline is referred to in support of clinical decision making, as per ICD-11. We would strongly urge the committee to consider the importance of developing an overall chronic pain guideline which takes into account management of both chronic primary and chronic secondary pain as per SIGN 136.[3]This approach supports a focus on the wider holistic needs of the person presenting with persistent pain and management options in line with the Scottish Government's strategic priority for NHS Scotland to ensure person-centred care.	comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
The Scottish Government	Guideline	General	General	**Non-pharmacological interventions:** • The guideline highlights a paucity of high-quality research evidence for interventions for chronic primary pain. • The guideline therefore recommends an extremely limited number of (mainly) non-pharmacological management strategies, many of which are not currently readily accessible in existing UK health system pathways. • In general, the Committee should consider that given the highly individualised experience of chronic pain	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

[3] SIGN 136: https://www.sign.ac.uk/patient-and-public-involvement/patient-publications/managing-chronic-pain/

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				there must be a degree of flexibility and choice for both clinicians and patients in the shared development of a treatment regime. • It is also important to recognise that as a chronic long term condition, appropriate management approaches to chronic pain may be more or less important at particular stages in the patient journey. The need to treat people living with chronic pain as individuals is important, acknowledging that the evidence is usually based on the "average" response.[4] • This is especially true of non-pharmacological interventions which can support a more holistic and compassionate approach to pain management – a biopsychosocial approach. The Committee should consider how the guideline can reflect this when presenting its recommendations for non-pharmacological management of chronic primary pain. • The challenge of moving towards minimising the dependency on medication and the transition towards self-management should be not be under-estimated and the possible requirement for provision of coaching and support for patients to do this should also be acknowledged by the guideline.	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert

[4] Moore RA, Derry S, McQuay HJ, et al. Clinical effectiveness: an approach to clinical trial design more relevant to clinical practice, acknowledging the importance of individual differences. Pain. 2010;149(2):173-176. doi:10.1016/j.pain.2009.08.007

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				• We also recommend that the guideline put a greater emphasis on self-management to support patients with chronic pain, especially in the initial assessment. There is evidence to suggest that moderate reduction in pain severity and disability can be achieved for both chronic pain both with and without additional medication.[5,6]Given evidence that suggests patients require specific instruction to promote active self-management, the committee should consider how the guideline can ensure it highlights this approach which may be beneficial for those experiencing chronic pain.[7] • The Committee should also consider how the guideline can support clinicians to undertake positive conversations with patients around psychological interventions and ensure these are carried out in a thoughtful and sensitive manner. • Furthermore, there appears to be a lack of consistency in the committee's approach to recommendations with regards to the duration of treatment effect. For example, there is limited evidence for the long-term efficacy of some of the non-pharmacological interventions recommended e.g. acupuncture. However, other non-	consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits. The recommendations in the assessment section have been amended to strengthen elements highlighted in your comment including ensuring discussions are carried out in a thoughtful and sensitive manner, treating people as individuals and acknowledging their experience and supporting self-management options. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term

[5] Kroenke K et al. Optimized antidepressant therapy and pain self-management in primary care patients with depression and musculoskeletal pain: a randomized controlled trial. JAMA 2009;301(20):2099-110.
[6] Du S et al. Self-management programs for chronic musculoskeletal pain conditions: A systematic review and meta-analysis. Patient Educ Couns 2011;85(3):e299-e310.
[7] Liddle SD, Gracey JH, Baxter GD. Advice for the management of low back pain: a systematic review of randomised controlled trials. Man Ther 2007;12(4):310-27.

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				pharmacological (e.g. electrical physical modalities) and pharmacological (e.g. opioids) interventions were not recommended despite evidence of their short-term utility in management of chronic pain. The Committee should clarify how these decisions were reached. The issues above could reduce opportunities for patients to access and be offered interventions that may improve their quality of life as part of short and longer-term pain management strategies.	courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.
The Scottish Government	Guideline	General	General	**Impact of COVID-19:** • NHS-led data collection suggests that the prevalence of chronic pain is higher in more deprived groups, therefore this cohort are likely to have been significantly impacted by the COVID-19 pandemic. Furthermore, there is evidence to suggest that the pandemic has resulted in a further increase in existing health inequalities. This is likely to be a short to	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance and restrictions relating to

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				medium-term barrier to the implementation of the guideline as patients are unlikely to welcome changes to their pain management treatment regime at present. Furthermore, the impact of lockdown restrictions across the UK are likely to have both exacerbated pre-existing persistent pain issues (e.g. reduced physical activity support to manage pain) and may lead to increases in the cohort of patients experiencing chronic pain.[8]There is also some emerging evidence that persistent pain may be a symptom associated with post-COVID-19 recovery.[9]These factors are likely to add further complexity to the development and improvement of clinical management pathways for chronic pain, and introduce further heterogeneity to this patient group.	COVID-19, with social distancing where appropriate. This is an evolving situation and so the recommendations remain based on where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account. Your comments regarding the challenges to implementation will also be considered by NICE where relevant support activity is being planned.
The Walton Centre NHS Foundation Trust	Guideline	004	002 - 020	**Topic: Assessing all types of chronic pain** We agree with this section.	Thank you for your comment.
The Walton Centre NHS Foundation Trust	Guideline	006	001 - 004	**Topic: Pain Management Programmes - evidence** NICE requires a randomised controlled trial study design as proof of treatment efficacy. Very little PMP evidence is in this format. Most evidence is in the form of outcome studies, and not admissible to NICE. Some of the studies that NICE	Thank you for your comment. RCTs are considered the best quality evidence for intervention reviews. There were a large number available in the literature, but the results from

[8] Puntillo F et al. Impact of COVID-19 pandemic on chronic pain management: Looking for the best way to deliver care, Best Prac & Res Clin Anaesthesiology 2020
[9] Kemp HI, Corner E, Colvin LA. Chronic pain after COVID-19: implications for rehabilitation. Br J Anaesth. 2020

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				included in their analysis would not be considered to provide an adequate therapeutic PMP treatment bundle by PMP clinicians. Consequently, in our view, NICE does not utilise an appropriate analysis for PMP treatment and mistakenly concludes there is inadequate evidence for PMP therapy. With regard to the PMP treatment bundle we consider that an 'Intensive PMP' comprises 90 hours group treatment which should include physiotherapy supervised exercise, psychological group therapy, pain education and pacing training. Patients should be correctly selected, and they often require individual preparation prior to attending a PMP. We have 35 years experience of developing PMP therapy and we can demonstrate clinically significant, durable results and high levels of patient satisfaction for our Intensive PMP. We welcome the suggestion for more PMP research, if that results in increased research funding for UK PMPs. We are well placed to perform research as we provide several different PMPs based on age group, level of disability and nature of pain, including a 90 hour PMP, and our patients are routinely assessed for outcome, using established outcome measures. We have established a PMP Registry to collect these outcomes for all cases.	these were inconsistent across all types of chronic pain. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research. The committee were aware of the recommendation in NG59. Evidence in low back pain was included in this review where relevant to the review protocol, however the committee agreed the evidence couldn't inform a recommendation for chronic pain as a whole. They were also aware the recommendation in NG59 was partly based on the ability to stratify people based on risk, which wasn't possible across the whole chronic pain population. This guideline will include a cross reference to the low back pain

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				We note that a key NICE recommendation for the treatment of persistent low back pain or sciatica in 2016 (NG59) was *'to consider a combined physical and psychological programme, incorporating a cognitive behavioural approach (preferably in a group context that takes into account a person's specific needs and capabilities) …when they have significant psychosocial obstacles torecovery…and when previous* (NICE recommended) *treatments have not been effective'*. This treatment is essentially a PMP, but with a different name, and we are surprised that NICE have not recommend this in the current guidance, four years later, as many chronic pain patients in the UK are patients with chronic low back pain.	guideline and other related NICE guidelines. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Further detail of the committee's consideration has been added to the rationale in the guideline.

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The Walton Centre NHS Foundation Trust	Guideline	006	007 – 008	**Topic: Chronic pain and chronic primary pain section 1.2 transitioning to section 1.3** The guideline is for chronic pain, but at section 1.2 all reference to chronic pain ceases and at 1.3 onwards the document only refers to chronic primary pain. The effect is to conflate chronic pain, chronic secondary pain and chronic primary pain, even though NICE apparently wishes to define these separately. This will be confusing and unhelpful to the reader and was confusing to our NICE guideline reviewing group, of consultants in Pain Medicine. It is highly likely that the reader will assume that the recommendations for chronic primary pain are also the recommendations for chronic secondary pain. This ambiguity was also noted in the national press at the time of the launch of this draft guidance. Chronic secondary pain is significantly more prevalent than chronic primary pain. By focussing on chronic primary pain in this guidance, NICE have actually overlooked the majority of patients with chronic pain. The term chronic primary pain was invented by a group of experts in 2019; prior to 2019 it was never used. The term is NOT in general use and is only just beginning to be used by a few specialist clinicians. It is a catch-all term	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was

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				for chronic pain without identified aetiology, further specified by causing disability and/or distress. The unfamiliarity of this pain classification will further confuse the reader. Due to the absence of positive biomarkers for chronic primary pain, the process of diagnosing this correctly is complex, and requires education and training, such as the training provided by the Faculty of Pain Medicine training programme. We recommend that NICE clarifies the training requirements for diagnosticians responsible for differentiating between chronic primary and chronic secondary pain and between the various different primary pain conditions. As it stands, the NICE guidance is at danger of supporting a process where a misdiagnosis of chronic primary pain is delivered by unexperienced staff, mainly in a community setting, to the detriment of patient care. We believe the draft should recommend improved access to secondary care to confirm a primary cause, establish any secondary contributions and advise on the type of primary pain that applies, before labelling a patient with chronic primary pain. We note that NICE uses the new ICD-11 WHO diagnostic category, but it chooses to largely ignore the WHO second level classification where different kinds of primary pain are clearly outlined. This is confusing and will lead to oversimplification of primary chronic pain.	consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the

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					recommendations (for example, separate research recommendations for pharmacological management of CRPS). Additional recommendations have been added to the assessment section, including when to consider a diagnosis of chronic primary pain.
The Walton Centre NHS Foundation Trust	General	Gene ral`	General	**<u>The Walton Centre SWOT Analysis re NICE Chronic Pain Guidance 2020</u>** This is a specific strengths, opportunities, weaknesses and threats analysis performed by the Pain Service at The Walton Centre Hospital for our own use, and included because it may be helpful to NICE **General comments** It is very difficult to assess the impact of these guidelines on the medical management of patients by GPs It is also very difficult to assess potential changes in commissioning, and how these changes would impact on Walton Centre as a Tertiary Centre for Pain **Strengths**	Thank you for your comment. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a

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				• NICE recognises ICD-11 'chronic primary pain' as a classification • NICE specifies appropriate assessment and management for pain patients, including in primary care • NICE recommends appropriate clinician communication with patient • NICE advises that analgesics are generally unhelpful in chronic primary pain • In response to this guideline patients should not be routinely be prescribed progressively escalating doses of analgesics/gabapentinoids by GPs in chronic primary pain and the futile extended patient journey related to multiple medication adjustments will be shortened • Reduced medication prescription will result in patients being less cogitatively impaired and less sedated, and more able to manage chronic pain effectively **Weaknesses** • NICE generalises all chronic primary pain as a single problem and this could cause communication difficulties among health care practitioners who share the management of our chronic pain patients with us	difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations (for example, separate research recommendations for pharmacological management of CRPS). The baseline level of pain was considered in all evidence reviews where available in studies. The committee considered this in their interpretation of the evidence. There was no evidence to make different recommendations for different levels of pain. A recommendation has now been added for when to consider a diagnosis of chronic primary pain. The committee agreed that the evidence did not support recommending the majority of

