Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Acupuncture Association of Chartered Physiotherapists	General	General	The draft scope is not going to re-look at acupuncture regarding its negative recommendation in the 2014 guideline. In the notes from the workshops leading up to the draft scope, it is mentioned that acupuncture will not be included as it is being looked at in the guideline for 'Chronic Pain: Treatment & Management'. The AACP would like to clarify if this means that acupuncture and the fact that it was not recommended in the 2014 Osteoarthritis guideline will be removed from the new guideline altogether? Or is it going to appear in both the Osteoarthritis and Chronic Pain guidelines?	Thank you for your comment. We have updated the scope to include acupuncture in the areas to be reviewed in this osteoarthritis guideline update. Acupuncture for chronic pain is being looked at in the guideline on chronic pain in development.
Acupuncture Association of Chartered Physiotherapists	General	General	In the evidence surveillance (Appendix A) concerning acupuncture, it states that "there was no topic expert feedback relevant to this evidence". Perhaps if a topic expert had been consulted regarding the comparison of acupuncture to sham to judge its effectiveness, rather than comparing to standard care, then the evidence would have been interpreted differently. Sham acupuncture has never and never will be a treatment provided in clinical practice, so although it may be used in clinical studies, due to its nature it often leads to results that are not significantly different to the acupuncture group. This does not mean that acupuncture has not been effective, just because both groups showed a positive outcome.	Thank you for your comment. We have updated the scope to include acupuncture in the areas to be reviewed in this osteoarthritis guideline update. Acupuncture for chronic pain is being looked at in the guideline on chronic pain in development.
Advanced Physiotherapy Practice Network	General	General	I am pleased to see the recognised need for a radiologist now part of the committee make up after discussion at the guideline scoping workshop	Thank you for your comment.
Advanced Physiotherap	3	1-3	The need for Shared Decision Making in the use of treatment options based on what is clinically appropriate	Thank you for your comment. All NICE guidance is intended to be used within the shared decision

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
y Practice Network			and how that leads to better healthcare outcomes and involves making the approach patient centred and best involved in their care.	making framework that is accepted best practice within the NHS. Patients and health professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their health professionals. Health professionals should follow the Department of Health's advice on consent. If a person does not have capacity to make decisions, health and social care practitioners should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards. Further recommendations on person-centred care can be found in the NICE guidance on patient experience in adult NHS services.
Advanced Physiotherapy Practice Network	5	27-28	The removal of acupuncture and manual therapy. I do not recall the conclusion of the scoping workshop to remove these from the original draft.	Thank you for your comment. The scope has been amended to include acupuncture and manual therapies.
Advanced Physiotherap	5 8	3, 15 8-10,	Pleased to see that weight loss is part of the management options, but also the referral for consideration of Joint	Thank you for your comment. Question 8.2 within the scope intends to assess whether particular patient

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
y Practice Network		32-33	replacement needs to accurately consider criteria that commissioning bodies are currently using weight to ration referral for intervention, despite the previous NICE guideline.	factors such as BMI are associated with increased benefit or harms after surgery. The implications of delayed surgery will therefore be covered.
Advanced Physiotherapy Practice Network	8	1-2	Appropriate addition of the assessment and diagnosis part to the guideline based on the table discussions about X-ray and appropriate and timely diagnostics in the OA pathway	Thank you for your comment. We have included a question on the use of x-ray to support diagnosis to look at the benefit of this. We also have a question on imaging during management to determine the value of imaging later in the pathway based on the discussions from the scoping workshop.
Advanced Physiotherapy Practice Network	8	13-14	Discussion about aids and devices - we as a table group discussion felt the use and evidence about bracing, particularly unloader bracing warranted its inclusion as a non-surgical management option on its own and not to confuse it with over the counter supports, foot orthotics or mobility aids.	Thank you for your comment. We have amended the question to focus on devices (such as supports, splints and braces).
Advanced Physiotherapy Practice Network	9	1	Pleased to see that weight loss is part of the management options, but also the referral for consideration of Joint replacement needs to accurately consider criteria that commissioning bodies are currently using weight to ration referral for intervention, despite the previous NICE guideline.	Thank you for your comments. The list was not intended to be exhaustive, and the factors included will be discussed with the committee when developing the review protocol. You are correct that we are not intending to cover the effectiveness of joint replacement itself as this is being covered by the joint replacement guideline in development. However, this osteoarthritis guideline will look at who should be referred for joint

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				replacement surgery and whether particular factors predict the success of surgery. In order to determine whether particular patient factors predict this, it has to be determined whether surgery is more or less successful in a particular group of people that have the factor of interest. Surgical outcomes therefore need to be measured to determine this. However, the wording of the question is a draft and may be amended further when the guideline committee define the clinical question and protocol fully.
Avanos Medical Inc.	1	21, 22	The draft scope states that *the condition (OA) does not inevitably get worse, but symptoms fluctuate and flare-ups are common.* This addresses the patient population with ***acute*** pain symptoms but ***does not appear to cover patients affected with chronic pain from the condition.*** While we agree that the condition does not "inevitably get worse", symptomatic OA encompasses more than fluctuation and flare ups. In fact chronic joint pain is included among the top five most commonly reported medical conditions according to the US Bone and Joint Initiative's (USBJI) 4th edition of *The Burden of Musculoskeletal Diseases in the US*, and more than half of all adults in the US now report a chronic musculoskeletal condition—a rate that outpaces the prevalence of reported respiratory and circulatory conditions including high blood	Thank you for your comment. NICE guidelines do not usually cover a different population from that for whom the guideline is intended (i.e. people with chronic pain without osteoarthritis), unless the committee determine that outcomes would not differ within this population and are generalisable. The guideline is however intended for all people with osteoarthritis, including those who have chronic pain. Furthermore, NICE is currently developing a guideline on chronic pain. Please see the following link for further details: https://www.nice.org.uk/guidance/indevelopment/gid-ng10069

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			pressure. Chronic pain is also implicated in adverse mental health outcomes like depression.[1] In fact, some of the physical adverse outcomes of pain overlap with common symptoms of depression, including insomnia or hypersomnia, weight loss or weight gain, fatigue, and decreased interest in self-care. ***We recommend that the guidance fully consider the progression and chronicity of the disease process and include the chronic pain population when considering the pathway and guidance for intervention.*** [1] Rosenquist, EWK. Overview of the treatment of chronic non-cancer pain. 11/30/2017. Up to Date. [UpToDate Web site]. http://www.uptodate.com/home/index.html. [via subscription only]. Accessed October 4, 2018.	
Avanos Medical Inc.	2	27-30	We agree with the draft scope conclusion that *"although joint replacement surgery can be effective, not everyone needs it and….there is uncertainty about whether treatment for osteoarthritis flare-up should be different to treatment for on-going symptoms."* We believe that on-going symptoms need to be managed effectively with longer-term solutions than those addressed	Thank you for your comment. Non-pharmacological interventions are covered in the guideline update, but we will not be covering radiofrequency ablation. This is a specialised technology that might be better addressed under NICE's Medical Technologies programme. See the following link for more information: https://www.nice.org.uk/About/What-we-do/Our-

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			in the draft scope as again studies demonstrate limited efficacy and duration of injections and adverse risks of opioid pain management. There are many technological advances in interventional pain management currently being successfully used to be considered in the development of this guidance. Radiofrequency has been used for more than 75 years[1] with a safety profile supported by long term and wide spread clinical use across diverse therapeutic areas such as neurology, cardiology, and oncology and is currently used to successfully relieve pain generating from the facet joints of the cervical, thoracic and lumbar spine, as well as the sacroiliac, knee and hip joints, and the intervertebral discs. Cooled radiofrequency ablation (C-RFA) is safe, FDA cleared for multiple anatomies, and can be performed on an outpatient basis with minimal sedation in about 45 minutes. A radiofrequency generator transmits a small current of RF thermal energy through an insulated electrode placed within tissue. Ionic heating, produced by the friction of charged molecules, thermally deactivates the nerves responsible for	Programmes/NICE-guidance/NICE-medical-technologies-evaluation-programme

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			sending pain signals to the brain. Delivering RF thermal energy through water-cooled electrodes enables more RF thermal energy to be safely delivered to target nerves creating spherically-shaped lesions. A twelve-month study (Davis et al 2019) shows that C-RFA treated patients demonstrate a significant improvement in both pain relief and overall function when compared to patients treated with Intraarticular Steroid Injection.[2] ***An evidence-based, minimally invasive and cost-effective option for conservative treatment of chronic musculoskeletal pain is necessary to help combat the opioid crisis and offer alternatives to invasive and costly surgical procedures as well as the current limited duration conventional therapies.*** [9] https://www.medscape.com/viewarticle/718292_2 [10]Davis T, Loudermilk E, DePalma M, Hunter C, Lindley D, Patel N, Choi D, Soloman M, Gupta A, Desai M, Cook E, Kapural L. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multi-center, randomized, cross-over trial. Reg Anesth Pain Med 2019;**0**:1–8.	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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			doi:10.1136/rapm-2018-100051	
Avanos Medical Inc.	2	9, 10	We agree with the draft scope statement that *many people with osteoarthritis have multi-morbidity which can increase the complexity of their care.* Many people, due to these comorbidities are not surgical candidates and can fail conservative treatment including exercise, therapy, weight management, NSAIDS, narcotics and injections. Approximately half of the people diagnosed with heart disease or diabetes and a third of those with obesity also are affected by arthritis and rheumatic conditions and contribute to the comorbidity profile.[3] An important issue for patients covered by this guideline is that the guidance must address the multi-morbidity factor and identify pathway alternatives for those who fail conservative treatment and present with comorbidities precluding pharmacological intervention or surgery. ***We suggest that the committee consider government trends such as those recommended by the Centers for Medicare & Medicaid to promote access to non-opioid pain intervention[4] in the development of this guidance.***	Thank you for your comment. NICE is aware of the complex issues related to care provision for people with multiple health needs. The multimorbidity guideline aims to provide recommendations related to this, including recommendations to support treatment decisions for people with multimorbidities (https://www.nice.org.uk/guidance/ng56). In relation to conditions that may be comorbid to (or associated with) osteoarthritis, the guideline committee will consider these groups when each evidence review protocol is drafted. For each evidence review, the committee will consider appropriate population stratifications or subgroups, in order to determine whether sub-populations in those with osteoarthritis should be separated within the analysis of each evidence review (for example, separating the evidence for people with comorbid conditions). Where appropriate this may result in different recommendations for subgroups within the osteoarthritis population, although recommendations

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			[2] United States Bone and Joint Initiative. The Impact of Musculoskeletal Disorders on Americans – Opportunities for Action. Executive Summary of The Burden of Musculoskeletal Diseases in the United States: Prevalence, Societal and Economic Cost 3rdEdition.2016. Available from: http://www.boneandjointburden.org/docs/BMUSExecutiveSummary2016.pdf. Accessed on October 4, 2018. [3] https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf	are always intended to be interpreted with normal clinical judgement (for example, knowing when an exercise intervention may be contraindicated in a patient). Furthermore, as part of normal clinical judgement the BNF should always be used alongside NICE guidance when making medication decisions, and cautions and contraindications should be taken into account.
Avanos Medical Inc.	2	20, 21, 22	We disagree with the draft scope conclusion that *patients may not present to their GP because of "common myth—for example, that nothing can be done or that joint pain is part of normal aging".* As indicated in lines 6-9 on page 2 of the draft scope, 8.75 million people in the UK aged 45 or more have sought treatment for osteoarthritis and in 2018 there were over 65,000 hip and 65,000 knee replacements undertaken in the NHS. In 2009 approximately 905,000 knee and hip replacements were performed in the US at cost of $42.3 billion dollars,[5] and in 2013, the total economic burden of fatal overdose,	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline. The number of people and the impact of the health economic costs or savings from recommendations made in this guideline will be considered during development.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			abuse and dependence of prescription opioids was estimated to be $78.5 billion dollars.[6] This suggests that people are not just accepting OA and joint pain as part of ageing and are seeking treatment to manage chronic pain and maintain their quality of life. ***We suggest that the magnitude of people and health economic costs impacted by this guideline be fully considered as it appears to be larger than the draft scope suggests.*** [4] Murphy, L., Helmick, C., The Impact of Osteoarthritis in the United States: A Population-Health Perspective. American Journal of Nursing. Mar 2012. Vol.112, No.3 [5] Florence, Curtis S. PhD; Zhou, Chao PhD; Luo, Feijun PhD; Xu, Likang MD. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Medical Care: October 2016 - Volume 54 - Issue 10 - p 901–906 doi: 10.1097/MLR.0000000000000625	
Avanos Medical Inc.	2	23, 24	We disagree with the draft scope conclusion that *"a range of non-pharmacological, pharmacological and surgical interventions can reduce joint pain and improve function"*. We feel that the current pathway of intervention for OA	Thank you for your comment. The guideline is planning to carry out evidence reviews for a range of non-pharmacological interventions including the ones you describe.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			starting with physical therapy/exercise, weight management, NSAIDS, narcotics, injections of either corticosteroid or hyaluronic acid and ending with surgical intervention/joint replacement leaves a ***gap*** in treatment for those who have failed first-line conservative treatment, are non-surgical candidates and have conditions contraindicating intraarticular injection. The pathway also fails to effectively and adequately address chronic pain management. Opioid pain medication use presents serious risks including opioid adverse events and opioid use disorder. Three million US citizens and 16 million citizens worldwide have had or currently suffer from opioid use disorder.[7] The reported duration of pain relief of intraarticular corticosteroid injections from review of clinical trials is predominately one to two weeks with a small number of trials demonstrating pain relief of up to three to four weeks.[8] The reported effects of Hyaluronic Acid injections varies as well with some reports of effect sustained for up to 26 weeks[9]. In spite of the limited evidence for both, corticosteroid injections and hyaluronic acid injections are	In addition, NICE is currently developing a separate guideline on chronic pain: assessment and management, which is covering pharmacological and non-pharmacological interventions for people with chronic primary pain. Please see the following link for further details: https://www.nice.org.uk/guidance/indevelopment/gid-ng10069.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			commonly received repetitively and serially over the course of many years in patients with symptomatic knee osteoarthritis. The American Academy of Orthopedic Surgeons indicates they are unable to recommend for or against the use of acetaminophen, opioids, or pain patches for patients with symptomatic osteoarthritis of the knee (AAOS#7b). Rates of steroid injection leveled off after the AAOS concluded that no recommendation could be made, while the rate of hyaluronic acid injection decreased in response to recommendation against this procedure. Based on the growing numbers of joint replacements, a conclusion can be made that the current pharmacological and non-pharmacological treatment interventions are ineffective in sufficiently reducing pain and improving function, particularly longer-term (6-24 months) to address the chronic pain population. ***We recommend consideration of a more comprehensive range of treatment to include longer-term, minimally invasive non-narcotic pain intervention.*** [6]Huecker MR, Gossman WG. Opioid, Addiction. [Updated 2017 Oct 2]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2018 Jan-. Available from:	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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			https://www.ncbi.nlm.nih.gov/books/NBK448203/. Accessed on October 4, 2018. [7] Cheng OT, Souzdalnitski D, Vrooman B, et al. Evidence-based knee injections for the management of arthritis. *Pain Med*. 2012; 13(6):740-753. [8] Miller L, Block J. US-Approved Intra-Articular Hyaluronic Acid Injections are Safe and Effective in Patients with Knee Osteoarthritis: Systematic Review and Meta-Analysis of Randomized, Saline-Controlled Trials. Clinical Medicine Insights: Arthritis and Musculoskeletal Disorders 2013:6 57–63	
Avanos Medical Inc.	3	1, 2, 3	The draft scope acknowledges that *"an increasing breadth of multidisciplinary professionals provide care for people with osteoarthritis" and "all need to be equipped to deliver high-quality and cost-effective care across the care pathway*" yet the review committee does not include representation from pain management. ***We recommend that the committee recruit and retain an interventional pain management physician to participate in the development of the guidance for treatment of OA.***	Thank you for your comment. We will consider recruiting a pain specialist to the guideline committee once the final review questions are agreed with the committee.
Avanos Medical Inc.	5	1-15	The draft scope identifies *key areas that will be covered for the management of OA to be: 1) non-pharmacological management 2) pharmacological management 3) Follow-up and Review 4) Arthroscopic procedures and 5) Referral for joint replacement surgery.*	Thank you for your comment. Non-pharmacological interventions are covered in the guideline update, but we will not be covering radiofrequency ablation. This is a specialised technology that might be better addressed under NICE's Medical Technologies

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Ablative techniques are heavily utilized and endorsed by professional nerve and pain management societies both stateside and abroad, such as ASRA (American Society of Regional Anaesthesiologists), Spine Intervention Society (SIS), ESRA (European Society of Regional Anaesthesia), etc. In fact, the American Society of Regional Anaesthesiologists dedicated an entire plenary session of its November 2018 Annual Pain Medicine meeting to the use of these interventions in patients with osteoarthritis. (https://www.asra.com/content/documents/program-faculty_pm18.pdf). A radiofrequency generator transmits a small current of RF thermal energy through an insulated electrode placed within tissue. Ionic heating, produced by the friction of charged molecules, thermally deactivates the nerves responsible for sending pain signals to the brain. Delivering RF thermal energy through water-cooled electrodes enables more RF thermal energy to be safely delivered to target nerves creating spherically-shaped lesions. Of significance, the technology of RF has been used for more than 75 years[10] with a safety profile supported by long term and wide spread clinical use (neurology, cardiology, and oncology)	programme. See the following link for more information: https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-medical-technologies-evaluation-programme

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			and is currently used to successfully relieve pain generating from the facet joints of the cervical, thoracic and lumbar spine, as well as the sacroiliac, knee and hip joints, and the intervertebral discs.[11] COOLIEF* Cooled Thermal Radiofrequency *optimizes* the technology of standard thermal RF and is the only radiofrequency cleared by the FDA for use for osteoarthritis knee pain. ***The draft scope has not included and has not considered cost-effective non-narcotic interventional pain management treatment as part of their guidance scope. We respectfully recommend interventional pain techniques, including Coolief* Radiofrequency Ablation, be included in the key areas covered.*** [11] https://www.medscape.com/viewarticle/718292_2 [12] Stelzer W. MD, Use of Radiofrequency Lateral Branch Neurotomy for the Treatment of Sacroiliac Joint-Mediated Low Back Pain: A Large Case Series. Pain Medicine, 2013 Jan (1) 29-35	
Bioventus			In the assessment of oral pharmacological treatment we feel it important to specify patient cohort who have increased risk of GI, renal, cardiac complications and provide alternative treatment recommendations specifically	Thank you for your comment. We are aware of the complex issues related to care provision for people with multiple health needs. The multimorbidity guideline aims to provide recommendations related

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			for this comorbid patient group.	to this, including recommendations to support treatment decisions for people with multimorbidities (https://www.nice.org.uk/guidance/ng56). In relation to conditions that may be comorbid to (or associated with) osteoarthritis, the guideline committee will consider these groups when each evidence review protocol is drafted. For each evidence review, the committee will consider appropriate population stratifications or subgroups, in order to determine whether sub-populations in those with osteoarthritis should be separated within the analysis of each evidence review (for example, separating the evidence for people with comorbid conditions). Where appropriate this may result in different recommendations for subgroups within the osteoarthritis population, although recommendations are always intended to be interpreted with normal clinical judgement (for example, knowing when an exercise intervention may be contraindicated in a patient). Furthermore, as part of normal clinical judgement the BNF should always be used alongside NICE guidance when making medication decisions, and cautions and contraindications should be taken into account.
Bioventus	8	16-	Osteoarthritis is a chronic condition which manifest itself in	Thank you for your comment. This guideline does not

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
		17	many forms mechanical, inflammatory and idiopathic. Treatment should be tailored to address the primary underlying cause. Clinical and cost effectiveness should be assessed longitudinally across the whole treatment pathway.	intend to identify the underlying causes of osteoarthritis and the interventions that may be most appropriate based on this. This is because the surveillance review did not identify evidence related to this that would warrant addition to the guideline scope. When developing review protocols, the committee will discuss the length of follow up necessary for making recommendations in each area. Long term outcomes are usually considered and prioritised within NICE guidelines.
Bioventus	8	20-22	The draft scope is intending to assess the clinical and cost effectiveness of Hyaluronic Acid Injection as a class. We believe that hyaluronic acid assessment should be segment with particular focus on HA source, molecular weight, half-life, the residency time in the joint which has a correlation with the number of injections the patient requires in a course of treatment. The multiple number of injections required is pertinent to the cost effectiveness and NHS resource utilisation.	Thank you for your comment. This information will be considered by the guideline committee when drafting this review protocol.
Bioventus	8	20-22	When assessing effectiveness of Hyaluronic Acid injection we feel it is important to consider the impact across the whole treatment pathway including any delay to joint replacement.	Thank you for your comment. The committee will consider this when developing the review questions related to intra-articular injections.
Bristol	2	2-3	30.8 million relates to back pain, neck and upper limb	Thank you for your comment. We have revised the

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Medical School			problems Perhaps, "People of all ages with osteoarthritis face disruption to their physical, social and emotional life, and more than half of people report that it seriously affects family and working life."	sentence as suggested.
Bristol Medical School	2	7-8	"65,000 hip and 65,000 knee replacements". This is lower than in the NJR in 2017/18 (72,714 hip replacements were recorded as being performed in the NHS and 75,439 knee replacements in England, Wales, Northern Ireland and Isle of Man). This does not include the number performed by the NHS in Scotland, reported byt the Scottish Arthroplasty Project. The NJR data is available at: http://www.njrreports.org.uk/Data-Completeness-and-quality	Thank you for your comment. We have updated this to state "….over 70,000 hip replacements and 75,000 knee replacements undertaken in the NHS…"
Bristol Medical School	2	16	In describing the impact of osteoarthritis, it should be acknowledged that having osteoarthritis leads to an increased risk of mortality: Nüesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Jüni P. All cause and disease specific mortality in patients with knee or hip osteoarthritis: population based cohort study. BMJ. 2011;342:d1165.	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
Bristol Medical School	5	5	Are "Osteoarthritis programmes" a well-defined entity? Are they "self-management" or multifactorial interventions?	Thank you for your comment. We have changed this to 'treatment packages' which include a combination of interventions and may involve self-management.
Bristol Medical	5	5	"Stand-alone psychological interventions". Seems odd to exclude these at this stage and not include them in "Key	Thank you for your comment. We have excluded psychological interventions because we are not