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				○ *CPP is a catch-all diagnosis with no evidence of a common aetiology* • NICE does not consider severity of chronic pain - eg Acupuncture for mild musculoskeletal chronic primary pain might help, but is very unlikely to significantly benefit severe musculoskeletal chronic primary pain • Identifying chronic primary pain can be difficult in primary care and there is no recommendation for training in primary care to diagnose chronic primary pain **Opportunities** • Reduced referrals and reduced waiting lists for Walton Centre Pain Clinic, but the opposite effect also possible • Opportunity to set up a large research project for efficacy of PMP for chronic primary pain compared with, for example, exercise therapy or ACT. ○ *funding may become available as NICE recommends research* • Set up Medication reduction clinics at Walton Centre • Community pain clinics with a medical clinical lead could become popular which would improve UK chronic pain management for patients and we may become involved in this	medicines reviewed for chronic primary pain due to lack of evidence of effect and evidence of harm. They agreed the risk of harms outweighed the benefits in the majority of cases. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also

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				• Strong need to develop effective therapy for chronic primary pain has been implicitly identified by this NICE guidance as currently few options are available **Threats** • Potentially helpful medication for chronic primary pain would not be supported by NICE - eg tramadol and PGN for FMS • Potential withdrawal of useful medications from patients by GPs - eg tramadol and PGN for FMS • Risk of decommissioning of Walton Centre PMP because PMP treatment is not recommended by NICE o *Probably protected from decommission by NHSE funding* • Risk of local secondary care pain services being decommissioned o *Walton Centre may get more patients who are less filtered* • No mention of specialist physiotherapy for chronic pain such as for CRPS or female pelvic pain o *Risk of loss of physiotherapy expertise for chronic pain locally*	be considered by NICE where relevant support activity is being planned.

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The Walton Centre NHS Foundation Trust	Comment form question 4	N/A	N/A	***The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.*** No group therapy can take place currently and consequently pain management programme therapy research cannot take place at the moment. It is not known when group therapy will be able to restart.	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain with considerations of where evidence demonstrates interventions are clinically and cost effective. Implementation of these should take the current context into account.
The Walton Centre NHS Foundation Trust	Comment form question 3	N/A	N/A	**What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** GP training in chronic pain management. GP training in medication management for chronic pain including the management of reduction and withdrawal of medication Physiotherapy training in managing chronic pain, including managing specific conditions such as CRPS and	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure

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				chronic pelvic pain syndrome. Some of these conditions are rare, therefore realistically such training will often need to take place in secondary or tertiary care. Setting up medically managed MDT primary care pain clinics.	that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
The Walton Centre NHS Foundation Trust	Comment form question 2	N/A	N/A	**Would implementation of any of the draft recommendations have significant cost implications?** Reduction in primary care drug costs for chronic pain.	Thank you for your comment.
The Walton Centre NHS Foundation Trust	Comment form question 1	N/A	N/A	**Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.** It is difficult to estimate the impact of this Guideline, but in the present climate of inadequate NHS funding it is likely, in our view, that commissioners will use the guidelines to reduce spending on, or decommission, secondary care pain clinics. If this occurs, it would need a concurrent expansion in medically led primary care pain clinics. Specialist chronic pain training would be needed for the clinicians running the primary care pain clinics. Facilitated referral to secondary care specialists, who can	Thank you for your comment. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This

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				confirm the primary diagnosis, identify any secondary causes, and advise in the appropriateness of specialised treatment would also be needed, especially whilst the primary care team were receiving training in chronic pain management. Patients expect analgesic medication when they visit a doctor with chronic pain. This guideline will result in conversations between doctors and patients which most patients will find frustrating and unhelpful. This will be particularly challenging for clinicians in primary care. There is a danger that treatments which are not recommended for pain will be decommissioned. PMP therapy is not recommended and may be decommissioned, even though there is a recommendation for research within the guidance. PMP decommissioning would prevent PMP research. Chronic pain patient populations are known to have three times the suicide rate of the general population. The loss of access to PMP treatment may have a direct impact on patients' mental wellbeing. This will increase the demand on primary care teams and mental health teams, who may be poorly resourced to manage this.	guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned. The committee agree that some conversations informing people of the lack of evidence of some treatments may be challenging. However they agree it is important that full discussions are had about the risks, benefits and evidence for each treatment. The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least

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					equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review. The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline. As noted above, the committee do agree that resource will be required to implement the recommendations, and potentially longer appointment times will be required. However the guideline recommends best practice and demonstrates where there is

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					evidence that treatments are effective, with the intention of improving patient care.
The Walton Centre NHS Foundation Trust	Guideline	009	012 – 021	**Topic: opioids, NSAIDS, gabapentinoids, paracetamol** We do not agree the blanket ban on opioids, NSAIDS, gabapentinoids and paracetamol in all patients with chronic primary pain. Additionally we believe that this guidance will be misconstrued by some to mean that these drugs should not be used for any chronic pain including secondary pain. Some patients with chronic primary pain benefit, to some degree, from opioids, NSAIDS, gabapentinoids and paracetamol, and encounter minimal side effects. This has been shown using individual responder analysis in clinical trials with a 50% benchmark for pain relief - which translates into improved function and quality of life. To do this clinically, patients should be individually trialled with these medications with specific targets, such as significant pain reduction and increased activity, before prescribing them longer term. These medications, if prescribed long term, should be reviewed annually. Furthermore, flare ups are common in chronic pain patients. In one study of nonspecific low back pain, 51%	Thank you for your comment. To help clarify what population each recommendation applies to further detail has been provided in the headers of each section in the guideline and a visual summary will accompany the guideline indicating what populations are covered by each recommendation topic. The title of the guideline has also been updated to clearly indicate that it also focusses on chronic pain. We hope these changes will aid readers and clarifies that recommendations such as the pharmacological management only apply to chronic primary pain. The evidence reviewed in this guideline, and committee expert opinion was that there is insufficient evidence than these medicines are helpful for chronic primary pain and

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				of the participants reported flare-ups during the two year period following the initial diagnosis, (Suri P, Saunders KW, Von Korff M. Prevalence and characteristics of flare-ups of chronic nonspecific back pain in primary care: a telephone survey. *Clin J Pain*. 2012;28(7):573-580).One of the above drugs is likely to be efficacious for such flare ups. We recommend that flare up management should be part of any guidance dealing with chronic pain conditions. We note that there is no recommendation in this guidance to withdraw these medications from patients with chronic pain, unless this is a shared decision after explaining the risks to the patient. We think that the wording should be stronger as many patients are on inappropriately high doses of unhelpful un-trialed sedating medication, particularly opioids and gabapentinoids. We think that the guidance should suggest that clinicians '*shouldencourage patients to reduce and withdraw*'from these medications. We are aware that separate guidelines are to be produced by NICE for this (GID-NG10141).	there is evidence of harms. The committee discussed the suggestion of trialling medicines to determine responders but agreed that this was not practical in clinical practice. Unless these trials have a control phase, it would not be possible to determine whether any positive benefit seen in an individual was due to the placebo effect which is known to be particularly strong in chronic pain. Trials of treatments that are not demonstrated to be effective could lead to harm, particularly when there is a risk of dependence and withdrawal symptoms. The committee agreed that recommended management options should focus on those with evidence of benefit and do not agree that there should be a recommendation to trial interventions that do not have evidence that they benefit the majority of people. Instead resource should be directed towards more beneficial management options.

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					An additional recommendation has been added to the first section of the guideline to detail considerations for management of flare-ups of pain. The committee do not agree that it is appropriate to recommend pharmacological management in this circumstance if the cause of the pain has not changed, as there remains no evidence that they are effective. Other causes for the pain should be investigated however, and if appropriate, additional management. Additional wording has been added to the recommendation for people already receiving these medicines, encouraging them to reduce or stop using them where possible, in line with your suggestion.
The Walton Centre NHS Foundation Trust	Guideline	008	013 - 015	**Topic: antidepressants for chronic primary pain** We agree with this recommendation but it is unclear if the same recommendation is intended for all chronic pain, and we believe it should be.	Thank you for your comment. The evidence reviewed was only for chronic primary pain. Recommendations for other chronic

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					pain conditions are covered in the topic specific guidelines.
The Walton Centre NHS Foundation Trust	Guideline	007	001 – 004	**Topic: psychological therapy for chronic primary pain** We agree with this recommendation for chronic primary pain, but it is unclear if the same recommendation is intended for all chronic pain, and we believe it should be a recommendation for all chronic pain.	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics.

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The Walton Centre NHS Foundation Trust	Guideline	006	010 – 017	**Topic: group exercise therapy for chronic primary pain** We agree that group exercise therapy is helpful in chronic primary pain. It is also helpful in chronic secondary pain and this is not mentioned. Additionally, we consider that *individual*exercise therapy is also helpful in chronic primary pain. There are certain, often rarer conditions, which benefit from syndrome-specific individual physiotherapy treatment such as CRPS, chronic pelvic pain and some facial pains. For these conditions there is little evidence for the effectiveness of nonspecific exercise therapy as recommended in this guidance. In our clinical practice, patients with such conditions often report that their condition worsened with nonspecific exercise therapy delivered in the community, often designed for patients with acute pain or with common chronic pains such as back pain. Having experienced unhelpful physiotherapy, many patients then loose confidence in *all*physiotherapy and exercise therapy. We are therefore concerned that the NICE guideline, as it stands, will fail to help patients, who could have been helped by syndrome specific individual exercise therapy. A published international electronic survey concerning CRPS treatment reports that physiotherapists generally	Thank you for your comment. The reviews for specific interventions included in this guideline are all for the chronic primary pain population only, rather than all types of pain. Chronic pain already covered in existing NICE guideline was also excluded from the specific intervention reviews. This is detailed in the scope, but further clarification has been provided in the headers of each section in the guideline and with a visual summary to accompany the guideline indicating what populations are covered by each recommendation topic. The title has also been amended to reflect that chronic primary pain is also a focus of this guideline. The NICE pathway will also link to all the relevant guidelines to enable more easy navigation between the recommendations for different topics. The evidence reviewed in the guideline demonstrated effectiveness

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				lack knowledge and confidence to reliably diagnose and manage CRPS, (Grieve S, Llewellyn A, Jones L, Manns S, Glanville V, McCabe CS. Complex regional pain syndrome: An international survey of clinical practice. Eur J Pain. 2019;23:1890–1903. https://doi.org/10.1002/ejp.1463). We think there should be a recommendation for training of physiotherapists to treat patients with chronicpain on an individual basis, with appropriate adaptations to the type of CPP that requires treatment.	of supervised group exercise programmes. The committee agreed that the type of exercise may depend on the type of pain, but also that people are more likely to continue with exercise if the programme offered suits their lifestyle and physical ability and addresses their individual health needs. They agreed that the choice of programme as well as the content should take into account people's abilities and preferences. This might include providing individual exercise advice for different members of a group. This was highlighted in the recommendation and in more detail in the rationale underpinning the recommendation. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive

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					the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
UKCPA	Guideline	General	General	1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) 4. The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.	Thank you for your comments. We have responded below.