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
School			areas that will be covered". They may not have value but surely that is for guidelines to consider and provide a recommendation that they are ineffective. If not, people may consider psychological interventions as an area for intervention missed by the guidelines.	aware of standalone components of these being given for osteoarthritis. They may be part of treatment packages, which we will be covering in the guideline.
Bristol Medical School	5	14	Avoid using the term "minimally invasive" to describe arthroscopic surgery, they are different entities with minimally invasive being used to describe traditional incisions but where the surgeon has adopted strategies to minimise the length of the incision or the damage to soft tissues during the procedure. [1] Moore A et al. Expect analgesic failure; pursue analgesic success. BMJ 2013;346:f2690 doi: 10.1136/bmj.f2690	Thank you for your comment. We have deleted the words 'minimally invasive'.
Bristol Medical School	8	9	As earlier, is the term "osteoarthritis programme" widely recognised/ defined?	Thank you for your comment. We have redefined this as 'treatment packages (combinations of interventions)
British Acupuncture Council	5	28	We are responding to the decision in the surveillance review not to include acupuncture in the scope of the update. The review's impact statement concludes that the new evidence (since the 2014 guideline) is unlikely to clarify uncertainty around the benefits of acupuncture. This is true in the sense that this more recent evidence does not change the general picture that came out in the Vickers (2012) individual patient meta-analysis of acupuncture for chronic pain, seen also in the NICE guidelines for osteoarthritis, headache and low back pain. Thus	Thank you for your comment. The scope has been amended to include acupuncture.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			acupuncture is found to be superior to no acupuncture or usual care with a moderate effect size, and superior to sham acupuncture but with a small effect (which may not meet NICE's minimum threshold for clinical significance). Since the earlier osteoarthritis guideline we have the Corbett (2013) network meta-analysis to consider, which showed acupuncture to be highly ranked against other non-pharmacological treatments, ahead of both types of exercise. It was also significantly better than sham, and at least one of the exercise types, in most of the variants of this analysis. The surveillance review chose to take the only variant where it wasn't superior to sham. However, whatever the actual level of significance the results are entirely consistent in showing acupuncture to be at least as good as exercise. Why then is it not included with exercise in the list of recommended interventions?	
British Acupuncture Council	5	28	There is a suspicion here that the playing field is not quite a level one (echoed currently in respect of psychological treatments, and acupuncture, for the depression guideline, where there has been sufficient stakeholder disquiet to force it to a third iteration). Perhaps NICE takes it as axiomatic that sham acupuncture is a credible sham but that sham exercise is not. Most of the non-pharmacological interventions recommended by NICE across its guidelines	Thank you for your comment. The scope has been amended to include acupuncture. Thank you for the references, these will be considered for inclusion when the review question protocol is agreed.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			are not supported by sham controlled trial evidence but by comparison against no treatment or some sort of standard care. In Henriksen et al's (2016) meta-analysis of Cochrane review trials on knee osteoarthritis (this was cited in the surveillance review) only one out of 35 studies used a sham comparator. The authors concluded that exercise was similarly effective to analgesic drugs but noted the limitations as regards lack of blinding and uncertainties about contextual factors. Also there was insufficient evidence on safety and on the type and dose of exercise to offer. This amounts to a lot of uncertainty, but it doesn't deter NICE from recommending it. With acupuncture, though, such uncertainty leads unerringly to a non-recommendation, even though the best evidence says it may be better than exercise. In fact acupuncture has a stronger evidence base because there is at least some indication of superiority over sham. This is quite an achievement because none of the sham methods to date can be said to be inert (Zhang 2015, Linde et al 2006, Lund and Lundeberg 2006, Lund et al 2009). The non-insertion or superficial/shallow insertion methods act as 'gentler' forms of 'real' acupuncture. Styles of acupuncture vary from strong manipulation with deep insertion right through to the no insertion styles. Classically some types of needles were blunt, non-penetrating	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			instruments and non-penetrating skin stimulation is seen today in some styles. In addition, it's not clear that the 'gold standard' non-penetrating sham devices do in fact achieve blinding (Zhang 2015). Other shams are meant to work by needling away from designated acupuncture points and channels, but these are equally unfit for purpose: specified locations may be associated with particular effects but there's no literary record of any location having no effect, and no experimental verification of this. Brain imaging evidence indicates some, though a lesser, effect from non-channel vs channel points (Wu et al 2002, Nierhaus et al 2016). Neuroimaging studies support the idea of a partial overlap between acupuncture and sham, but also that the two interventions activate different pathways (Dhond et al 2007, Cai et al 2018, Harris et al 2009), i.e. each has its own specific effects as well as overlapping contextual effects. It is thus not surprising that contextual effects from sham acupuncture controls are consistently of a moderately large size (Linde 2010), and that sham outperformed many of the active interventions in the osteoarthritis network meta-analysis. Indeed the argument is that use of sham controls leads to systematic underestimation of the effects of acupuncture (Birch 2006).	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			There does not appear to be any discussion of sham exercise in the osteoarthritis guideline though there is a possible rationale for excluding sham exercise trials in the back pain guideline: this suggests that the shams were of other interventions, not exercise itself. For acupuncture the issue is not that shams of other treatments are used but that the shams are variants of the real thing, not sham versions of it. It would be helpful if NICE were to address this in review protocols. It is also instructive to consider where acupuncture stands in relation to pharmaceutical interventions. A recent meta-analysis found that no drugs could be recommended for longer-term use for knee osteoarthritis: there was insufficient evidence of effect to weigh against the possible harms (Gregori et al 2018). The long-term effectiveness of acupuncture may also be less well substantiated than for the short-term but the best evidence so far indicates that most of the benefits persist at least up to 12 months (MacPherson et al 2017), and it is much safer than drugs. We refer also to another recent systematic review, that confirmed the efficacy of those medications against which acupuncture was found to be 'non-inferior' for migraine prophylaxis in the 2016 Cochrane review (Trinh et al 2019). If acupuncture is at least as good as proven conventional treatments then why is it rejected by NICE in many areas	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			on the basis that it is largely a placebo? NICE currently endorses acupuncture for migraine but the nature of the evidence, and the arguments, are exactly the same as for osteoarthritis and back pain. The uncertainty is surely about the nature of placebos and placebo effects, and underlying mechanisms of action, for acupuncture but also more generally; it is not about whether acupuncture is as good a treatment option for patients as existing recommendations, for the evidence on that is quite clear. The primary argument used against acupuncture in the past by NICE concerns the ethical issues with promoting placebos, but there is no more reason to think of acupuncture as a placebo treatment than exercise, psychological interventions or many drugs. Rather, there are more compelling ethical problems in withholding treatments shown to benefit patients - and not to harm them, even long-term. It must be quite clear to you that some other respected guideline bodies have adopted different interpretations of the acupuncture research data (e.g. the American College of Physicians for back pain; SIGN for back pain and knee osteoarthritis) and we would hope that you are sufficiently open and flexible to consider alternatives. Above all, we expect NICE to provide the level playing field that is not evident at the moment.	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			References Birch S. A review and analysis of placebo treatments, placebo effects, and placebo controls in trials of medical procedures when sham is not inert. J Altern Complement Med. 2006 Apr;12(3):303-10 Cai RL, Shen GM, Wang H, Guan YY. Brain functional connectivity network studies of acupuncture: a systematic review on resting-state fMRI. J Integr Med. 2018 Jan;16(1):26-33 Corbett MS, Rice SJC, Madurasinghe V et al. (2013) Acupuncture and other physical treatments for the relief of pain due to osteoarthritis of the knee: network meta-analysis. Osteoarthritis and Cartilage 21:1290-1298 Dhond RP, Kettner N, Napadow V. Do the neural correlates of acupuncture and placebo effects differ? Pain. 2007 Mar;128(1-2):8-12 Gregori D, Giacovelli G, Minto C, Barbetta B, Gualtieri F et al. Association of Pharmacological Treatments With Long-term Pain Control in Patients With Knee Osteoarthritis: A Systematic Review and Meta-analysis. JAMA. 2018 Dec	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			25;320(24):2564-2579 Harris RE, Zubieta JK, Scott DJ, Napadow V, Gracely RH, Clauw DJ. Traditional Chinese acupuncture and placebo (sham) acupuncture are differentiated by their effects on mu-opioid receptors (MORs). Neuroimage. 2009 Sep;47(3):1077-85 Henriksen M, Hansen JB, Klokker L et al. (2016) Comparable effects of exercise and analgesics for pain secondary to knee osteoarthritis: a meta-analysis of trials included in Cochrane systematic reviews. Journal of comparative effectiveness research 5:417-431. Linde K, Niemann K, Meissner K. Are sham acupuncture interventions more effective then (other) placebos? A re-analysis od data from the Cochrane review on placebo effects. Forschende Komplementarmedizin. 2006;17(5):259-63 Linde K, Niemann K, Schneider A et al. How large are the nonspecific effects of acupuncture? A meta-analysis of randomised controlled trials. BMC Medicine. 2010:8,75 Lund I, Näslund J, Lundeberg T. Minimal acupuncture is not a valid placebo control in randomised controlled trials of	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			acupuncture: a physiologist's perspective. Chin Med. 2009 Jan 30;4:1. Lund I, Lundeberg T. Are minimal, superficial or sham acupuncture procedures acceptable as inert placebo controls? Acupunct Med. 2006 Mar;24(1):13-5 MacPherson H, Vertosick EA, Foster NE, Lewith G, Linde K et al. The persistence of the effects of acupuncture after a course of treatment: a meta-analysis of patients with chronic pain. Pain. 2017 May;158(5):784-793. Nierhaus T, Pach D, Huang W, Long X, Napadow V et al. Difficulties Choosing Control Points in Acupuncture Research. Response: Commentary: Differential Cerebral Response, Measured with Both an EEG and fMRI, to Somatosensory Stimulation of a Single Acupuncture Point vs. Two Non-Acupuncture Points. Front Hum Neurosci. 2016 Aug 11;10:404. Trinh KV, Diep D, Chen KJQ. Systematic Review of Episodic Migraine Prophylaxis: Efficacy of Conventional Treatments Used in Comparisons with Acupuncture. Med Acupunct. 2019 Apr 1;31(2):85-97.	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Vickers AJ, Cronin AM, Maschino AC, Lewith G, MacPherson H et al. Acupuncture for chronic pain: individual patient data meta-analysis. Arch Intern Med. 2012 Oct 22;172(19):1444-53 Wu MT, Sheen JM, Chuang KH, Yang P, Chin SL et al. Neuronal specificity of acupuncture response: a fMRI study with electroacupuncture. Neuroimage. 2002 Aug;16(4):1028-37 Zhang CS, Tan HY, Zhang GS, Zhang AL, Xue CC, Xie YM. Placebo Devices as Effective Control Methods in Acupuncture Clinical Trials: A Systematic Review. PLoS One. 2015 Nov 4;10(11):e0140825	
British Orthopaedic Association	General		The BOA welcomes the revision of the current guideline and its intended scope.	Thank you for your comment.
British Orthopaedic Association	General		However, we have some concerns which we hope will be addressed.	Thank you for your comments. We have responded to each in turn.
British Orthopaedic Association			Although we accept that surgery is not appropriate for most of the population with osteoarthritis, we would suggest that it has a very specific and efficacious place for those who require it as long as its timing is correct. Surgery should not	Thank you for your comment. Draft clinical questions 7.1 and 7.2 within the scope intend to identify evidence related to referral for surgery. These evidence reviews intend to determine what factors

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			be delayed inappropriately and a suitable pathway including this option should be developed.	indicate the need for referral for joint replacement surgery, as well as determining whether patient factors are associated with increased benefits or harms after joint replacement surgery. The criteria for and timing of referral for surgery are being considered in the guideline update.
British Orthopaedic Association	5 and 8	9 15-22	The scope includes oral medications. We are keen to ensure that within this element, NICE will review the usage of ALL types of pain-relieving medications, including paracetamol, NSAIDs and, particularly, opioid analgesics. We have attended and advised at the Opioids Roundtable meeting Chaired by Professor Dame Sally Davies Chief Medical Officer (29th May 2019) on the National Opioid crisis. Dr Paul Chrisp, NICE Head of Guideline Development was listed as an attendee at this meeting. Opioid use is clearly an important national topic and it would be important that this guideline looks at this. We note that some CCG policies require patients to take 'optimal tolerated' doses of analgesics including opioids before they can be referred for surgery. We are very concerned about the increasing use of opioids in patients with arthritis, given this is a chronic deteriorating condition. An APPG (All Party Parliamentary Group) has been set up specifically to look at the issue of patients developing involuntary dependence on drugs which they did not know	Thank you for your comment. The draft pharmacological questions intend to cover all relevant pharmacological agents, including opioids, NSAIDs and paracetamol. Please also see the NICE guideline on safe prescribing and withdrawal management that is currently in development: https://www.nice.org.uk/guidance/indevelopment/gid-ng10141 Thank you for providing information related to referral for surgery and pharmacological treatment that may currently be required before referral is considered. This information will be taken into account by the committee when drafting the review question, in order to assess the appropriate timing of referral.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			were addictive. There is evidence from North America that the prolonged use of these drugs can result in dependence and its negative and harmful sequelae. We feel it is very important that the cost and clinical effectiveness questions need to consider the implications of the long-term use of opioids. In our view if a patient has such pain that increasing opioid doses are required for effective pain relief then they should be referred for consideration of surgery. Opioids should only be considered as a short-time approach to management of pain from osteoarthritis and usually with a tapering dose protocol. We additionally highlight that evidence from the USA suggests that patients admitted for total joint replacement who are taking opioids on admission have a longer hospital stay, and more complications including infections, respiratory and gastrointestinal complications. 20% of these patients are still taking opioids 12 months later. We advise that NICE should look at whether pre operative opioid use in arthritis patients (a) detrimentally affects the outcome of joint replacement and (b) leads to dependence.	
British Orthopaedic Association	9	1	Currently the scope proposes to cover: "Are patient factors (for example, BMI, age) associated with increased benefits or harms after joint replacement surgery in people with osteoarthritis?" Smoking has also been used as a barrier to referral for joint replacement surgery. We believe that this should be	Thank you for your comments. The list was not intended to be exhaustive, and the factors included will be discussed with the committee when developing the review protocol. You are correct that we are not intending to cover the

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			considered as the alternative to surgery in patients with pain and immobility from arthritis, who have an addictive personality are limited. We suggest that this item as currently worded is appropriate to include in the scope for this document. Since this particular guideline is not intended to look at the cost and clinical-effectiveness of joint replacement surgery in general (based on p5, line22), it appears illogical that it should be proposing to look at benefits/harms of surgery for particular population groups? There is currently a NICE guideline in development on hip, knee and shoulder replacement. The scope for that piece of work excludes 'indications for joint replacement' but includes other aspects of joint replacement (https://www.nice.org.uk/guidance/gid-ng10084/documents/final-scope-2). In the current scoping, we would suggest that joint replacement issues covered should relate only to indications for or referral for joint replacement. We suggest rewording, as: "Are there any patient factors (for example, BMI, age) that should be considered as barriers to referral for joint surgery?"	effectiveness of joint replacement itself as this is being covered by the joint replacement guideline in development. However, this osteoarthritis guideline update will look at who should be referred for joint replacement surgery and whether particular factors predict the success of surgery. In order to determine whether particular patient factors predict this, it has to be determined whether surgery is more or less successful in a particular group of people that have the factor of interest. Surgical outcomes therefore need to be measured to determine this. However, the wording of the question is a draft and may be amended further when the guideline committee define the clinical question and protocol fully.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			The current guidance document states that: "Patient-specific factors (including age, sex, smoking, obesity and comorbidities) should not be barriers to referral for joint surgery." We would suggest that the future guidance includes the same statement. Patients with very high BMI benefit from surgical assessment and a discussion of the risks and benefits of surgery, often with a detailed anaesthetic assessment of risks. Only then can a proper informed decision be made on optimal management. This may involve bariatric surgery in some. Being immobile and/or in considerable pain causes great difficulty for patients with a high BMI as much it would for anyone else, and this group of patients should not be denied a surgical assessment and discussion.	
British Orthopaedic Association	31	7	Regarding referral for possible joint replacement, there is current wording in the Scope that reads: *"What factors indicate the need for referral for possible joint replacement surgery in people with osteoarthritis?"* We suggest that there should be two points for consideration within this: (1) about which patients should be referred without having to undertake conservative therapies first, and (2) for those who do undertake conservative therapy, what is a suitable duration to determine whether or not non-operative management is effective for that patient	Thank you for your comment. To make clear that optimal timing of referral for surgery is being covered, we have reworded the question 8.1 to: When should people with osteoarthritis be referred for possible joint replacement surgery, and what factors should this be based on?" The final questions will be agreed by the committee when the review protocols are discussed.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			before it is appropriate to be referred? Any patient management algorithm must have a 'fast track route' to secondary care for patients in intolerable pain or whose disease is progressing such that it risks making the surgery more complex. We are concerned about undue delays for patients who are expected to undergo extended periods of non-operative management even though the initial experience has clearly demonstrated it to be ineffective. As an example, in some CCGs the threshold for referral for surgery includes the statement that the patient should be have "uncontrolled, intense, persistent pain resulting in substantial impact on quality of life" and they should have "symptoms refractory to at least 6 months conservative management" (e.g. NHS Cambridgeshire And Peterborough CCG). It is very concerning that some patients should be expected to endure such severe levels of pain for at least 6 months before even being referred. We would also encourage NICE to consider within this guideline the effects on mental and physical health for patients waiting an extended time before referral when either they are experiencing high levels of pain or their condition is rapidly deteriorating. We are also concerned about the variable access to	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			orthopaedic surgery for arthritis across CCGs in England and trust that the guideline will recommend more uniform and appropriate criteria for access to surgery.	
British Pain Society	General	General	On behalf of the British Pain Society to raise our concern that no pain specialists are being considered for the Osteoarthritis Update guideline committee. As noted within the original guideline pain is one of the principle symptoms of osteoarthritis and its long term management is intrinsically linked with persistent musculoskeletal pain management. In the years following the last guideline this long term management has become intertwined with pain management and many of our patients are those who have failed all other strategies for ostoearthritic pain control. We therefore ask that a pain clinician be added to the guideline group to prevent concerns being raised at a later date.	Thank you for your comment. We will consider recruiting a pain specialist to the guideline committee once the final review questions have been agreed with the committee.
British Society for Surgery of the Hand	8 9	28-33 1-3	"Arthroscopic procedures" is too generic a term as it can range from quite specific and proven techniques such as arthroscopic assisted fusion/ resection to ineffective treatments such as joint washouts. Joint replacements are not the only effective form of surgical treatment and in several small joints, resection arthroplasty or fusion operations are highly effective.	Thank you for your comment. 'Arthroscopic procedures' is intended to be a broad term that captures interventions such as joint washout. Inclusion within the scope of the guideline does not imply an intervention will be recommended. Rather, the clinical and cost effectiveness of interventions included within the scope will be assessed.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Patient characteristics that indicate a benefit from joint replacements is not generalizable and outcomes depend on several other factors, not least the specific joint that is being replaced. Based on the above observations, it may be better to combine and rephrase questions 6 and 7 to "What factors indicate the need for referral for possible surgery in patients with osteoarthritis?" The specific form of surgery that is then undertaken should be the subject of a separate guideline specific to that condition such as the existing guidelines on hip replacements, trapezio-metacarpal replacements, etc. This over-arching guideline should focus on the broader treatment principles, perhaps with a view to suggesting which forms of conservative management are recommended (pharmacological, exercise, splints, combination, injection), how long should these conservative measures be tried for and finally, what the indications for referral for possible surgical treatment are.	In relation to factors that indicate the need for referral, the full protocol for this evidence review will be determined by the committee. This will take into account possible variations in outcomes depending on the form of surgery or location of surgery. Furthermore, data analysis within prognostic review can take into account the treatment effect of various factors via multivariate analysis that adjusts or accounts for confounders. In relation to your final point, this guideline does intend to answer the questions you have outlined, although the surveillance review did not identify evidence related to the length or duration of interventions and thus a specific question related to this has not been added to the scope.
Cell Regeneration Limited	5	6	When I attended the initial scope meeting I spoke about the MBST technology ands told to bring up all in information at this stage. It is a form of electrotherapy. We have submitted the MTEP form to medtech@nice.org.uk and I	Thank you for providing this information. We agree that MBST is better addressed as a medical technology and it will not be covered in this guideline update guideline. It may be considered in future

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			will also attached all the relevant information here also.	updates.
European Technology for Business Holdings Limited	8	1-2	Under assessment and diagnosis only one draft question has been raised. There are many published studies that consider other diagnosis measurements. Will alternatives be explored?	Thank you for your comment. Clinical discussions at the scoping workshop indicated that clinical assessment is established practice for the diagnosis of osteoarthritis, and that x-ray is the main test used in practice as part of diagnosis, although the previous guideline did not recommend its use. This update will therefore look at the benefit of imaging in the diagnosis of osteoarthritis.
European Technology for Business Holdings Limited	9	6-14	It is recognised that these guidelines cover OA in the lower or upper limbs. In the previous sections the interventions are more specific to upper or lower limb OA. However, the outcome measures are very generic. Would these become more detailed when looking at the different intervention strategies?	Thank you for your comment. Outcomes are defined further by the committee during guideline development. Actual outcome measurements will vary depending on what is reported within the literature, but currently outcome measures that are specific to a certain body part have not been excluded. However, it should be noted that general patient-reported scales should also pick up this information. For example, the VAS pain scale is applicable to pain in any body part.
Faculty of Pain Medicine of the Royal College of Anaesthetists	5	27	Manual therapies, including physiotherapy, should be included in the scope for review	Thank you for your comment. The scope has been amended to include manual therapies.
Faculty of	5	28	Acupuncture is mentioned in the surveillance report and	Thank you for your comment. The scope has been