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UKCPA	Guideline	General	General	Overall I agree with the recommendations of the guideline; However: Taking existing patients off opioids will be challenging and a slow process which will add to capacity issues already experience in pain clinics and which have been made more challenging due to Covid. Coupled with this we need to ensure that the small cohort of patients who do benefit from the use of opioids and gabapentinoids in other chronic pains are not disadvantaged from access to therapy as a result of these guidelines and the parameters within which these guidelines are used are explicit so that assumptions aren't made for patients outside this cohort. Weaning patients off these agents will add to costs within the service as already identified in the guidance Overall it is a useful document.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The committee agree there are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic

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					primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas.
University College London Hospitals NHS Foundation Trust	Guideline	P 010	Lines 014-021	We are grateful for the effort that has gone into putting together these guidelines and recognise this represents a large body of work. • "The issue is a fundamental flaw in the use of 'Chronic Primary Pain' (CPP). Assuming Chronic Primary Pain is a single disease entity is flawed" • "Definition of CPP is vacuous. Conditions have been included which should be defined /have been classified separately, such as primary headache and orofacial pain as well as CRPS. This is unclear." • "This is a collection of disorders where there is pain without an apparent specific cause. As such, there may NOT be a single common pathophysiology causing symptoms for which pain may be the main one."	Thank you for your comment. The use of the ICD-11 terminology was proposed by stakeholders during the scope consultation, suggesting this would ensure the guideline was consistent with how types of chronic pain were to be recorded and tracked as a condition in its own right and its association to other classifications. The ICD-11 brings together different conditions under the heading chronic primary pain. The search terms used to identify literature were broad to identify any of the conditions that may fall under this definition. Inclusion criteria was not based on the use of

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				• "This is a concept, not a diagnosis. It groups together a number of conditions where possible altered nociceptive processing: either increased amplification or reduced inhibition leads to chronic pain. The trigger that initiates pain is not obvious, which is why it is classed as primary. o What this means is that there was NO obvious initiating event or disease causing the pathophysiology but, as always, it depends on how hard you look: just like pyrexia of unknown origin, the harder you look the more likely you are to find the cause. How many of these patients are fully investigated? Will assessment by pain physicians, many of them anaesthetics trained in the UK, be sufficient compared to "diagnosticians" such as Neurologists? o The concept itself implies one initiating cause BUT this may not be the case. There may be multiple small triggers leading to pain rather than one. We see this in neurology where more than half of patients with peripheral neuropathy may have no obvious cause. With time however, the underlying problem may emerge. In developed countries, glucose intolerance or diabetes is the most	the term 'chronic primary pain'. The details of the populations included within the studies were reviewed, considering whether they were under the umbrella term of chronic primary pain, as listed in ICD-11 at the time of development. The committee are aware the ICD-11 categorisation is fluid and conditions may be added or removed from this category, however it was agreed the population covered the relevant conditions at the time of development. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain; despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were

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				common aetiology that emerges. How many patients with primary chronic pain get re-assessed and re-classified? o Therefore, Chronic Primary Pain is a diagnosis of exclusion. Like many similar diseases, it is likely to be a syndrome rather than a disease." • "Conflation of terminology – 'Chronic Pain-CP' and 'Chronic Primary Pain-CPP' are used interchangeably and the statistics used interchangeably. CPP affects about 5% of the population; CP incidence is much higher. In the press and interviews, they don't clarify distinctions that CPP is a subset of CP without (clearly defined?) underlying aetiology. If Pain Consultants are confused by the terminology, how will GPs cope?!" • "The direction to other NICE guidance for specific pain conditions (1,2) is too hidden, not made clear enough and could be strengthened. Moreover, the use of CPP is not consistent - whilst we welcome the research recommendation to further the evidence base, three of the main recommendations are not about the treatment of primary chronic pain: number 1 is for pain management programmes for chronic pain,	pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations. We agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been

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				number 3 is for insomnia (related tochronic primary pain) and number 4 is for CRPS, and the longer recommendations list includes more that relate to chronic pain e.g. for barriers to the management and social interventions . This will only add to the confusion for patients and clinicians." • "There are obviously various guidelines for other conditions (e.g. neuropathic pain, low back pain etc). I am unsure how any differing recommendations fit alongside these as many of our patients present with multiple difficulties." • "To call fibromyalgia a primary pain condition is simplistic and incorrect. Some with this diagnosis have small fibre dysfunction and neuropathic elements. Many such conditions lumped together may have no clear aetiology. This is also true for Irritable Bowel Syndrome (IBS). The clue is the word "syndrome" which means clinicians recognise that it is not a single condition." • "Issues about when secondary pain becomes primary and vice versa are not resolved."	included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The assessment recommendations have now been amended to include consideration of other causes of the pain and when to consider a diagnosis of chronic primary pain. This also includes acknowledgement that primary and secondary chronic pain can coexist. The committee were aware of recommendations in related NICE guidelines. The reviews have considered different evidence bases and therefore in some cases recommendations differ for particular conditions. It is important to note that the recommendations on assessment and development of a care and

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				• "Diagnosis of CPP fails to take account of biological mechanisms they can't be proven. This links to problems with ICD-11." • "Any guideline that attempts to group evidence for 'chronic pain' is concerning. To suggest that the same principles apply for managing non-specific low back pain, headaches, pelvic pain and intractable neuropathic pain is a little problematic, and undermines the aetiological mechanism that contribute to symptoms" • "We need to be able to work out which subsets of patients are where treatments work – this is what NICE should focus on and not lumping together." "The recommendations also directly contradict other guidelines – with a proviso that the guide applies to pain conditions for which there are no other guidance. So, acupuncture for 'non-spec' low back pain is bad – but acceptable for 'chronic pain'. Anti-epileptics recommended for Neuropathic pain, but not for sciatic, and now not for chronic pain – although maybe a bit for CRPS."	support plan are for all types of chronic pain, where considerations apply to the broader population. However the recommendations for management are specific to chronic primary pain only, and not other types of chronic pain.
University College London	Evidence Review C	p 004-048	All	Pain Management programmes (PMPs): • "We do not recognise the studies that the guidelines about PMPs have been based on	Thank you for your comment. The committee agreed that the following definition would be used to identify

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Hospitals NHS Foundation Trust				(Evidence Review C). None include Acceptance and Commitment Therapy (ACT) intervention elements; 6 have no clinical psychologist, 9 do not detail professions of people delivering treatment and 3 are uni-disciplinary (run only by physiotherapists -contradicting inclusion criteria?)." • "These studies do not reflect what happens clinically in the majority of PMPs at Pain Management Centres across London (e.g. ULCH, Input at St Thomas', Charing Cross Hospital, Lewisham, St George's, Homerton, Chelsea and Westminster) nor in other parts of the country with well-known Pain management programmes (e.g. Bath, Bristol, Glasgow). Most of these services are using or integrating an ACT model without or without traditional Cognitive Behaviour Therapy (CBT) approaches. Key studies that have been excluded, but which our centre and many others base their treatment decisions on, include 2 key meta-analyses as well as other studies which examine ACT and mindfulness-based intervention treatment methods. o Eccleston et al.,1999 o Williams et al., 2012	studies for inclusion in the pain management programme review in the guideline: any intervention that has 2 or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the 2. This was detailed in the protocol in Appendix A, and in the PICO table, table 1. The studies included in the review are those that met this definition. The committee agreed that the components were the important factor rather than the person delivering it, so this could be delivered by one person (or speciality). The systematic reviews you highlight were reviewed when completing this review, and have been double checked again following stakeholder consultation. Any studies that met the protocol criteria for pain management

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				And several Randomised Controlled Trials (RCTs) and other meta-analyses: • Thorsell et al., 2011 • Wetherell et al., 2011 • Ruiz, 2012 • McCracken et al., 2013 • Wicksell et al., 2013 • Pincus et al., 2015 • Vehof et al., 2016 • Wicklund et al., 2018." • "Why are there so many fewer trials of psychological treatment, with or without physical therapy etc, than in the recently published Williams et al. Cochrane systematic review (2020)? Of the 74 studies Williams et al include in their meta-analysis, only 6 are included in the NICE Guidelines (Evidence Review C). Why were they excluded?" • "This may be about the definition parameters of PMPs used by the Guidelines committees in Evidence Review C. When reviewing the Psychological Therapies in Evidence Review F, a range of ACT and CBT based group interventions are reviewed which much more closely resemble	programmes in this review had been included. The guideline includes a separate review for psychological therapies, however the population of interest for that review is only chronic primary pain. Any studies included in these reviews that were relevant to the psychological therapies review had been included there. However a number were not relevant to include due to being chronic pain populations other than chronic primary pain. The committee acknowledge that some pain management programmes currently available might be set up differently, or described differently. The committee agreed that the evidence reviewed in the guideline was not sufficient to make a recommendation for or against pain management programmes. The committee are aware they are recommended in other topic specific guidelines for types of chronic pain

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				the (psychology part) of our content on our (UCLH) PMPs and, as far as we know, those of several other London and National services. It may then be important to clarify the difference between PMPs and group treatments for people with pain based on a particular psychological therapy (ACT or CBT) which include physiotherapists and nurses' content. We call these PMPs and will draw on much of the literature in Evidence Review F to develop our psychological content. This is somewhat reflected in this comment under Evidence review C. This needs to be clarified so that commissioners do not assume that PMPs have no evidence based on the unrepresentative set of studies used in Evidence review C: • The committee noted that some of • 32 the interventions included in pain management programmes such as supervised exercise • 33 and ACT/CBT are recommended in this guideline as single interventions for chronic primary • 34 pain. The committee discussed that it may be expected that combination of these single • 35 interventions within apain management programme would result in aggregated benefits or at • 36 least equal benefits to those shown from the interventions delivered individually. However,	however and acknowledge that these recommendations should be followed where appropriate for chronic pain. The review of evidence for pain management programmes was considered in light of stakeholder comments and it was agreed that for consistency with other management topics in the guideline a post-hoc sensitivity analysis would be undertaken to separate evidence specifically for chronic primary pain. The evidence in the review is now presented separately for chronic primary pain and other types of chronic pain (including mixed types of chronic pain). The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. For chronic primary pain the committee agreed that the majority of evidence did not show a benefit for quality of

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				• 37 this was not reflected in the evidence for pain management programmes. The committee • 38 discussed possible reasons for this which might include that the interventions might not be • 39 delivered in programmes in the same way or with the same intensity compared to when • 40 delivered individually, or may be more tailored to the individual when delivered in isolation. • 41 The committee were also aware that people recommended for programmes may have • 42 already tried single interventions and so might be a different subgroup of the population, • 43 even though they have the same diagnosis. It was agreed that the evidence reviewed was • 44 too inconsistent; where benefits were observed they were only small, there was uncertainty • 45 around them and they were shown for specific conditions, therefore the committee could not • 46 make a positive recommendation for pain management programmes.	life, and no benefit was observed for any other outcome. The evidence for other types of chronic pain demonstrated a more favourable benefit for quality of life, but it was noted this was primarily for low back pain and was not representative of all chronic pain. The guideline cross refers to related NICE guidelines for management where appropriate for the type of chronic pain being treated.
University College London Hospitals NHS Foundation Trust	Guideline – Lack of definition of 'Education'	P 018	Line 027	• "Education has been commented on, but it is unclear from the guidance how this is defined: Leaflet? Interactivesession? It is difficult to know how definitions and comparisons have been made. This needs to be clarified."	Thank you for your comment. The protocol included any study definition of pain education. The specific details of the interventions are given in the evidence tables and in the summary of included studies in evidence review F.