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Pain Medicine of the Royal College of Anaesthetists			should therefore be included in the scope and reviewed.	amended to include acupuncture.
G.R Lane Health Products	5	8	The draft scope currently excludes the galactolipid compound GOPO as a self-management option for the treatment of OA. We feel that the galactolipid compound GOPO should be considered as a self-management treatment option for OA, to potentially reduce pain and consumption of analgesics (alongside diet and exercise). GOPO (glycoside of mono and diglycerol) is the active compound isolated from the rose-hip Rosa canina and has been clinically proven to help reduce joint pain[1], reduce the need for rescue medications (such as paracetamol and opioids)[2], and to improve flexibility and mobility[3,4,5]. Studies have shown that due to its anti-inflammatory properties, GOPO is more effective at reducing pain and improving mobility than other supplements for OA, such as glucosamine[6]. GOPO is currently undergoing a Cochrane Review exploring the effects of the galactolipid on pain, physical function and stiffness, joint structure, and quality of life of those with OA. The results from The Cochrane Review are	Thank you for your comment. We have not included this as part of the scope because the current evidence base for these interventions makes it unlikely that the committee would be able to make a recommendation to influence practice. This decision is supported by the lack of evidence identified on rose-hip in the 2017 NICE surveillance: https://www.nice.org.uk/guidance/cg177/evidence.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			expected in the next 6 months. The compound GOPO is supported by a breadth of clinical data for the treatment of OA, including the impact on pain[7], inflammation[8], movement[9] and its cartilage regenerating properties[10,11]. For further information on the galactolipid GOPO, please refer to the clinical overview document provided previously to norma.oflynn@rcplondon.ac.uk, following the NICE OA Care and Management guideline scoping workshop. [1.]Winther K et al. Scand J Rheumatol 2005; 34: 302-308 [2.]Willich SN et al. Phytomedicine 2010; 17: 87–93 [3.]Willich SN et al. Phytomedicine 2010; 17: 87–93 [4.]Rein E et al. Phytomedicine 2004; 11: 383–391 [5.]Warholm O, Skaar S, Hedman E et al. The effects of a standardized herbal remedy made from a subtype of Rosa caninain patients with osteoarthritis: a double-blind, randomized, placebo-controlled clinical trial. Curr Ther Res Clin Exp 2003; 64: 21–31 [6.]SchwagerJ, Richard N, Wolfram S. Anti-inflammatory and chondro-protective effects of rose hip powder and its constituent galactolipids GOPO. Poster presentation at the World Congress of Osteoarthritis (OARSI), Rome, 18–21 September 2008 [7.]Winther K et al. Scand J Rheumatol 2005; 34: 302-308 [8.]Schwager J, Richard N, Wolfram S. Anti-inflammatory and	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			chondro-protective effects of rose-hip powder and its constituent galactolipids GOPO. Poster presentation at the World Congress of Osteoarthritis (OARSI), Rome, 18–21 September 2008 [9.]Warholm O, Skaar S, Hedman E et al. The effects of a standardized herbal remedy made from a subtype of Rosa caninain patients with osteoarthritis: a double-blind, randomized, placebo-controlled clinical trial. Curr Ther Res Clin Exp 2003; 64: 21–31 [10.]Schwager J, Richard N, Wolfram S. Anti-inflammatory and chondro-protective effects of rose-hip powder and its constituent galactolipids GOPO. Poster presentation at the World Congress of Osteoarthritis (OARSI), Rome, 18–21 September 2008 [11.]Scaife R, The effect of GOPO® supplementation on passive joint forces and subjective assessment of pain in a non-arthritis population. The Centre for Sport & Exercise Science, Sheffield Hallam University. 2013	
Grünenthal Limited	5	1–12	Individual pharmacological and non-pharmacological therapies are only effective in a significant minority of patients with chronic pain conditions such as osteoarthritis. Failure with one drug does not necessarily mean failure with others, even within a class[1]. These findings have implications for the development of guidelines for the management of osteoarthritis. Patients need access to a broad range of medicines to maximise the chance of	Thank you for your comment. The committee will consider the appropriate interventions and comparisons to include within the pharmacological evidence reviews, taking into account possible variations in treatment effects across and within drug classes.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			treatment success rather than restricting options to one or two treatments. Furthermore consideration should be given to differences in mechanism of action, pharmacokinetics, pharmacodynamics and drug interactions between drugs in the same class[1]. [1] Moore A et al. Expect analgesic failure; pursue analgesic success. BMJ 2013;346:f2690 doi: 10.1136/bmj.f2690	
Grünenthal Limited	5	13	The efficient use of NHS resources is best managed by the prompt discontinuation of ineffective therapies, rather than denying their use from the outset. Success or failure of pain medications can be determined within 2-4 weeks of titration to the optimal dose, and success, when achieved, tends to be long lasting[1]. Thus the effectiveness and tolerability of treatments should be assessed after 4 weeks and patients failing to respond be offered alternative therapy.	Thank you for your comment. The appropriate follow-up periods for outcomes will be considered by the committee when they develop the review question protocols.
Grünenthal Limited	8	16-17	There is evidence that descending inhibitory pain pathways are disrupted in chronic musculoskeletal pain conditions, and pharmacotherapies that target descending pain pathways (eg, those that block serotonin or norepinephrine reuptake) may be more appropriate for managing chronic pain than pure μ-opioid receptor agonists[2,3,4]. Variations in patient response to opioid analgesia and the contribution of dysfunction of descending inhibitory pain pathways may leave some patients treated with pure μ-	Thank you for your comment and the references. Opioids will be looked at as part of the review on pharmacological treatments and the references will be considered for inclusion in the pharmacological evidence review.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			opioid receptor agonists or co-analgesics with undermanaged osteoarthritis pain and corresponding poor health status and quality of life[2,5]. Tapentadol is a strong, centrally-acting analgesic that combines two mechanisms of action in a single molecule. Tapentadol acts as a μ-opioid receptor (MOR) agonist and noradrenaline reuptake inhibitor (NRI) throughout the whole duration of action of the drug, which may explain its synergistic effect on pain relief[6]. Despite an 18-fold lower affinity for human μ receptors than morphine[6,7], tapentadol's NRI mechanism of action has an opioid-sparing effect resulting in strong analgesia, comparable to that of classical strong opioids, but with a reduced opioid load. This results in reduced opioid-typical side effects such as nausea and vomiting, constipation, and the potential for abuse[6]. A pooled analysis of two double-blind, randomized, placebo-, and active-controlled trials showed numerically better pain relief with tapentadol PR compared with oxycodone CR. In addition the overall and the gastrointestinal tolerability profile in particular were better in all tapentadol PR groups[8]. Significant improvements in effectiveness were observed for tapentadol PR (50–250 mg twice daily) versus WHO step III opioids in a multicentre, multinational, open-label	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			phase 3b study evaluating the effectiveness and tolerability of tapentadol PR in patients with severe, chronic osteoarthritis knee pain who had responded to WHO step III opioid therapy but showed a lack of tolerability[9]. Similarly, tapentadol treatment resulted in significant improvements in pain intensity, health-related quality of life, and function in patients with severe, chronic osteoarthritis knee pain that was inadequately managed with World Health Organization (WHO) Step I or II analgesics or co-analgesics, or that was not treated with regular analgesics[10]. Consideration should be given to including tapentadol prolonged release as an alternative to conventional strong opioids for the treatment of chronic, severe (osteoarthritis) pain. [2] Arendt-Nielsen L et al. Sensitization in patients with painful knee osteoarthritis. Pain. 2010;149(3):573-581. [3] Management of chronic pain syndromes: issues and interventions. Pain Med. 2005;6(Suppl 1):S1-S20. [4] Curatolo M et al. Central hypersensitivity in chronic pain: mechanisms and clinical implications. Phys Med Rehabil Clin N Am. 2006;17(2):287-302.	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			[5] Wieland HA et al. Osteoarthritis - an untreatable disease? Nat Rev Drug Discov. 2005;4(4):331-344. [6] Tzschentke T.M. et al. The mu-opioid receptor agonist/noradrenaline reuptake inhibition (MOR-NRI) concept in analgesia: the case of tapentadol. CNS Drugs 28(4): 319-329. [7] Tzschentke T.M. et al. Tapentadol hydrochloride: a next-generation, centrally acting analgesic with two mechanisms of action in a single molecule. Drugs Today (Barc) 45(7): 483-496. [8] Lange B et al. Efficacy and safety of tapentadol prolonged release formulation in the treatment of elderly patients with moderate-to-severe chronic osteoarthritis knee pain: a pooled analysis of two double-blind, randomized, placebo-, and active-controlled trials. Current Medical Research and Opinion, 2018; 34:12: 2113-2123 [9] Steigerwald I et al. Effectiveness and Tolerability of Tapentadol Prolonged Release Compared With Prior Opioid Therapy for the Management of Severe, Chronic Osteoarthritis Pain. Clin Drug Investig 2013; 33:607–619 [10] Steigerwald I et al. Effectiveness and safety of tapentadol prolonged release with tapentadol immediate release on-	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			demand for the management of severe, chronic osteoarthritis-related knee pain: results of an open-label, phase 3b study. Journal of Pain Research 2012; 5: 121–138	
Keele University	General	General	EULAR has updated its evidence for hand osteoarthritis so the systematic review (1) will highlight specific research newly published. This will also include reference to evidence for electrotherapy (2). Whilst electrotherapy is used across Europe it has declined in the UK because of perceived evidence for its ineffectiveness. The recommendation may/may not include the use of TENS here but this needs revisiting. 1: Kroon FPB, Carmona L, Schoones JW, Kloppenburg M. Efficacy and safety of non-pharmacological, pharmacological and surgical treatment for hand osteoarthritis: a systematic literature review informing the 2018 update of the EULAR recommendations for the management of hand osteoarthritis. RMD Open. 2018 Oct 11;4(2):e000734. doi: 10.1136/rmdopen-2018-000734. eCollection 2018. PubMed PMID: 30402266; PubMed Central PMCID: PMC6203105. 2: Kloppenburg M, Kroon FP, Blanco FJ, Doherty M,	Thank you for your comment and for providing these references. They will be assessed for inclusion within the relevant evidence reviews during guideline development. We will be reviewing the evidence for electrotherapy within the guideline.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Dziedzic KS, Greibrokk E, Haugen IK, Herrero-Beaumont G, Jonsson H, Kjeken I, Maheu E, Ramonda R, Ritt MJ, Smeets W, Smolen JS, Stamm TA, Szekanecz Z, Wittoek R, Carmona L. 2018 update of the EULAR recommendations for the management of hand osteoarthritis. Ann Rheum Dis. 2019 Jan;78(1):16-24. doi: 10.1136/annrheumdis-2018-213826. Epub 2018 Aug 28. PubMed PMID: 30154087.	
Keele University	General	General	Transparency – this will be really important for electrotherapy to see whether the new evidence would be considered implementable in current care	Thank you for your comment. This guideline will review evidence for electrotherapy.
Keele University	General	General	Physical activity is important e.g. with social prescribing, with PHE Making Every Contact Count (MECC) so linking the document to other forms of evidence for a range health and care professionals is important. A Public Health approach to physical activity in OA is also increasingly common.	Thank you for your comment. This guideline intends to cover exercise and other non-pharmacological interventions for osteoarthritis. The committee will make appropriate recommendations related to these, depending on the evidence, and will take other guidance into account when doing so, including the Public Health England advice you have outlined.
Keele University	General	General	Since the last guidance NICE has had an increasing role in public health and social care. Practitioners in these disciplines will also use the NICE OA guidance so a revision of the map of holistic care might be needed.	Thank you for your comment. This section of the guideline is not included in the scope for this update and the holistic care map will consequently be removed from the updated guideline. A new algorithm for the management of osteoarthritis may be developed by the committee.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Keele University	General	General	Vocation support for work in older adults is another key development e.g. PHE ROI report (5) suggest using SWAP (6). Whilst work outcomes are not used as core measures by NICE, an intervention to support remaining at work has been shown to be effective on key outcomes. 5. https://www.gov.uk/government/publications/musculoskeletal-conditions-return-on-investment-tool 6: Wynne-Jones G, Artus M, Bishop A, Lawton SA, Lewis M, Jowett S, Kigozi J, Main C, Sowden G, Wathall S, Burton AK, van der Windt DA, Hay EM, Foster NE; SWAP Study Team. Effectiveness and costs of a vocational advice service to improve work outcomes in patients with musculoskeletal pain in primary care: a cluster randomised trial (SWAP trial ISRCTN 52269669). Pain. 2018 Jan;159(1):128-138. doi: 10.1097/j.pain.0000000000001075. PubMed PMID: 28976423.	Thank you for your comment. When considering outcomes, we avoid looking at those that specifically refer to work, as this could discriminate against those who do not work. A similar outcome that is often used is instead 'return to daily activity'. Outcomes will be finalised by the committee for each question when developing the review protocols during guideline development. Thank you for providing these references. We will assess these for inclusion within the relevant evidence reviews during guideline development.
Keele University	General	General	Stratification of care is recommended in other NICE Guidance for MSK e.g. LBP. What are the key features of this for OA? Whilst review is to some extent stratified on the basis of the condition and the treatment, the STarT MSK	Thank you for your comment and for providing these references. For each evidence review, the committee will consider appropriate population stratifications or subgroups in order to determine whether sub-

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Tool for stratification of care might also apply here (7) although testing of matched treatment is underway. 7: Campbell P, Hill JC, Protheroe J, Afolabi EK, Lewis M, Beardmore R, Hay EM, Mallen CD, Bartlam B, Saunders B, van der Windt DA, Jowett S, Foster NE, Dunn KM. Keele Aches and Pains Study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. J Pain Res. 2016 Oct 14;9:807-818. eCollection 2016. PubMed PMID: 27789972; PubMed Central PMCID: PMC5072582.	populations in those with osteoarthritis should be separated within the analysis of each evidence review (for example, by age or location of pain). The committee will consider all relevant subgroups, including those within the STarT MSK tool.
Keele University	General	General	Are there any implementation research questions than can build upon existing knowledge?	Thank you for your comment. All recommendations in NICE guidelines take into account resource impact. We do not usually include review questions directly related to implementation. Implementation of guidance is considered by NICE's implementation team. Please see the following link for more information: https://www.nice.org.uk/about/what-we-do/into-practice/implementing-nice-guidance
Keele University	General	General	Taking a solely 'intervention' based approach may not be as successful as a 'care' approach	Thank you for your comment. Although many of the clinical review questions within this guideline relate to specific interventions, recommendations will be made that aim to translate evidence into appropriate

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				practice, in order to promote best practice for care. The guideline also includes other review questions related to treatment packages and questions that may aim to identify the best care approaches.
Keele University	Paracetamol	Paracetamol	We welcome to review of paracetamol in particular in light of the recent evidence and the low back pain recommendations	Thank you for your comment.
Keele University	General	General	Comorbidity/multimorbidity, that is prevalent in people with osteoarthritis and may be a barrier to recommending and carrying out guideline recommendations (i.e. exercise) and there is new RCT evidence suggesting that comorbidity-tailored exercise is clinically effective in this clinically important subgroup. Should the guideline also consider recommendations for highly prevalent subgroups of people with OA? (see references 13/14 above)	Thank you for your comment. We are aware of the complex issues related to care provision for people with multiple health needs. The multimorbidity guideline aims to provide recommendations related to this, including recommendations to support treatment decisions for people with multimorbidities (https://www.nice.org.uk/guidance/ng56). In relation to conditions that may be comorbid to (or associated with) osteoarthritis, the guideline committee will consider these groups when each evidence review protocol is drafted. For each evidence review, the committee will consider appropriate population stratifications or subgroups, in order to determine whether sub-populations in those with osteoarthritis should be separated within the analysis of each evidence review (for example, separating the evidence for people with comorbid conditions). Where appropriate this may result in