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					The committee have expanded on the discussion of this in the discussion of evidence in the evidence review for clarity.
University College London Hospitals NHS Foundation Trust	Inconsistency in recommendation - specific in places, vague in others	P 007	002-004	• "What could be changed is to recommend ACT specifically given that they say (in the review of the evidence), that there is no evidence CBT is better and found that ACT was actually better for certain aspects like sleep. Why so prescriptive here when so vague about other things such as: "returning to normal" and exercise?"	Thank you for your comment. The committee agreed that the evidence for both ACT and CBT wasn't sufficient for a strong recommendation to offer these for all people with chronic primary pain due to their being some variation in effects for both ACT and CBT and a relatively small amount of evidence compared to some other interventions. The committee agreed both did have sufficient evidence to recommend that they are considered. The committee discussed that it might be thought the evidence was slightly more positive for ACT, but it was very similar levels of evidence when considered across outcomes. The differing benefits seen for each are detailed in the rationale for the recommendations and in the

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					discussion of the evidence in Evidence report F.
University College London Hospitals NHS Foundation Trust	Guideline – Acupuncture Evidence Review G	007	007-015 All	• "When you combine all the conditions together as CPP, the recommendation for acupuncture is on very thin grounds." • "Most of these studies were on patients with fibromyalgia and musculoskeletal pain. How can this be the same for the other chronic primary pain disorders? Is the potential benefit of acupuncture for fibromylagia the same as chronic pelvic pain?" • "You combined evidence for acupuncture, traditional and non-traditional,"electro-acupuncture" and dry needling : mixing studies where the needles were inserted in different areas." • "In the "sham" studies, some employed "non-meridien" insertion which is still acupuncture to my mind." • "This is not the case with medications: 300mg of gabapentin is the same treatment whether it is administered in China, Europe or America. This is	Thank you for your comment. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly because of this varying evidence

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				not the case with acupuncture. The treatment was simply not standardised." • "Nine studies were not blinded at all: acupuncture versus usual care. These are just case series. Why are they included in the analysis?" • "Is "sham electro-acupuncture" accepted as a placebo? Even then, the 5 studies included showed no difference in pain and quality of life scores between active treatment and "sham" on the Forest plots (Page 184 of the Acupuncture evidence section)." • "Acupuncture versus "sham" acupuncture: see my comment above: the studies lump together "traditional" and non-traditional acupuncture. o 13 studies included in the analysis (Forest plot 1 Page 174). In 6 studies, results for pain after treatment crossed the line of no effect which means there is no statistically significant difference between active and sham treatment. 1 study in chronic pelvic pain appear to suggest active treatment patients reported more pain than sham. o Studies included "myofascial" pain with trigger points: is this a chronic primary	quality, and uncertainty in the maintenance of the effects long term. The committee took great care to ensure that there was consistency in decision making across the level and amount of evidence underpinning recommendations. The acupuncture review had considerably more positive evidence than other interventions reviewed in the guideline and had cost effectiveness evidence supporting the recommendation. The evidence review was for all types of chronic primary pain where evidence was available. There was no evidence in the review to indicate a difference in effect according to subtype of chronic pain. Where there was heterogeneity in pooled analysis, subgroup analysis was undertaken by type of chronic primary pain, but this did not explain the heterogeneity. The committee therefore agreed there

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				pain condition or musculoskeletal pain? Some studies recruited patients with this disorder with fibromyalgia as an EXCLUSION criteria to enter their studies (Aranha et. al) ○ Discontinuation rate is higher in some studies for active treatment: example 164 patients with fibromyalgia randomised to acupuncture versus sham acupuncture. Discontinuation at 3 months 4/82 on active treatment versus 1/82 "sham". At 1 year, 9/82 active versus 2/82 "sham". Therefore acupuncture is not without side-effects. ○ In the GRADE assessment of studies EVERY study used in the acupuncture analysis is judged to be at risk of SERIOUS or VERY Serious bias. ○ GRADE analysis also judged quality of the evidence to be VERY LOW ○ In minutes of the committee discussion, it was actually stated that If the main outcome of pain confidence interval crosses the MID then there is statistically no difference between active and sham treatment.	was no reason that the recommendation should not apply for all types of chronic primary pain. When setting the protocol, the committee discussed whether it was appropriate to pool different types of acupuncture. All types of acupuncture and dry needling were agreed appropriate to pool with the exception of electroacupuncture which was considered as a separate intervention. This decision was also informed by expert opinion from an acupuncturist. Acupuncture and dry needling were explored in subgroup analysis when heterogeneity was present, but this did not explain any observed heterogeneity within this review. Shams employed by different studies were verified with an expert for inclusion. It was acknowledged in the discussion of the evidence that there

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				The judgement of the committee cannot be to say "we think the effect is significant enough" therefore ignore if the confidence interval does not bear this out. Cost effectiveness of acupuncture only modelled on data from acupuncture versus usual care. As mentioned above, these are NOT placebo-controlled studies. The benefit may come fromhaving regular contact between the acupuncturist and the patient. NICE must be consistent here. Economic analyses are usually from placebo-controlled studies. Why was this not done for acupuncture? How about analysing acupuncture versus "sham" acupuncture?"	were a variety of sham techniques included, some of which may have had a therapeutic effect themselves. If so, the result would be to underestimate an observed effect of verum acupuncture. The committee agreed that it was therefore promising that benefits of acupuncture were observed compared to sham. The nine studies referred to compared to usual care are not case studies. These are unblinded randomised studies. Usual care was included in the protocol as a relevant comparator for this evidence review, as it was in the protocols for other non-pharmacological treatments considered in the guideline. In some of these studies the outcome assessor was blinded to the intervention, and this is accounted for in the risk of bias and quality assessment ratings.

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					Electroacupuncture was considered as a separate intervention. Where studies compared this to sham electroacupuncture, this was considered an appropriate comparator as stated in the review protocol. The committee agreed there was insufficient evidence to recommend electroacupuncture. Myofascial pain is included under the ICD-11 definition of chronic primary pain and therefore was included in the evidence review. The methods followed for rating of risk of bias, and subsequently quality of the evidence are detailed in the methods chapter. The committee noted that there was risk of bias associated with all outcomes included in the evidence. This is also true of other non-pharmacological interventions included in the guideline and many of the outcomes in the pharmacological interventions review.

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					The committee take into account all of these factors when determining the recommendation, alongside the other elements of the quality rating, the balance of benefits and harms, the magnitude of the effect and size of the evidence base amongst other factors. The committee noted that although some of the evidence varied in quality, the benefit of acupuncture was a consistent finding, also supported by some moderate quality evidence. The committee consider clinical importance of the effect size, compared to what is considered to be the 'minimal important difference' (MID) to patients. This is different to statistical significance which demonstrates whether or not an effect is due to chance. The effect for pain for acupuncture compared to sham from the meta-analysis of 13 studies does have confidence intervals crossing one of the MID boundaries,

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					but they do not cross the line of no effect (see Forest plot Figure 2 in appendix E of the evidence report). While sham evidence was considered important for assessing whether there are treatment-specific effects from acupuncture, it was agreed that the data comparing acupuncture as an adjunct to usual care with usual care alone should be used in the economic evaluation as sham is not a real-world comparator. A detailed discussion of the rationale for this decision is included in Section 2.1.1.1 of the acupuncture modelling report.
University College London Hospitals NHS Foundation Trust	Evidence review H	All	All	Electrical physical modalities for chronic primary pain • "To say there's no basis for the use of TENS does not make sense especially since you cannot blind people to the study of TENS." • "TENS was developed from a well-established mechanism of action called the "Gate control theory of pain". This model, developed by Melzack and Wall, has stood the test of time, so to say	Thank you for your comment. The review included comparisons with TENS and sham where participants were blinded to treatment, as well as comparisons to usual care where participants were not blinded to treatment. This is accounted for in the risk of bias assessment and

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				there is no basis for TENS is to refute a neurobiological model that is established within neuroscience."	subsequently the quality rating of the evidence. Neither comparison demonstrated benefit for TENS. NICE guideline recommendations are for interventions to be provided within the NHS and therefore the committee agreed that without any evidence of benefit this should not be recommended.
University College London Hospitals NHS Foundation Trust	Evidence review J	All	All	Pharmacological interventions: • The lack of recommendation for Gabapentin is based on small numbers" • "The NICE document casts aside certain treatments by failing to take into account the complex multimodal aspects that effect the management of those living with 'real' primary chronic pain." • "Looking for evidence and lumping together published data is incorrect: Most of the papers on pharmacological treatment was on fibromyalgia	Thank you for your comment. The committee agreed that the evidence reviewed within the guideline, although in some cases limited, was consistent with their expert consensus opinion. Whilst it is true that a number of studies included in the review were in women with fibromyalgia, the evidence review included other chronic primary pain populations such as chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Where present,

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				Following on from above, the data should be reanalysed for separate conditions (with some examples): ○ Fibromyalgia: Selective Norepinephrine Reuptake Inhibitors (SNRIs) are more effective at reducing pain (931 patients 6 studies) and improving quality of life (SF-36 scores) in Fibromyalgia (563 patients 3 studies) at less than 3 months (Forest plot page 261). There was only 1 study of 195 patients with fibromyalgia treated with Duloxetine where the SF-36 score was not statistically better compared to placebo. With this data, I would conclude that SNRI's are useful for alleviating pain and improving quality of life for fibromyalgia but avoid long term treatment over 3 months. This in spite of the fact that fibromyalgia is not a single condition: some studies have shown that patients with Fibromylagia have C-fibre dysfunction and may be a form of neuropathic pain. This should be stated explicitly and it is correct for the committee to recommend an anti-depressant for treating chronic primary pain. Why was this not given more prominence? ○ Pelvic Pain: Combining the Lewis and Abdelhafeez studies (33 patients, 2 studies) showed that gabapentin is effective in alleviating pelvic pain (see Forest plot page 255) ○ Facial Muscle pain:	heterogeneity was explored with subgroup analysis by type of chronic primary pain. This did not explain the heterogeneity, so the committee agreed it provided no evidence against making these recommendations for all people with chronic primary pain. Where there was reason to believe separate considerations were required, this was detailed in the recommendations, for example the research recommendations for gabapentinoids and local anaesthetic for CRPS. Whilst it is true that a number of studies included in the review were in women with fibromyalgia, the evidence for antidepressants included other chronic primary pain populations such as chronic pelvic pain, somatoform pain, interstitial cystitis, chest pain and neck pain. Heterogeneity was not observed between types of chronic primary