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				different recommendations for subgroups within the osteoarthritis population, although recommendations are always intended to be interpreted with normal clinical judgement (for example, knowing when an exercise intervention may be contraindicated in a patient). Furthermore, as part of normal clinical judgement the BNF should always be used alongside NICE guidance when making medication decisions, and cautions and contraindications should be taken into account.
Keele University	5	2	New RCT evidence is available regarding the effectiveness of exercise for people with knee OA and comorbidity and a systematic review has been published on the safety of long-term physical activity in older adults with knee OA. 13. De Rooij M, van der Leeden M, Cheung J, van derEsch M, Hakkinen A…Dekker J. Efficacy of tailored exercise therapy on physical functioning in patients with knee osteoarthritis and comorbidity: a randomsied controlled trial. 14. Quicke JG, Foster NE, Thomas MJ, Holden MA. Is long-term physical activity safe for older adults with knee pain?: a systematic review. Osteoarthritis Cartilage. 2015;23(9):1445-56.	Thank you for your comment and for providing these references. These will be assessed for inclusion within the relevant evidence reviews.
Keele University	5	7	New systematic review and RCT evidence has been published since the last guidelines regarding the clinical effectiveness and safety of herbal and nutritional supplements which may influence whether or not to cover	Thank you for your comment. We have excluded these treatments from the scope because the current evidence base for these interventions makes it unlikely that the committee would be able to make a

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			these treatments within the guideline update. For example, a Cochrane systematic review on rosehip for osteoarthritis and an RCT on the use of turmeric powder for osteoarthritis. 9. Hu XY, Corp N, Quicke J, Lai L, Blondel C, Stuart B, Abdelmotelb A, Leweth G, Mallen C, Moore M. Rosa Canina fruit (rosehip) for osteoarthritis: a Cochrane review. Osteoarthritis cartilage. 2018; 26(Suppl 1):S344 10. Hu M-X, et al. Rosa canina fruit (rosehip) for osteoarthritis: A Cochrane Systematic Review (under Cochrane review) 11. Shep D, Khanwelkar C, Gade P, Karad S. Safety and efficacy of curcumin versus diclofenac in knee osteoarthritis: a randomized open-label parallel-arm study. Trials. 2019;20(1):214. 12. Runhaar J, Rozendaal RM, van Middelkoop M, Bijlsma HJW, Doherty M, Dziedzic KS, Lohmander LS, McAlindon T, Zhang W, Bierma Zeinstra S. Subgroup analyses of the effectiveness of oral glucosamine for knee and hip osteoarthritis: a systematic review and individual patient data meta-analysis from the OA trial bank. Ann Rheum Dis. 2017;76(11):1862-1869.	recommendation to influence practice. This decision is supported by the lack of evidence identified on rose-hip in the 2017 NICE surveillance: https://www.nice.org.uk/guidance/cg177/evidence. The references you have provided are mainly abstracts which would not be sufficient to base a recommendation on.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Keele University	5	9	Recent work from Keele that has been submitted for publication data suggests that this is being prescribed although it's unlicensed.	Thank you for your comment.
Keele University	5	9	The HERO study (8) showed for hand OA that Hydroxycholorquine was not clinically effective. 8: Kingsbury SR, Tharmanathan P, Keding A, Ronaldson SJ, Grainger A, Wakefield RJ, Arundel C, Birrell F, Doherty M, Vincent T, Watt FE, Dziedzic K, O'Neill TW, Arden NK, Scott DL, Dickson J, Garrood T, Green M, Menon A, Sheeran T, Torgerson D, Conaghan PG. Hydroxychloroquine Effectiveness in Reducing Symptoms of Hand Osteoarthritis: A Randomized Trial. Ann Intern Med. 2018 Mar 20;168(6):385-395. doi: 10.7326/M17-1430. Epub 2018 Feb 20. PubMed PMID: 29459986.	Thank you for your comment and for providing this information.
Keele University	5	9	Splinting for thumb OA outcomes will be known by the time the guidelines are complete (OTTER Trial)	Thank you for this information. Splints are covered under the review related to braces. If the results are published in time then the committee will consider the study for inclusion in the review.
Keele University	5	13	The model OA consultation in primary care (MOSAICS) studied the linked consultation for OA with a GP and practice nurse and included a short term review by a practice nurse (within a three-month window). GPs only	Thank you for your comment. The question within the scope related to the information needs of people with osteoarthritis could allow the committee to develop recommendations that aid patient−healthcare

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			referred to a practice nurse in less than 20-25% of cases (3). Subgroup analysis showed a trend for more strengthening exercises in those with a review but numbers were small. Finney et al (4) defined the content of an opportunistic review. Inquiring about the condition, the type and amount of pain the patient has, and whether analgesia is being taken forms a core set of questions that are considered important by both lay and health professional groups. 3: Dziedzic KS, Healey EL, Porcheret M, Afolabi EK, Lewis M, Morden A, Jinks C, McHugh GA, Ryan S, Finney A, Main C, Edwards JJ, Paskins Z, Pushpa-Rajah A, Hay EM. Implementing core NICE guidelines for osteoarthritis in primary care with a model consultation (MOSAICS): a cluster randomised controlled trial. Osteoarthritis Cartilage. 2018 Jan;26(1):43-53. doi: 10.1016/j.joca.2017.09.010. Epub 2017 Oct 14. PubMed PMID: 29037845; PubMed Central PMCID: PMC5759997. 4: Finney A, Porcheret M, Grime J, Jordan KP, Handy J, Healey E, Ryan S, Jester R, Dziedzic K. Defining the content of an opportunistic	professional conversations in clinical practice.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			osteoarthritis consultation with primary health care professionals: a Delphi consensus study. Arthritis Care Res (Hoboken). 2013 Jun;65(6):962-8. doi: 10.1002/acr.21917. PubMed PMID: 23225782.	
Keele University	5	14	NICE recommend this as a technology but patients need early XR and access to surgery so these NICE recommendations could help describe where on the pathway this should sit.	Thank you for your comment. We think you are referring to the reference to NICE's technology appraisal guidance TA304 on total hip replacement and resurfacing for end stage arthritis. We will be reviewing the criteria for referral for joint replacement surgery in this guideline update but will not be covering surgery.
Lancashire Care NHS Foundation Trust	general	General	This is an update of the previous NICE Osteoarthritis guideline. The guideline scope looks very thorough and will cover all aspects of care from diagnosis through to conservative management and when to refer for joint replacement surgery. Particularly interested to note that they will be reviewing the evidence on the role of investigations (x-ray and MR) and the role of non-pharmacological interventions including osteoarthritis programmes.	Thank you for your comment.
Neurocare Europe Limited	General		Electrotherapy is a very broad field and many distinct modalities exist each with applications to particular medical conditions, many with strong supporting clinical evidence. Neuromuscular Electronic Stimulation (NMES) is one such	Thank you for your comment and for providing information on NMES. The committee will consider various types of electrotherapy when drafting the protocol for this evidence review.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			modality.	
Neurocare Europe Limited	General		According to FDA, Neuromuscular Electronic Stimulators (NMES devices) have 6 indications which are as follows: 1). Increase of Local circulation; 2) Muscle re-education; 3) Relaxation of muscle spasms; 4) Maintaining or increasing range of motion; 5) Prevention or retardation of disuse atrophy; 6) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.	Thank you for your comment and for providing information on NMES devices.
Neurocare Europe Limited	General		From these indications it will be apparent that this is a versatile therapy with a broad range of applications in virtually all situations where improving muscle condition and increasing local blood circulation are important therapeutic objectives. In many of its applications, whatever the underlying condition the patient is suffering from, and irrespective of whether it is a primary disease, a co-morbidity or a complication which requires treatment, the prospects for eventual full recovery will usually be enhanced if muscle condition and circulation can be progressively improved.	Thank you for your comment and for providing this information.
Neurocare Europe Limited	General		In strengthening muscles and improving local circulation NMES treats the underlying causes of osteoarthritis unlike pharmaceutical interventions which at best temporarily relieve pain symptoms and inflammation. Some of the clinical trials cited below have studied pain reduction alongside improvement in function and activities of daily	Thank you for your comment and for providing information on NMES devices.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			living and all show statistically significant improvements. There are very few reported side effects in the use of NMES whereas the widely prescribed high dosage pharmaceuticals will, according to category, bring numerous side effects ranging from the inconvenient to the positively dangerous.	
Neurocare Europe Limited	General		The use of opioids brings significant risk of addiction. A freedom of information response revealed that in England in 2018, 6.2 million people were prescribed opioids at an estimate (drug) cost to the NHS of £350 million and the addiction rate was estimated to be 4%, i.e. circa 250,000 people. This freedom of information response did not address the long term cost of rehabilitation of addicts and the related societal costs.	Thank you for your comment and for highlighting information related to opioid substance use. This guideline will review the effectiveness of pharmacological interventions for the management of osteoarthritis and this will include assessment of adverse events. Please also see the NICE guideline on safe prescribing and withdrawal management that is currently in development: https://www.nice.org.uk/guidance/indevelopment/gid-ng10141
Neurocare Europe Limited	General		In the USA the State of Oklahoma has recently commenced an action against Johnson and Johnson alleging "a cynical, deceitful multimillion-dollar brainwashing campaign" to drive up sales of its powerful painkillers at the opening of the first trial of a pharmaceutical giant over the US opioid epidemic. Oklahoma's attorney general, Mike Hunter, told the civil trial, that Johnson & Johnson played a leading role in "the worst manmade health crisis in the history of the country and the state".	Thank you for providing this information. This guideline will review the effectiveness of pharmacological interventions for the management of osteoarthritis.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Neurocare Europe Limited	General		We have previously submitted (under the NICE consultation on joint replacement) comment and clinical evidence of NMES treatment both pre and post joint replacement and we have therefore confined the following remarks and clinical evidence presented to the use of NMES in its application in treating Osteoarthritis.	Thank you for your comments. We have responded to each in turn.
Neurocare Europe Limited	General		In the majority of its applications NMES can be used as a stand alone intervention but is more usually used as an adjunct to volitional exercise and several of the clinical trials cited below reflect this form of usage. In situations of temporary (e.g. immediately post operation) immobility, it can be used to avoid atrophy and maintain muscle condition so that the subsequent return to full mobility can be accelerated. In cases of permanent immobility it is used to achieve similar outcomes and also as a means of avoiding and/or healing pressure ulceration.	Thank you for your comment. This information will be considered by the committee when drafting the protocol for the review of electrotherapy.
Neurocare Europe Limited	General		The clinical evidence which we would like to present is as follows: **1].** Effects of home-based resistance training and neuromuscular electrical stimulation in knee osteoarthritis: a randomized control trial.Robert A. Bruce-Brand, Raymond J. Walls, Joshua C. Ong. Barry S. Emerson, John M. O'Byrne and Niall M. Moyna BMC Musculoskeletal Disorders 2012, 13:118 doi:120.1186/1471-2474-13-118 –	Thank you for your comment and for providing this reference. It will be assessed for inclusion within the relevant evidence reviews.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Published 3 July 2012-10-19 RESULTS: There were similar, significant improvements in functional capacity for the RT and NMES groups at week 8 compared to week 1 ($p \leq 0.001$) and compared to the control group ($p < 0.005$), and the improvements were maintained at week 14 ($p \leq 0.001$). Cross sectional area of the QFM increased in both training groups (NMES: +5.4%; RT: +4.3%; $p = 0.404$). Adherence was 91% and 83% in the NMES and RT groups respectively ($p = 0.324$). CONCLUSIONS: Home-based NMES is an acceptable alternative to exercise therapy in the management of knee OA, producing similar improvements in functional capacity.	
Neurocare Europe Limited	General		**2].** Walls *et al.*, Effects of preoperative neuromuscular electrical stimulation on quadriceps strength and functional recovery in total knee arthroplasty. A pilot study *BMC Musculoskeletal Disorders* 2010, 11:119 Results: Overall compliance with the programme was excellent (99%). Preoperative QFM strength increased by 28% ($p > 0.05$) with associated gains in walk, stair-climb and chair-rise times ($p < 0.05$). Early postoperative strength loss (approximately 50%) was similar in both groups. Only the NMES group demonstrated significant strength (53.3%, $p = 0.011$) and functional recovery ($p < 0.05$) from 6 to 12	Thank you for your comment. We will not be covering any aspects of the patient pathway beyond referral for joint replacement surgery in this update.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			weeks post-TKA. QFM CSA decreased by 4% in the NMES group compared to a reduction of 12% in the control group (P > 0.05) at 12 weeks postoperatively compared to baseline.There were only limited associations found between objective and subjective functional outcome instruments Conclusions: This pilot study has shown that preoperative NMES may improve recovery of quadriceps muscle strength and expedite a return to normal activities in patients undergoing TKA for OA. Recommendations for appropriate outcome instruments in future studies of prehabilitation in TKA have been provided.	
Neurocare Europe Limited	General		**3].** The Treatment of Osteoarthritis of the Knee with Pulsed Electrical Stimulation. Zizic TM, Hoffman KC, Holt PA, Hungerford DS, O'Dell JR, Jacobs MA, Lewis CG, Deal CL, Caldwell JR, Cholewcynski JG, et al. J Rheumatol. 1995 Sep;22(9):1757-61. RESULTS: Patients treated with the active devices showed significantly greater improvement than the placebo group for all primary efficacy variables in comparisons of mean change from baseline to the end of treatment (p < 0.05). Improvement of > or = 50% from baseline was demonstrated in at least one primary efficacy variable in 50% of the active device group, in 2 variables in 32%, and	Thank you for your comment and for providing this reference. It will be assessed for inclusion within the relevant evidence reviews.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			in all 3 variables in 24%. In the placebo group improvement of > or = 50% occurred in 36% for one, 6% for 2, and 6% for 3 variables. Mean morning stiffness decreased 20 min in the active device group and increased 2 min in the placebo group ($p < 0.05$). No statistically significant differences were observed for tenderness, swelling, or walking time. CONCLUSION: The improvements in clinical measures for pain and function found in this study suggest that pulsed electrical stimulation is effective for treating OA of the knee. Studies for long term effects are warranted.	
Neurocare Europe Limited	General		**4].** Effects of quadriceps electrical stimulation program on clinical parameters in the patients with knee osteoarthritis.Durmuş D, Alayli G, Cantürk F.Clin Rheumatol. 2007 May;26(5):674-8. Epub 2006 Aug 1 Both groups showed significant improvements in pain, physical function, and stiffness scores after the therapy. There were statistically significant improvements in 50 m walking time and 10 steps stairs climbing up-down time and 1 RM and 10 RM values indicating the improvement in muscle strength. In addition, there were no significant differences between the groups after the therapy. We conclude that electrical stimulation treatment was as effective as exercise. We conclude that electrical stimulation treatment was as effective as exercise in knee osteoarthritis and	Thank you for your comment and for providing this reference. This will be assessed for inclusion within the relevant evidence reviews.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			electrical stimulation treatment can be suggested especially for the patients who have difficulty in or contraindications to perform an exercise program.	
Neurocare Europe Limited	General		**5].** Sao Paulo Med J. 2013;131(2):80-7.Is neuromuscular electrical stimulation effective for improving pain, function and activities of daily living of knee osteoarthritis patients? A randomized clinical trial.Imoto AM[1], Peccin MS, Teixeira LE, Silva KN, Abrahão M, Trevisani VF. RESULTS:Eighty-two patients completed the study. From intention-to-treat (ITT) analysis comparing the groups, the NMES group showed a statistically significant improvement in relation to the control group, regarding pain intensity (difference between means: 1.67 [0.31 to 3.02]; P = 0.01), Lequesne index (difference between means: 1.98 [0.15 to 3.79]; P = 0.03) and ADL scale (difference between means: -11.23 [-19.88 to -2.57]; P = 0.01). CONCLUSION: NMES, within a rehabilitation protocol for patients with knee osteoarthritis, is effective for improving pain, function and activities of daily living, in comparison with a group that received an orientation program.	Thank you for your comment. This intervention will be considered by the committee when drafting the protocol for the review of electrotherapy.
Neurocare Europe Limited	General		**6].** Neuromuscular Electrical Stimulation (NMES) Reduces Structural and Functional Losses of Quadriceps Muscle and Improves Health Status in Patients with Knee Osteoarthritis Marco Aure´lio Vaz,1 Bruno Manfredini Baroni,1 Jeam Marcel Geremia,1 Fa´bio Juner Lanferdini,1 Alexandre Mayer,1 Adamantios Arampatzis,2 Walter Herzog3 1	Thank you for your comment and for providing this reference. It will be assessed for inclusion within the relevant evidence reviews.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Received 17 January 2012; accepted 11 October 2012 Published online 8 November 2012 in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jor.22264 RESULTS: NMES training increased vastus lateralis thickness (from 12.6 to 14.2 mm) and fascicle length (from 19.6% to 24.6%). Additionally, NMES training increased the knee extensor torque by 8% and reduced joint pain, stiffness, and functional limitation. NMES training appears to offset the changes in quadriceps structure and function, as well as improve the health status in patients with knee OA. CONCLUSION: Patients with knee OA have decreased strength, muscle thickness, and fascicle length in the knee extensor musculature compared to age and sex-matched controls. NMES training of short duration appears to offset the changes in quadriceps structure and function, as well as reduces	
Neurocare Europe Limited	General		**7].** J Rheumatol. 2003 Jul;30(7):1571-8. A home-based protocol of electrical muscle stimulation for quadriceps muscle strength in older adults with osteoarthritis of the knee. Talbot LA[1], Gaines JM, Ling SM, Metter EJ. Results : The stimulated knee-extensor showed a 9.1% increase in 120 degrees PTIso compared to a 7% loss in the EDU group (time x group interaction for 120 degrees PTIso; p = 0.04). The chair rise time decreased by 11% in the NMES group, whereas the EDU group saw a 7%	Thank you for providing this information. This intervention will be considered by the committee when drafting the protocol for the review of electrotherapy.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			reduction (p = 0.01, time; p = 0.9, group). Similarly, both groups improved their walk time by approximately 7% (p = 0.02, time; p = 0.61 group). Severity of pain reported following intervention did not differ between groups. Conclusion: In older adults with knee OA, a home-based NMES protocol appears to be a promising therapy for increasing QF strength in adults with knee OA without exacerbating painful symptoms.	
Neurocare Europe Limited	General		Concluding remarks we are mindful of recent CCG pronouncements which impose new and increasingly stringent criteria on eligibility for joint replacement which now appear to include as candidates only those who are functionally immobile and/or suffering the most continuous intense pain. This will obviously exclude a very large number of patients whose symptoms are less severe and for whom no really effective alternative treatments are available in current NHS practice. Many patients who even quite recently would have been recommended for joint replacement are now receiving verdicts which are driven more by commercial considerations than clinical and only the most severely incapacitated are in most CCG areas candidates for early arthroplasty We have demonstrated in the above notes and clinical trial summaries that effective treatment alternatives to pharmaceuticals (and particularly opioids) do exist and	Thank you for your comment. We have responded to each in turn and have highlighted that NMES therapy will be considered for inclusion within the electrotherapy review. In addition, there are two clinical review questions related to referral for surgery. One question intends to identify the factors that indicate the need for referral for joint replacement surgery, whilst another is intended to determine whether particular patient factors are associated with increased benefits or harms after joint replacement surgery.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			very much hope that this NICE review when completed will bring NMES therapy (and any others which are financially accessible and clinically viable) into better prominence and more general usage.	
Neurocare Europe Limited	2	17	Within the section in the "Guideline scope" document noting current practice (p 2/10 line 17) the use of electrotherapy is not mentioned and therefore its inclusion (5/10 line 6) amongst non –pharmacological treatments which will be considered is to be welcomed	Thank you for your comment.
Neurocare Europe Limited	4		NMES can be used in any (p4/10 clinical 3.2) setting and in the majority of applications can be used for home self treatment	Thank you for your comment and for providing this information on NMES. This intervention will be considered for inclusion within the guideline.
Neurocare Europe Limited	7 & 8		***In general, NMES is, comfortable in use and safe with adverse incidents being extremely unusual. From the point of view of Health Economics it is inexpensive and direct costs (i.e. device cost plus consumables costs) can be around £2 per 45 minute treatment episode. We would strongly endorse your proposed economic evaluation (p7/10,3.4 and 8/10 3.2) and offer our participation in this exercise.***	Thank you for your comment. NMES will be considered as part of the electrotherapy review.
NHS Ealing CCG	5	15	Equity of access to joint replacement surgery remains a problem in England, in spite of the NICE guideline CG177 and subsequent NICE quality standard QS87. http://arma.uk.net/wp-content/uploads/2017/08/Policy-Position-Paper-Surgery_v5_Interactive.pdf	Thank you for your comment. Draft clinical questions 8.1 and 8.2 within the scope intend to address these concerns. These evidence reviews intend to determine what factors indicate the need for referral for joint replacement surgery, as well as determining whether patient factors are associated with increased