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				If you look at the Forest plot Page 255, You will conclude that gabapentin up to 4800mg a day is actually effective in alleviating masticatory muscle pain of more than 6 months: even if it is only 1 study" • "There is a long list of CPP treatments that will be stopped, eg, lidocaine for CPP that many patients find helpful. Chronic Primary Pain is an umbrella term for the lack of an obvious cause. However, there are underlying mechanisms and our treatments should be based on mechanisms physical and psycho behavioural. Consider lidocaine patches – allowed only for PHN, where as we would use them for all allodynia if the govt/NICE/CCGs would allow. The current NICE guidelines are flawed because they don't consider mechanisms, they use the umbrella of CPP and they will stop us treating patients except by exercise."	pain, so the committee agreed it provided no evidence against making this recommendation to be for all people with chronic primary pain. The rationale for the recommendation includes the committee's discussion of whether one antidepressant class could be recommended over another, they state 'Duloxetine (the only SNRI with evidence for chronic primary pain) had a larger amount of long-term evidence of effectiveness. However, due to the lack of head-to-head comparisons between the antidepressant classes, the committee could not recommend duloxetine in preference to the other antidepressants for which there was evidence.'
University College London Hospitals NHS Foundation Trust	Methods/ Algorithm	Appendix Methods	009, 009 012	The 'sifting' and review protocols were drafted by the 'NGC technical team' first which seems not to include clinicians. Only reviewed by clinicians after this initial sift? It seems inappropriately rigid methods were used to assess the evidence in this field?	Thank you for your comment. The technical team undertaking the reviews are skilled and trained in evidence based medicine and systematic review methodology. They

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				• Many of the recommendations cannot be made because of the evidence was too uncertain, not of high enough quality but the criteria used to assess this were inappropriately rigid." • "The end points they used to assess for efficacy are too rigid. Brief was too rigid" • "They also apply the wrong standards to the inclusion criteria: e.g. applying research standards 'risk of bias'. You cannot blind therapists to treatment they are providing. The wrong standards have been applied. Standardisation and fidelity are created by manuals, protocols and training." • "Theadom 2015323 was also excluded because the included interventions were mind-body interventions such as cognitive behaviour therapy, biofeedback, mindfulness meditation, movement and relaxation therapies, which did not meet the protocol definition of a pain management programme for this review. 'Indirectness': Mindfulness is PART of the ACT model – not a mix of therapies. Whoever made this decision was not familiar with the therapies they are deciding on: The below quote from guidelines shows that there is little appreciation by excluders of what the content of a PMP is: Mindfulness meditation,	undertake the sifting of the evidence at title and abstract stage, and again at full text, according to the agreed review protocols. The protocols are developed in close collaboration with the committee to contain all of the relevant information required to undertake the sift, and the review. At the title and abstract stage, if there is uncertainty as to whether an item should be included, the full text is ordered. If uncertainty remains on review of the full text, this is discussed with members of the committee as appropriate. Any potential missing items or queries of inclusion raised by committee members, or co-opted members, are checked by the technical team. Methods followed are consistent with the NICE guidelines manual. We do not agree these are too rigid, or that the wrong standards are applied – for

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				movement and cognitive behaviour therapy are core elements! PMPs consist largely of mind-body interventions	example risk of bias assessment is a critical component of any high quality systematic review. Whether or not the study blinded participants and/or investigators to the intervention is part of the risk of bias assessment. Inability to blind to a treatment does not remove the possibility of the placebo effect nor is it a reason not to undertake full risk of bias assessment and account for this in the quality assessment. The methods allow a thorough assessment of the body of evidence and all evaluations of the evidence are discussed and interpreted with the committee. Theadom et al. was not included as a systematic review in full in the pain management programmes review because it did not meet the protocol agreed criteria for the review as you state, however all included studies from Theadom et al. were checked for inclusion in the pain management

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					programme review and psychological therapies review and included as appropriate. The committee note and agree that cognitive behavioural or mindfulness approaches are components of a pain management programme, but when agreeing the protocol definition the committee agreed that there also needed to be interaction with a physical component to be considered a pain management programme rather than a psychological therapy that could be delivered outside of a pain management programme intervention. The committee were aware of guidelines produced by other organisations with differences in what was considered to be a pain management programme. The committee noted there is no single agreed definition used across these interventions consistently, but that psychological and physical

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					components were the most consistently included features.
University College London Hospitals NHS Foundation Trust	Methods – Analysing Evidence	016 - 020		• "The problem with pain research is that phenotyping is not done properly -dilutes treatment effects ++. Meta analyses compound this and you end up with generalisations that nothing is effective." • "Interpretation and application of data has potential for major errors."	Thank you for your comment. The committee acknowledge that pain research does not enable us to determine which groups may be more likely to benefit and agree that this may mean effects are not observed across a population of those with chronic primary pain (or chronic pain, where relevant in the review). Subgroup analysis by type of pain in our systematic reviews was considered where heterogeneity was observed to explore this further, but there was no consistent finding from subgroup analysis where required. Recommendations cannot therefore be made for more specific groups from the available research.
University College London Hospitals NHS Foundation Trust	Future Research Recommendations	012	Line 018	• "Relaxation trials – aren't there lots already that tell us it's a pretty weak treatment on its own?"	Thank you for your comment. For chronic primary pain there were 5 studies for relaxation compared to usual care identified relevant to the review protocol. The committee

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					agreed the results did suggest some benefit, but further research, particularly with long term follow up was required.
University College London Hospitals NHS Foundation Trust	Future Research recommendations	011 of 028	008-009	• "The suggestion on p11 – a key recommendation for research – that "optimum characteristics" of a PMP can be found by simple studies, is very naïve in the face of 20 years research trying to do that. It also assumes that one size will fit all, which is worse than naïve. Most of their recommendations for research will just lead to wasted effort and money repeating existing studies that have got us to this point."	Thank you for your comment. On consideration of comments from stakeholders regarding the extensive amount of research there has been to date on pain management programmes, the committee have decided not to recommend further research.
University College London Hospitals NHS Foundation Trust	Guideline as a whole	General	General	Suggested next steps for NICE recommendations • "There should be proper funding of combination studies: medications+ psychological intervention +acupuncture+exercise therapy" • "Health economists should calculate the cost of someone with primary chronic pain and economic costs: a. Social benefit b. Extra healthcare costs c. Lost taxes	Thank you for your comment. The committee cannot comment on funding of combination studies. Research recommendations have been made on key areas of uncertainty that were reviewed within the guideline and may inform future updates. The guideline follows standard NICE methods for taking into account

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				The Quality Adjusted Life Years (QALY) cost threshold of £20,000 for NICE to recommend treatment only reflect a tiny portion of the overall cost of chronic pain." • "Practical choices: 1. Allow use of pain modifying medications (and other treatment) for treating Chronic "primary" chronic pain: plan A (current treatment regime) and fund more research 2. If not, Plan B make sure every patient labelled with these conditions is properly investigated and other causes of their chronic pain excluded Problem with plan B is it will be: a. More expensive b. No capacity 3. If you stick to these proposed recommendations, what happens with the substantial proportion of patients where SNRI's, acupuncture, ACT and CBT plus exercise do not work? a. Promote repeated visits to GP, chronic pain services and exacerbate the current frustrations amongst clinicians and making recruitment more difficult b. Put them through the same treatment pathway you suggested:	economic considerations. More details about this are available on the NICE website. Cost effectiveness analyses are used to inform guideline recommendations. These compare the costs and health benefits of different courses of action in order to assess what is the most cost effective use of NHS resources to maximise population health. The potential resource impact of implementing recommendations is also considered. The committee agreed the evidence reviewed within this guideline did not demonstrate benefit for the majority of the medicines reviewed for the management of chronic primary pain and due to the risk of harms, they have been recommended against. The committee agree that a holistic assessment of people with chronic pain is essential to good management. Additional recommendations have

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				Supposedly a quote by Albert Einstein (although I cannot find the primary source) "The definition of insanity is doing the same thing over and over again, but expecting different results."" • "Apart from the ideological limitations of combining CP and CPP together in one document... the educated, motivated and informed reader will have to pay inordinate attention to separate the information pertaining to CP from CPP. So what hope do skim-readers/other professionals/public/journalists have of correctly interpreting the guidance?" • "I would suggest they abandon the idea of a document covering all of chronic pain - or at least, separate this document from guidance on CPP - or, if not this, then commission a review by a Human Factors consultant prior to preparation of their second draft." Conclusion Our overriding recommendations from the UCLH PMC are: 1. These guidelines must be put on hold until fundamental flaws are corrected, and nomenclature clarified and applied consistently. Pushing such unclear	been added this section of the guideline (1.1) to highlight the importance of ruling out possible causes of the pain and managing that accordingly. The importance of reassessing diagnosis over time particularly if presentation changes is also highlighted. A recommendation has also been made to develop a shared care and support plan with the person considering their abilities and goals. This should include consideration of all treatment options and should be revisited if one treatment is not beneficial for the person. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings

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				guidelines through during an unprecedented pandemic is inappropriate. 2. The committee needs to take external advice from those with the appropriate knowledge base on: A. The classification issues B. The evidence base used C. How the evidence base is applied to CP, CPP and individually defined conditions D. The committee and NICE musttake responsibility for transparent working with NHS England and the professional Societies and Colleges to ensure safe and equitable implementation of the final guidelines. Currently the guidelines place those living with chronic pain at significant risk.	throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where

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					resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
University College London Hospitals NHS Foundation Trust	Guidelines	General	General	We would like to express our appreciation to NICE and the CPP guideline authors for their effort in collating and summarising evidence that can improve patient's care and quality of life and guide healthcare professionals facilitating the best available care pathway. Our comments are specifically related to orofacial pain and we hope these are helpful.	Thank you for your comments.
University College London Hospitals NHS Foundation Trust	Methods	General	General	We see the term "Chronic primary pain" as a broad classification and not as a diagnosis and it is unclear which facial pain diagnosis are being classified as chronic primary pain. Whilst the broader description refers to orofacial pain, the search terms used on the search strategy include burning mouth syndrome, neuropathic pain and myofascial pain. Trigeminal neuralgia and post herpetic neuralgia are classified as orofacial neuropathic pains for which other NICE guidance would apply, so this can cause misinterpretation. We would like to see some clarification on this point. A comprehensive classification for orofacial pain diagnosis has been published earlier this year and could perhaps be taken into account in this work	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant

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				(International Classification for Orofacial Pain, DOI: 10.1177/0333102419893823).	recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. Inclusion criteria for conditions under the umbrella term of chronic primary pain was based on those listed in ICD-11 at the time of development and does include orofacial pain. This is detailed as a condition included in the review protocols that are provided in the appendices of the review chapters. The inclusion of 'neuropathic orofacial pain' in the search strategies was an oversight. We agree that this is a chronic secondary pain and studies specifically on neuropathic orofacial pain would not have been included when the

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					records were sifted. However the search terms would also have picked up chronic orofacial pain as a result of line 2 of the strategy where "Chronic adj4 pain" is considered; within it - ((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab. This was agreed in quality assurance of the search to cover the term chronic orofacial pain, amongst others from the protocol.
University College London Hospitals NHS Foundation Trust	Methods	General	General	We are concerned that the evidence gathered to make recommendations for or against different management options has been mostly extracted from studies assessing patients with fibromyalgia. For the reader of the guidance with more or less experience in scientific literature (health care professionals, members of the public, patients or carers or even members of the press) the advice will be the same for all the conditions under the umbrella of chronic primary pain. Again, this is misleading, because not all orofacial pain is classified as chronic primary pain.	Thank you for your comment. All of the evidence reviews for interventions were for all types of chronic primary pain where evidence was available. For some reviews there was a predominance of females with fibromyalgia, but evidence for other types of chronic primary pain was available. The view of the committee is that there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no

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					reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary pain. If there was reason to believe that specific considerations were required, this was detailed in the recommendations. The reasoning, exceptions and details regarding this are stated in each relevant rationale and relevant discussion of the evidence sections. Clarity has been added to the guideline overview page and context section regarding the populations covered within the guideline.

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University College London Hospitals NHS Foundation Trust	Guideline	015	004	Even though we are aware that robust evidence is lacking for the management of some orofacial pain conditions, we are concerned that patient education programmes are not indicated. Patients with chronic orofacial pain should be referred promptly to centres that specialise in managing facial pain e.g. dental schools, oral medicine or maxillofacial surgery units in district general hospitals. These centres have available pain management programs adapted to these patients where specific outcomes of treatment can be addressed. Again, we would like to point out that the evidence was extracted from populations of fibromyalgia, knee pain, and osteoarthritis patients, etc. The impact of orofacial pain in quality of life and physical function, for example, can cause difficulties in completing a meal or being intimate with family or friends in a way that we do not expect other chronic pains to cause. We certainly need to see more emphasis placed on psychology support.	Thank you for your comment. In consideration of stakeholder comments, the evidence in the pain management programmes review has been reanalysed to separate the chronic primary pain population, to be consistent with other reviews within the guideline. The view of the committee is that within the chronic primary pain umbrella there are likely to be shared mechanisms across different types of chronic primary pain, despite those not being fully understood, the similarities are such that there is no reason not to consider evidence to be relevant to all types of chronic primary pain unless evidence suggests otherwise. In the evidence reviews, types of chronic primary pain were pooled, but where heterogeneity was present this was explored with subgroup analysis when data allowed. Where carried out, in most cases it did not demonstrate a difference in effect according to type of chronic primary

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					pain. The committee agree that for this population most of the evidence did not show an improvement in quality of life and there was no evidence of benefit for pain, physical function or psychological distress. They therefore did not include a recommendation on the topic. The committee did agree that there was sufficient evidence to recommend CBT and ACT however. The rationale for pain education has been reworded to clarify that the committee consider education should be part of good clinical practice, and that providing information on pain is included in the recommendations for developing a care and support plan. Further detail on the committee's discussion on pain education has been added to the discussion of the evidence in Evidence review F. The committee discussed that education about the science of pain may be a useful enabler to people with chronic primary pain being able to effectively

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					cope with and manage their pain, but may not be expected to improve patient reported outcomes as a standalone intervention. They therefore agreed it was more appropriate to include as part of the care and support plan considerations rather than suggest further research specifically for its effects on management of chronic primary pain.
University College London Hospitals NHS Foundation Trust	Guideline	General	General	We would advise caution when utilising the present guidance as many patients will be inappropriately labelled, advised and cared for, which ultimately result in a higher health care utilisation with all underlying financial and societal implications.	Thank you for your comment. Clarification of definitions used in the guideline and additional recommendations for considering a diagnosis have been added to minimise the risk of inappropriate labelling and care.
University of Bristol	Guideline	General	General	We understand that the guidance relates to chronic primary pain as defined in ICD-11. We also understand that the definition is provided (page 11). We suggest that the definition of chronic primary pain is made even more clear so that the definition and therefore scope of the guidance is clear at the outset and throughout.	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received

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					we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation.
University of Bristol	Guideline	008 & 023		We are concerned that amitriptyline is included amongst a list of anti-depressants. In our experience of medications for adults with chronic pain, amitriptyline is given at 10 or 20mg where it is not thought to have any anti-depressant activity (which may require doses of 150mg) but instead works through regulation of sleep.	Thank you for your comment. The list of antidepressants stated in the recommendations are those that were demonstrated to be of benefit for chronic primary pain from the evidence review. There was evidence of benefit of amitriptyline at a range of doses, including one study of 5mg amitriptyline which did demonstrate positive effects on patient reported outcomes. These have been recommended because of the

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					evidence reviewed showing effects on pain, quality of life. We cannot comment on the mechanism by which they are working but the effects demonstrated were sufficient to recommend their use.
University of Leeds	Algorithm	General	General	Our group would be happy to discuss the intervention further and provide patient feedback to inform use of biopsychosocial interventions for chronic primary orofacial pain rather than use of invasive and irreversible treatments that are harmful to patients.	Thank you for your comments, we have responded below.
University of Leeds	Guideline, Evidence review C	General	General	Chronic primary orofacial pains, particularly TMD which is the most commonly reported, are classified as chronic primary pains by ICD-11 (Nicholas et al. Pain 2019) and are therefore relevant to the current NICE chronic pain guidance. In particular, we wish to highlight the burden on patients of current poor management of chronic primary orofacial pains and share positive outcomes from use of our biopsychosocial supported self-management intervention. Key evidence is as follows: • In our recently completed systematic review (attached) we have shown that biopsychosocial self-management interventions improve long term pain and depression in patients with TMD and chronic orofacial pain.	Thank you for your comment. Orofacial pain, and TMD, was included where evidence relevant to the review protocols was available.

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				• We have translated this work into a supported self-management intervention which was highlighted in the NIHR annual report page 21 (https://www.nihr.ac.uk/about-us/our-contribution-to-research/research-performance/12228_NIHR_Annual_Report_18_19.pdf)	
University of Leeds	Methods			• The intervention (https://licensing.leeds.ac.uk/product/self-management-of-chronic-orofacial-pain-including-tmd) has received very positive patient feedback. This feedback included patient experiences which draw parallels with the guideline findings of poor management and use of medications. For Chronic orofacial pain, the impact of poor management is much worse and often includes extraction of sound teeth, use of surgery and mouthguards with huge costs to patients.	Thank you for your comment and for this information. We will pass this information to our local practice collection team. More information on local practice can be found here: www.nice.org.uk/sharedlearning
Versus Arthritis	Comment form question 1	N/A	N/A	**1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.**	Thank you for your comment. The committee agree people should be able to make informed decisions on

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				Areas of the guideline which will be challenging to implement • The guideline makes recommendations about both non-pharmacological and pharmacological interventions for the management of chronic pain. There is variation in existing clinical practice in discussing options for management of chronic pain, and also local variation in the availability of some management options. Respondents stated concern that after having spent time (sometimes years) establishing what works for them, some options may be less likely to be available to them in future. People stated concern that the removal of choice, and hope, may have a negative and life-threatening impact for some people. • It was suggested that putting this guideline into practice would require longer consultation times for people to discuss pain management options. These may be with either with primary and secondary care clinicians. **Accurate interpretation of the guideline and implementation in practice** • Respondents stated concern that the draft guideline is already having an impact on clinical practice - ahead of its publication and implementation, and beyond its draft recommendations. For example, the	which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or significant harms and those who are receiving benefit and low harms. For

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				guideline recommends that '1.3.12 If a person with chronic primary pain is already taking any of the medicines in recommendation 1.3.11, explain the risks of continuing'. There are concerns that, in practice, this is resulting in people being advised to discontinue medication or other forms of healthcare, and that they may do so without a shared decision making discussion or adequate support. **Impact on relationships between health care professionals and people in chronic pain** • It was suggested that effective management of chronic pain can depend on strong relationships between the person with pain and the healthcare professionals they contact. It was suggested that the move away from some management options, and the potential reduction of choice and hope may damage working relationships, and cause frustration on both sides. **Limited options for those newly diagnosed** • Respondents stated the importance of recognising people as individuals (see also comments on section 1.1.1) and suggested that although the guideline can provide recommendations, there is a need for 'fluidity' to enable people try different management options and to find unique/personal ways of managing their pain. People expressed concern that	people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed. The scope for this guideline did not include reviewing interventions to support withdrawal and therefore recommendations on this topic cannot be included. The guideline highlights that there is a NICE guideline on safe prescribing and withdrawal management currently in development where this topic is covered. The committee note that this will not be published until after the current guidance, however they agree that there are sufficient considerations stated here, that can be used with clinical expertise to

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				those who are newly diagnosed with chronic pain will have a reduced range of options. The challenge in implementing the guideline is to ensure that it is implemented accurately in line with its recommendations, and that shared decision making is in place to enable people make informed decisions about their management options (page 4). Section 3.1.13 indicates that NICE is also developing another guideline on 'medicines associated with dependence or withdrawal symptoms' however this is not due for publication until November 2021. NICE should consider the most appropriate timeline for publishing both guidelines.	support people to reduce or stop safely in the absence of this guideline. The committee agree that longer consultation times may be required to fully implement the recommendations in the guideline. This is highlighted in their considerations of how the assessment recommendations might impact current practice. The committee agree people should be able to make informed decisions on which treatment to use. A recommendation has been included on developing a shared care and support plan stating that there should be a discussion of the benefits and harms of all treatments. The committee agree this should be based on those treatments demonstrated to be effective for chronic primary pain, and the evidence reviewed in this together with committee expert consensus opinion was that the

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					majority of medicines are not beneficial in the management of chronic primary pain or the risk of harm outweighs any benefits.
Versus Arthritis	Comment form question 3	N/A	N/A	**3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)** The importance of information and resources to help people learn more about pain and its management was stated. Australian engagement and educational materials were suggested to be at the forefront.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.
Versus Arthritis	Comment form question 4	N/A	N/A	**4. The recommendations in this guideline were developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.** The coronavirus pandemic has resulted in changes to healthcare, including the more widespread use of virtual consultations and referral to virtual/on-line interventions. This is perhaps most relevant to section 1.1 (assessment and management of chronic pain) and sections 1.3.1-1.3.2 (exercise for chronic pain). The guideline should take into account innovations developed during the pandemic which are relevant to people with chronic pain, for example: What are the differences/consequences of assessment of chronic pain made virtually rather than	Thank you for your comment. This guideline will note when published that it was developed prior to the COVID-19 pandemic. NHS services are adapting to implement interventions as appropriate following national guidance relating to COVID-19 measures and with appropriate social distancing. This is an evolving situation and so the recommendations remain with considerations of where evidence demonstrates interventions are clinically and cost effective.

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				face-to-face?; What are the opportunities created by an increase in virtual exercises classes?	Implementation of these should take the current context into account.
Versus Arthritis	Guideline	004	003-012	**1.1.1 Assessing all types of chronic pain** Recommendation 1.1.1 was strongly welcomed. Respondents stated the fundamental importance of being recognised as an individual and of being listened to. It was suggested that this should be the basic starting point for any assessment. Communication, information (including recent research and references) and shared decision-making were stated to be essential or important. People also stated the importance of being able to meet frequently, and with the same healthcare professional/s. It was also suggested that different approaches are needed for people who are not confident in communicating about their health.	Thank you for your comment.
Versus Arthritis	Guideline	004	013-017	**1.1.2 Assessing all types of chronic pain** Respondents stated that the holistic approach to understanding how pain affects someone's life was helpful. Consideration of the impact of pain on work, sleep and lifestyle were welcomed, and the impact on psychological well-being and relationships highlighted (these were described as ongoing support networks).	Thank you for your comment.
Versus Arthritis	Guideline	004-005	018-020; 001-003	**1.1.3 Assessing all types of chronic pain** Understanding people's understanding and acceptance of their condition was stated to be important. It was suggested that the *impact* on family, carers and others should also be included, alongside their understanding and acceptance.	Thank you for your comment. The committee agree this is important and this has been added to the recommendations.

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Versus Arthritis	Guideline	005	004-006	**1.1.4 Assessing all types of chronic pain** It was suggested that more neutral language should be used, e.g. 'pain may need to be managed', rather than 'pain may not improve or may get worse.'	Thank you for your comment. The committee understand the viewpoint, and agree this needs to be communicated sensitively, but believe this does need to be clear. Evidence from the review also demonstrated that people valued honest information about the prognosis.
Versus Arthritis	Guideline	005	007-008	**1.1.5 Assessing all types of chronic pain** The use of plans – described as 'personal plans' or 'care plans' - was supported. It was stated that these should be flexible and there was agreement with the recommendation that these should take into account individual preferences and ability.	Thank you for your comment.
Versus Arthritis	Guideline	005	012-014	**1.1.7 Assessing all types of chronic pain** Provision of information was suggested to be important, but it was stated that this should be tailored depending on individual level of engagement and should not overload people.	Thank you for your comment. The committee agree, and also cross refer to the NICE guideline on patient experience in adult NHS services (CG138) where this is discussed more.
Versus Arthritis	Guideline	005	015-016	**1.1.8 Assessing all types of chronic pain** Recommendation 1.1.8, which states the need for sensitivity in communicating negative or normal results, was welcomed. However, it was strongly stated that this recommendation could make broader points around communication generally, not just in relation to results. Respondents stated the importance of pain being recognised (not dismissed as 'all in your mind') and that a	Thank you for your comment. The committee agree this is important, but focussed specifically for communication of negative or normal test results as evidence highlighted that this was a particular are of importance to patients. The

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				reluctance to take medication should not be interpreted to mean pain levels were low. The importance of emphasising what could be tried or tested next was emphasised. It was also suggested that maintaining a sense of hope outweighed the risk of giving 'false hope'.	committee agree that the recommendation to foster a supportive and collaborative relationship also highlighted this approach. A comment has been added to the recommendations to highlight that quality of life can improve even if pain remains unchanged.
Versus Arthritis	Guideline	005	09-011	**1.1.6 Assessing all types of chronic pain** There was support for outlining the possible benefits, risks and uncertainties of management options. It was suggested that some people may not be aware of management options and would need signposting. It was suggested that people should be given clear, accurate information about risks and benefits, and that blunt negative language (i.e. being told that any particular option 'would not work') is unhelpful for some. It was noted that care should be taken when estimating how long a management approach would take to become effective as this could set expectations which if unmet may be harmful.	Thank you for your comment. More recommendations on giving information on treatment options to aid shared decision making are provided in the NICE guideline for patient experience in adult NHS services (CG138) which this guideline cross refers to.
Versus Arthritis	Guideline	006	011-014	**1.3.1 Exercise for chronic primary pain** A range of points were made in response to Recommendation 1.3.1 (offering a group exercise programme). It was suggested that people should be supported to find a method of exercise which they could sustain, and which would fit their lifestyle (rather than the	Thank you for your comment. The committee agree that the type of exercise should be sustainable for the person and tailored to their needs. They acknowledge this might require individual tailoring within a group

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				default being the offer of a group exercise programme). It was suggested that group exercise could lack adequate personalisation. In contrast, the benefits of social support within group exercise were welcomed by some respondents. Opportunities around virtual/on-line classes, including those which could be done in the home, were highlighted although there was also concern for exclusion of people without the necessary technology. The need for better availability of exercise classes was also stated. Lastly, it was stated that short-term pain relief through exercise may give way to a re-bound of pain to a more intense level, highlighting the need for a personalised and paced approach.	setting. They considered that people delivering exercise programmes are able to do this within a group and frequently tailor programmes to individual needs. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Versus Arthritis	Guideline	006	011-017	**Managing chronic primary pain: exercise for chronic primary pain** The guideline recommends the offer of a supervised group exercise programme.	Thank you for your comment. The evidence reviewed supported the clinical and cost effectiveness of

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				In evidence gathered by DJS Research Ltd for Versus Arthritis in 'Physical activity scoping research' (December 2019) people with musculoskeletal conditions reported a number of barriers which held people back from doing exercise, in particular joint pain, and fatigue and/or pain caused by a musculoskeletal condition. People reported uncertainty about the types of exercise to do or concerns that exercise could make their condition worse. Although this survey was among people with musculoskeletal conditions, these points may equally apply to those with chronic primary musculoskeletal pain. In this study, 64% of respondents said that they would prefer to get active on their own rather than in a group of people, and 52% said they would like it if there were more activities they could do at home. The guidance currently states that 'people's specific needs, preferences and abilities' should be taken into account, but should be expanded to clarify what should be offered to people with a preference to exercise alone. In the same study, 44% of respondents said that they associated physical activity with going to the gym, leisure centre, community centre or park, highlighting the importance of targeting exercise in a setting that is accessible to the individual where they live.	supervised group exercise programmes. No evidence was identified for online programmes, but the recommendation does not preclude the delivery in this format if deemed most appropriate. The committee acknowledge that some people may prefer to exercise alone, but this was not supported as an option to recommend as part of NHS treatment. The committee recommend that individual preferences and goals should be discussed and considered when making a shared care and support plan for management of their pain.

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Versus Arthritis	Guideline	006	011-017	**Managing chronic primary pain: exercise for chronic primary pain** 1.3.1 There should be an explicit recommendation in the guidance about the need for a conversation when making an offer (or the suggestion of) exercise to manage chronic pain. The conversation should include whether the person involved is currently physically active and if not, what are their barriers to being active. Barriers may be related to a person's belief or experiences of being active, or practical factors such as cost. A common instinct for people in chronic pain is to feel that they should rest to improve the pain they're experiencing. This misconception may need to explored. Some people with chronic pain may be active, but their level of activity either has little impact on their pain, or the improvements in their pain provided by activity have levelled off. For some, lifestyle/commitments/resources make staying active more challenging. These factors need to be understood and taken into account.[10]	Thank you for your comment. The committee agree that there should be an informed discussion about the person's preferences and goals when considering any management option. This has been included in recommendations that have been added in section 1.1 regarding developing a care and support plan. These recommendations also highlight that in the assessment there should be a discussion about how people's pain affects their life and vice versa, to highlight the need to take these factors into account.
Versus Arthritis	Guideline	007-008	002-015; 001-012	**1.3.3 – 1.3.7 Non-pharmacological management of chronic primary pain (other than exercise)** • Responses to recommendations 1.3.3 – 1.3.6 often reflected personal knowledge, experience and	Thank you for your comment. The guideline recommends the non-pharmacological interventions that

[10] DJS Research, Versus Arthritis Physical Activity Scoping Research (December 2019)

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				preference of particular pain management options. An overarching point was that it is important for a diverse range of non-pharmacologicalpain management options to continue to be offered/ recommended, enabling people to try a range of approaches. Responses on recommendation 1.3.5 (acupuncture) included agreement about a short course only, but conversely suggestion of the need for a longer course. Local availability of acupuncture was questioned and may be important for implementation of the guideline.	were demonstrated to be beneficial for people with chronic primary pain. The evidence reviewed didn't inform effectiveness of repeat courses of acupuncture. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments. The guideline reflects the evidence for best practice. The committee agree that there is variation in the delivery of some of the recommended services across the NHS. There are areas that may need support and investment, such as training costs, to implement some recommendations in the guideline. However, this will ensure that people with chronic primary pain will receive the appropriate care. This

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					guideline highlights areas where resources should be focussed and those interventions that should not be recommended, saving resource in other areas. Your comments will also be considered by NICE where relevant support activity is being planned.
Versus Arthritis	Guideline	008-010	013-015; 001-031; 001-010	**Pharmacological management of chronic primary pain** Feedback from Versus Arthritis 'Living well with arthritis'services indicates that people are concerned about losing access to medication that they currently use to manage their pain. The guideline states in section 1.3.12 that if people are taking any of the medicines in recommendations 1.3.11, the risks of continuing should be explained, but does not state that people should be advised to discontinue. Care needs to be given to ensure this recommendation is implemented accurately in clinical practice with robust shared decision making.	Thank you for your comment. This recommendation has now been reworded to include consideration of different circumstances, including explaining the lack of evidence of effectiveness, encouraging people to reduce or stop where possible, but also agreeing a safe plan to continue if people are receiving benefits from one of these medicines and low harms.
Versus Arthritis	Guideline	008-010	013-015; 001-031; 001-010	**1.3.11 Pharmacological management of chronic primary pain – pharmacological treatment not to be offered** • See also comment 1 above on the challenges of implementing the guideline. • Respondents stated concern that these pharmacological options would be not be offered. Respondents were aware of the complications associated with them but stated that at times people can reach a point when pain is unbearable and	Thank you for your comment. Evidence reviewed in this guideline, and the expert opinion of the committee is that there is insufficient evidence that these medicines benefit people with chronic primary pain. The guideline recommends antidepressants for their effects on

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				everyday activities (eating, moving, exercise, sleep) are impossible. Some of the pharmacological options (including opioids) were suggested to be the only option to enable some people to maintain quality of life and/or to continue at all. • It was stated that without some of these pharmacological options, people may seek out unregulated and potentially harmful alternatives (e.g. cannabis and other non-legal drugs). • A specific point was stated in relation to the availability of local anaesthetic infusions (which are listed in 1.3.11). It was stated that people have travelled significant distances (even going overseas) to receive this treatment when it was not locally available, indicating the value some people place on this management option. Other points included the need to consider not only the impact of pharmacological treatment, but of possible side effects including weight gain.	chronic primary pain, but also non-pharmacological options for which there is better evidence of benefit. The recommendations for assessment also recommend a holistic assessment of the person with pain and for developing a care plan to manage their pain. All of the benefits and harms of treatments should be discussed when considering the best care plan including making people aware of the lack of benefit of many pharmacological options.
Versus Arthritis	Guideline	010	001-002	**1.3.12 Pharmacological management of chronic primary pain – risks of continuing** It was stated that inclusion of Recommendation 1.3.12 was very important. It was stated that people should be able to assess and make individual choices around risk and management options.	Thank you for your comment. The committee agree that the review of people already receiving these medicines is an important consideration. This recommendation has been reworded to include considerations for both people who are receiving little benefit or

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					significant harms and those who are receiving benefit and low harms. For people who are receiving little benefit or significant harms the guideline now states that they should be encouraged and supported to reduce or stop where possible. For people who are receiving benefit and low harms it is recommended that a shared plan to continue safely can be agreed.
Versus Arthritis	Guideline	011	007-009	**Recommendations for research: 1 Pain management programmes for chronic pain** The guideline would benefit from a research recommendation specifically on the use of technology, especially in the pain management programmes, to support people manage chronic pain.	Thank you for your comment. Research recommendations can only be made on topics that have specifically been reviewed within the guideline.
Versus Arthritis	Guideline	011-013	004-026; 001-026; 001-003	**Research recommendations** • Research recommendations were welcomed, with specific reference to the need for research into manual therapy and social interventions. • It was stated that further research is needed to understand the different sub-groups of people with chronic pain, and to understand the effectiveness of management options on these sub-groups. It was suggested that management options which are not found to be effective on broad groups of people with	Thank you for your comment. Research recommendations can only be made on topics that have specifically been reviewed within the guideline. Where research recommendations have been made this is because of a lack of evidence for all types of

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				chronic pain may prove to be effective in specific sub-groups. • The need for research into pain education was stated, including research to improve understanding of how to have effective conversations about management options with people in chronic pain. Other areas where further research was suggested to be important included treatments not referenced in the guideline (including CBD oil, alternative treatments, use of heat pads).	chronic primary pain, and therefore specific subgroups have not been specified to focus on within the research, although the templates provided do not preclude that as an option. The committee discussed making a research recommendation for pain education. They agreed that pain education may be a useful enabler to people with chronic primary pain being able to effectively cope with and manage their pain, but may not be expected to improve patient reported outcomes as a standalone intervention. The committee therefore agreed not to include a research recommendation. This is detailed in the discussion of the evidence in evidence review F.
Versus Arthritis	Guideline	011-013	004-026; 001-026;	**Recommendations for research** The guideline would benefit from a recommendation for further research into the stratification and identification of risk factors (or high risk groups) for chronic pain, and the association of chronic pain and protected	Thank you for your comment. The committee did recommend further research into What risk factors enable stratification of treatment for people

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			001-013	characteristics. Moving away from a condition-based approach to treatment, towards a mechanistic, symptom-based approach has been demonstrated to be effective in chronic neuropathic pain.	aged 16 years and over with chronic pain, this is detailed in the research recommendations section at the end of the guideline, and in evidence review A.
Versus Arthritis	Guideline	011-013	004-026; 001-026; 001-013	**Recommendations for research** Implementation of new, or changed clinical practice and innovation is a complex, multi-faceted process. However, there is lack of research in health services implementation which could help to inform and improve the success of embedding interventions across healthcare settings. The guideline should recommend this. As an example, adoption of the Versus Arthritis-supported STarT Back Toolwhich has now been adopted across the UK and internationally, required early identification of possible barriers amongst healthcare professionals through local community of practice engagement, including lack of clinicians' time to undertake the approach, lack of training to deliver it and lack of understanding of the research underpinning it.	Thank you for your comment. Research recommendations can only be made on topics that have specifically been reviewed within the guideline.
Versus Arthritis	Guideline	011-013	004-026;001-026; 001-013	**Recommendations for research** The research recommendations are focused on individual interventions, including psychological therapy, pharmacological interventions and manual therapies. There is also a need for further research into approaches which take a more holistic approach to the management of chronic pain.	Thank you for your comment. Research recommendations can only be made on topics that have specifically been reviewed within the guideline. As these interventions were reviewed as single interventions and were identified to be lacking in

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				The MRC/ESRC/BBSRC-Versus Arthritis Advanced Pain Discovery Platform will support large and ambitious multidisciplinary consortia to pursue innovative, ambitious big ideas in chronic pain research. Its research agenda will be informed in part by Arthritis Research UK's 'A research roadmap for pain' which was co-produced by people with pain.	evidence, this is where the research recommendations are focussed.
Versus Arthritis	Guideline	N/A	General	**General** • **Recognition**: It was noted that approaches to the management of chronic pain have changed over time. Greater recognition and attention to this area of healthcare, through the development of the guideline, was welcomed by some respondents. • **Language**: The guideline is intended for readers including 'people with chronic pain, their families and carers' (page 1). Some respondents were unfamiliar with some management options, in particular biofeedback (1.3.4), and interferential therapy (1.3.6). It would be helpful to define these or to provide links/references. **Age range:**The guideline is drafted to apply to assessment and management of chronic pain in the over 16s. People suggested the guideline and its recommendations are not appropriate for people aged 16-18 years.	Thank you for your comment. A glossary is included to accompany the guideline, at the end of the methods chapter. The psychological therapies are also discussed in more detail in Evidence review F. The committee agree it was important to add some specific considerations for people aged 16-18. Recommendations have been added to the assessment section and pharmacological management, and where relevant discussion is included in the evidence reviews.
Wellmind Health Ltd	Guideline	006	002	This recommendation states that there is inconsistent evidence on the effectiveness of Pain management programmes with only 'small improvements in quality of	Thank you for your comment and for providing this information. The reference provided for this study has

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				life seen across 8 studies' a well as 'uncertainty about cost-effectiveness' seen in the rationale for this recommendation, page 15, line 4, leading to the recommendation for research, page 11, line 7-9. We have evidence from a research study conducted with the chronic pain service of Buckinghamshire Healthcare NHS Trust measuring outcomes for chronic pain patients enrolled on our fully online pain management programme 'Pathway Through Pain'. The study shows these patients showed significant improvements with regard to their perceived health status, level of disability, mood, confidence managing pain, problems in life due to pain and level of pain. Around one-third of participants made reliable changes in their levels of disability, depression and anxiety. This also showed a £240 cost saving per patient which was a 45% reduction in healthcare costs, 24% reduction of daily problems and 20% quality of life boost. The research findings evaluating the clinical effectiveness and cost-savings of Pathway Through Pain were published in the British Journal of Pain in July 2019 and boost the evidence base that Pain management programmes, including online ones are an effective and cost-effective way of treating chronic pain patients. Pimm, T. J., Williams, L. J., Reay, M., Pickering, S., Lota, R., Coote, L., Sarhan, F. (2019). 'An evaluation of a digital pain management programme: clinical effectiveness and cost savings', British Journal of Pain.	been reviewed, but as it is not an RCT it does not meet the protocol inclusion criteria for this review.

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Welsh Pain Society	Guideline	general	general	The Welsh Pain Society represents multidisciplinary teams and practitioners, who are working and developing services to treat acute and chronic pain across Wales. The council of the society has read with concern the current draft, which aims at the recently published ICD11 definition of chronic primary pain. The title of the draft however states: 'chronic pain in over 16s…'. NICE effectively mixes conclusions aimed at 5 % of the population and applies it to all patients with chronic pain (up to 45 % of the population in the UK according to BPS). Chronic primary pain by definition is a diagnosis of exclusion, and therefore depends on the ability and experience of primary care practitioners to consider the vast field of potential somatic and other treatable diagnoses. In addition there is the concern that primary pain may often coexist with secondary pain and as such will lead to confusion over the correct treatment approach. The WPS is generally in agreement that chronic primary pain, with no discernible cause, and primarily defined by psychosocial factors, needs to be approached differently to other causal pain conditions. We however are concerned about specific recommendations within the guidance:	Thank you for your comment. The committee agree that it is important this guideline is clearly labelled; definitions are clear and that there are relevant signposts to other guidance where appropriate. In consideration of the stakeholder comments received we have renamed the guideline and added subheadings throughout as well as adding wording to relevant recommendations in order to clarify and avoid any misinterpretation. Further detail about the definition of chronic primary pain has been included on the overview page and in the context section which is now placed at the start of the guideline, and a visual summary has been added clarifying what populations are covered by each recommendation. A recommendation has also been added for when to consider a diagnosis of chronic primary pain. Healthcare professionals in primary

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				- The selection of evidence omits a number of published Cochrane reviews. This leads to selective bias.
				- The recommendation of acupuncture in very specific setting ignores the poor evidence that generally surrounds acupuncture for pain conditions whilst limiting provision for a chronic condition that requires ongoing support.
				- The exclusion of virtually all available pain medication risks that patients will have their individual circumstances ignored and medication stopped
				  - even if they are beneficial in an individual patient,
				  - even if there is a secondary pain also present, for which those medications are indicated
				- The recommendations regarding PMP risk a defunding of established MDT led PMPs even though those programmes are primarily based on ACT and CBT, whilst adding aspects that can focus on patient specific issues. Based on local experience such PMPs produce very good outcomes for correctly selected patients.
				The general concern is that the recommendations risk undermining the stated goal of patient involvement in
					care should feel confident to be able to distinguish between pain secondary to underlying disease and chronic primary pain and can carry out these assessments in most cases. However, it is recognised that distinguishing between primary pain and pain secondary to other causes can be difficult, so if doubt exists referral for specialist advice or assessment might need to be considered
					A recommendation has also been added to highlight that chronic primary pain and chronic secondary pain can coexist. This guideline cross refers to other NICE guidelines for the management of chronic secondary pain. In these cases clinical judgement should be used to determine management for the type of pain being treated according to the relevant NICE guideline. All Cochrane reviews were considered for inclusion, they were not selectively included. Where they met the protocol criteria

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				decision making process when commissioners and Health Boards implement the guidance without further scrutiny, for reasons of a cost cutting exercise and a destruction of services that were established with great difficulty. However, the main concern of the welsh pain society is that the title and content of the guidance are incongruent and as such the guidance is wide open to misrepresentation. The inevitable consequence is the further curtailing of service provision at the detriment of the majority of pain conditions that require more specific medical treatment and medication trials. Furthermore, the guidance may lead to indiscriminate withdrawal of pain medication without checking efficacy in terms of functional abilities, leading to unnecessary distress and a failure of a patient centred approach. The Welsh Pain Society strongly recommends an overhaul of the draft guidance and to make absolutely and unequivocally clear the aim of the guidance within the title, along with a clear distinction of the difference between primary pain and secondary pain. With best regards The Officers of the WPS Council	to be included they were, and in cases that they could not be, the reference lists of all of their included studies were checked for relevance for inclusion in the guideline reviews. The committee agreed that overall the large body of evidence demonstrated a benefit of acupuncture, and although some of the evidence varied in quality, this was a consistent finding, also supported by some moderate quality evidence. Consistent benefits were observed for quality of life and pain compared to sham as well as usual care from a large evidence base. Benefits were also observed in function and psychological distress. De novo economic modelling also supported the recommendation for chronic primary pain demonstrating it to be cost effective. The recommendation is written as 'consider' rather than 'offer' partly

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					because of this varying evidence quality, and uncertainty in the maintenance of the effects long term. The committee agree that chronic primary pain requires long term management. The evidence base for all management options considered in this guideline is based on shorter term courses of treatment as reflected in the recommendations. The committee agreed that there should be a holistic assessment to develop a care and support plan with the person with chronic primary pain and that the treatment options should be discussed at all stages of care. In the case of acupuncture specifically, the evidence didn't inform effectiveness of repeat courses. The committee agreed this was important to determine and therefore included a research recommendation to inform future updates of this guideline. This research recommendation has been made high priority in response to stakeholder comments.

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					The committee agreed that the evidence reviewed for the majority of medicines did not support recommending them for chronic primary pain. There was a lack of evidence of effectiveness and evidence of harm. The committee agreed it appropriate to recommend against their use for this population. The committee agree that the evidence reviewed within the guideline did not inform a recommendation for or against pain management programmes. The committee discussed that although it may be expected that combinations of single interventions within a pain management programme might result in aggregated benefits or at least equal benefits to those shown from the interventions delivered individually, this was not reflected in the evidence. The committee discussed that there may be a number of possible reasons for this which were not apparent from this evidence review.

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					The committee discussed whether pain management programmes may be beneficial to some people with chronic pain and may also be cost effective, but that the evidence did not allow conclusions to be drawn. Decisions on existing services will be determined by local commissioners. Further detail of the committee's consideration has been added to the rationale in the guideline.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*