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			https://www.abhi.org.uk/media/1379/hip-and-knee-replacement-the-hidden-barriers.pdf https://www.ageuk.org.uk/Documents/EN-GB/For-professionals/Health-and-wellbeing/access_all_ages_final_web.pdf?dtrk=true **Please consider making reference to wide variation in access to surgery in the scope, and consider what type of review would inform a recommendation and quality standard.**	benefits or harms after joint replacement surgery. The implications of delayed surgery will therefore be covered.
NHS Ealing CCG	5	25	The draft scope currently excludes people who are prescribed nutritional supplements. NHS England issued advice to CCGs for implementation in primary care regarding stopping prescribing nutraceuticals (e.g. glucosamine). The NHS England advice shows that the NHS is still spending £0.45mil on nutraceuticals, in spite of publication of NICE Guideline CG177 (which recommended 'do not use…'). If this item is removed from the scope, and not otherwise carried forwards, this will expose patients to increased variation in practice, and divert NHS expenditure to this treatment but with poor evidence of cost-effectiveness. https://www.england.nhs.uk/wp-content/uploads/2017/11/items-which-should-not-be-routinely-precscribed-in-pc-ccg-guidance.pdf	Thank you for your comment. We are still excluding nutritional supplements in this update. Therefore, the previous recommendation will not be carried forward into the new guideline. However, we note that some glucosamine-containing products are now classified as medicines. We will consider looking at these within the review of pharmacological treatments.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Please consider including prescribing of nutritional supplements in the scope.	
NHS Ealing CCG	5	28	The draft scope currently excludes people who could be treated with acupuncture. Acupuncture is expensive for the NHS to provide. (£97 at 19/20 tariff per treatment per person). https://improvement.nhs.uk/documents/4981/AnnexA_1920_National_tariff_workbook.xlsx If 30 people per CCG received 6 sessions of acupuncture for osteoarthritis, this would cost the NHS £3mil. Given that 8 million people consult health professionals with osteoarthritis, the potential cost to the NHS by removing the 'do not use…' recommendation from NICE Guideline CG1777 is much more than £3mil. https://www.arthritisresearchuk.org/~/media/Files/Data%20and%20stats/State%20of%20MSK/PHS-08_StateOfMSKReport.ashx?la=en If this item is removed from the scope, and not otherwise carried forwards, this will expose patients to increased variation in practice, and divert NHS expenditure to this treatment but with poor evidence of cost-effectiveness. **Please consider including acupuncture treatment in the scope.**	Thank you for your comment. The scope has been amended to include acupuncture.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS Ealing CCG	8	28	Does the scope include subacromial decompression of the shoulder for degenerative disease? If so, there are high quality sham-controlled surgical trials: https://www.bmj.com/content/362/bmj.k2860 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32457-1/fulltext NHS England estimate that 7,000 of these procedures 2017-18 could have been managed without surgery. This was not reviewed in CG177. https://www.england.nhs.uk/evidence-based-interventions/ebi-programme-guidance/ **Please consider including arthroscopic surgery for subacromial decompression of the shoulder in the scope.**	Thank you for your comment. This will be discussed when the committee develops the review questions. The orthopaedic surgeon recruited to the committee will be able to advise.
NHS Ealing CCG	8	28	The scope should include surgery for degenerative knee arthritis and meniscal tears as there is high quality evidence published that could inform recommendations: https://www.bmj.com/content/357/bmj.j1982 Current NICE guidance and NHS England Evidence-Based Interventions have not considered surgery for degenerative meniscal tears, only arthroscopic washouts and removal of loose bodies causing true locking. There were over 3,000	Thank you for your comment. This will be discussed when the committee develops the review questions. The orthopaedic surgeon recruited to the committee will be able to advise.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			procedures in England in 2017-18 that could be included in a broader scope than CG177. https://www.england.nhs.uk/evidence-based-interventions/ebi-programme-guidance/ **Please consider including arthroscopic surgery for meniscal degeneration of the knee in the scope.**	
Ossur UK	3	1-3	We feel that following diagnosis and education on self-management strategies, patients should be referred to community care coordinated by an Extended Scope Practitioner (ESP), Integrated Musculoskeletal Service (iMSK)and in line with the Long Term NHS Plan the First Contact Physio – or if these are unavailable within a trust or region – the orthopaedic department of the local hospital, or orthopaedic surgeon, to continue with the treatment through the community care cycle. The guidelines should direct users to information on these alternative community care pathways for patients.	Thank you for your comment. The guideline is not intending to address service delivery areas but will consider directing users to relevant documents if appropriate.
Ossur UK	3	1-3	From our review of the current protocol and services available to patients, we feel the iMSK or ESP should offer a series of treatments which can be prescribed in combination or individually. The iMSK or ESP would offer specialist practitioners to offer or refer for non-pharmalogical support with mental health, weight management, exercise and strength training; pharmalogical prescriptions such as pain management and injections, and	Thank you for your comment. The guideline will review the evidence for weight management, exercise, pharmacological interventions and braces. The recommendations may cover combinations of treatment.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			medical device interventions such as knee unloader bracing for unicompartmental knee osteoarthritis.	
Ossur UK	8	1-2	We feel that while an X-ray will give a clear indication of the condition of the joint, there is often a poor link between changes visible on an X-ray and symptoms of osteoarthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms. All of the diagnostic tools (physical assessment, verbal assessment, X-ray) should be used together to diagnose a patient with osteoarthritis as well as advise them on the appropriate treatment for their particular condition and situation. Management of the condition should be supported by appropriate scoring tools.	Thank you for your comment. The question is focusing on the additional benefit of imaging beyond a clinical diagnosis, which will include a clinical assessment as you state.
Ossur UK	8	4-6	We believe surgeons should provide all options to patients, including non-operative solutions as a primary consideration before prescribing invasive surgery – and this should be made clear in the guidelines as there is a current tendency to assume surgery is appropriate in most cases, whereas many patients could benefit from alternative treatment as a primary option.	Thank you for your comment. The emphasis for this guideline is non-surgical management and it is anticipated the interventions investigated would be offered to the majority of patients before they are referred to a surgeon. The guideline will cover the factors that indicate referral and when this should happen.
Ossur UK	8	8-10	We agree that weight loss should be seen as a core treatment option for osteoarthritis.	Thank you for your comment. We can confirm that the clinical and cost effectiveness of weight loss will be assessed within the guideline.
Ossur UK	8	13-14	When I attended the scoping session, our table engaged in a discussion about bracing, in particular in the case of unicompartmental knee osteoarthritis. Studies have shown	Thank you for your comment. The impact of braces on the need for surgery will be discussed by the committee for inclusion as an outcome in the review

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			that the use of unloader bracing postpones or prevents the need for invasive surgery. We agreed it should be prescribed alongside a cycle of community care therapies including weight loss and exercise, but also mental health support, physiotherapy and strength training, among others. In closely reviewing the 2014 update of the guidelines, we discussed Figure 3 in section 4.1.2 Targeting Treatment in which bracing is described as '[an] adjunctive treatment of less well-proven efficacy, less symptom relief or increased risk to the patient.' Given the more recent studies proving the effectiveness of bracing as a primary treatment option, my discussion group agreed that diagrams such as Figure 3 should be updated to reflect this, with bracing placed alongside options such as strengthening, fitness, weight loss, education and advice which are all also seen as precursors to surgery or other more invasive options. One clinical study in particular, published in the British Medical Journal, has shown unloader bracing to be a viable alternative, or precursor to invasive surgery. According to the study, increased pressure on the underlying bone is a cause of pain experienced by most osteoarthritis sufferers. The wear and tear on the cartilage will gradually cause the knee to become painful and feel stiff when moving. An unloading brace applies a gentle force designed to reduce	on braces. The committee will also consider the diagram on targeting treatment when developing recommendations.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			the pressure on the affected part of the knee, resulting in pain reduction which enables the patient to increase their functional activities.	
Pfizer Limited	2	20	Pfizer suggest changing line 20 in section 1 (page 2) of the draft scope to "This may be due to social stigma and isolation for individuals with pain related to common myths – for example, that nothing can be done or that joint pain is part of normal ageing." As outlined by the references below, there may be other reasons at play, such as social stigma, for patients to persevere with osteoarthritis, thus contributing not to seek advice for their condition next to the feeling of not receiving adequate support from healthcare professionals. References: • Agaliotis M, Mackey MG, Jan S, Fransen M. Perceptions of working with chronic knee pain: A qualitative study. Work. 2018(Preprint):1-2. • Collier R. "Complainers, malingerers and drug-seekers"—the stigma of living with chronic pain. CMAJ: Canadian Medical Association Journal. 2018 Feb 20;190(7):E204. • Naushad N, Dunn LB, Muñoz RF, Leykin Y. Depression increases subjective stigma of chronic pain. Journal of affective disorders. 2018 Mar 15;229:456-62. Goldberg DS. Pain, objectivity and history: understanding	Thank you for your comment. We have edited the text as suggested.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			pain stigma. Medical humanities. 2017 Dec 1;43(4):238-43.	
Pfizer Limited	7	3	Please add: Tanezumab for treating moderate to severe chronic pain caused by osteoarthritis or low back pain after 2 therapies. NICE technology Appraisal. Publication date to be confirmed. This technology appraisal is currently being scheduled by NICE and likely to conclude before the NICE guideline for osteoarthritis is consulted on. https://www.nice.org.uk/Media/Default/About/what-we-do/Topic-selection/topic-selection-ta-decisions.xls	Thank you for your comment. This section of the scope only lists relevant NICE guidance that has published or entered development. All relevant technology appraisal guidance will be included in the NICE Pathway on osteoarthritis on publication.
Pfizer Limited	7	22	It is unlikely that economic benefits are sufficiently captured using the NHS+PSS perspective. As acknowledged in section 1 and by the stakeholders during the scoping workshop the impact on patient, NHS and society is substantial, and that a broader perspective may need to be considered. Pfizer suggest changing the sentence to comprehensively reflect the high unmet need and potential societal opportunity costs, which currently are underestimated using a strict NHS+PSS perspective. Please change the sentence to: "We will review the economic evidence and carry out economic analyses, using a NHS and personal social services (PSS) perspective. If appropriate, a broader perspective may be used in sensitivity analyses (for example, including non-NHS costs, consequences and	Thank you for your comment. Although it is accepted that there is likely to be a wider economic impact of the recommendations for osteoarthritis, NICE guidelines primarily focus on the economic impact for the NHS & PSS alone, and therefore do not consider costs incurred or saved outside of the NHS. This is the standard perspective adopted for NICE guidelines

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			societal aspects, such as work presenteeism, absenteeism and productivity)."	
Pfizer Limited	8	4	In line with the comment number 4 made for page 8 line 25, Pfizer suggests to change line 4 on page 8 in section 3.5 to "What information on osteoarthritis, including the management of flare-ups or signs of rapid disease progression, do people with osteoarthritis, their family and carers need after diagnosis."	Thank you for your comment. The exact question will be agreed by the committee. Our current question does not preclude including information about disease progression. This is because this will be a qualitative review which is often more exploratory. Because of this, the themes expected to come out of the literature are not pre-specified.
Pfizer Limited	8	25	During the draft scope workshop (7th of April 2019) the stakeholder group broadly agreed that x-rays are over-utilised as a diagnostic tool in current practice. However, amongst other indicators, x-ray was deemed by the workshop attendees to be an appropriate criterion for the referral to surgery, especially for identifying certain risk groups such as rapid joint progression, as supported in the below listed references: • Halilaj E, Le Y, Hicks JL, Hastie TJ, Delp SL. Modeling and predicting osteoarthritis progression: data from the osteoarthritis initiative. Osteoarthritis and cartilage. 2018 Dec 1;26(12):1643-50. • Cibere J, Sayre EC, Guermazi A, Nicolaou S, Esdaile JM, Kopec JA, Singer J, Thorne A, Wong H. Predicting OA progression: results from the Vancouver knee osteoarthritis progression study. Osteoarthritis and Cartilage. 2012 Apr 1;20:S186.	Thank you for your comments. The clinical scenarios within this question are intended to be examples only and not an exhaustive list. The use of imaging in order to identify risk groups will be considered by the committee when drafting and refining this review question and protocol.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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			• Reijman M, Hazes JM, Pols HA, Bernsen RM, Koes BW, Bierma-Zeinstra SM. Role of radiography in predicting progression of osteoarthritis of the hip: prospective cohort study. Bmj. 2005 May 19;330(7501):1183. Pfizer suggest explicit inclusion of this by changing line 25 in section 3.5 (page 8) of the draft scope to "What is the clinical and cost effectiveness of X-ray or MRI during the management of osteoarthritis (for example; in the management of flares, for identification of risk groups, such as rapidly progressing osteoarthritis, or before consideration for referal to surgery)"	
Pfizer Limited	9	9	During the draft scope workshop (7th of April 2019) the stakeholder group discussed and agreed the need to include "life responsibilities", namely to account for the impact of osteoarthritis on the ability to carry out work and non-work related social activities, e.g. sports, by inclusion of patient reported outcomes that sufficiently capture these elements. These aspects are unlikely to sufficiently captured in the EQ-5D matrix. In addition, to life responsibilities, the stakeholders listed that carer burden is an important outcome that needs to be accounted for in osteoarthritis. Pfizer suggests inclusion of the following outcomes that in section 3.6 (page 9) of the draft scope: - Carer burden	Thank you for your comment. Outcomes will be finalised by the committee for each question when developing the review protocols during guideline development. When considering outcomes, we avoid looking at outcomes that specifically refer to work, as this could discriminate against those who do not work. A similar outcome that is often used is return to daily activity. The impact on work is likely to be reflected in quality of life outcomes, which is included in the list of main outcomes in the scope and reflected in economic considerations.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Life responsibilities, e.g. ability to work or participation in social activities	
Pfizer Limited	9	14	In line with NICE Clinical Guidance CG177 (Osteoarthritis: care and management), opioids are a recommended treatment for osteoarthritic pain. There is sufficient evidence that opioids used as long-term treatment can lead to dependence (e.g. as outlined by RCOA: https://www.rcoa.ac.uk/faculty-of-pain-medicine/opioids-aware/opioids-and-addiction). Given this adverse event of special interest, it would be prudent to explicitly list dependence and withdrawal as key adverse event for the evidence assessment. Pfizer suggest changing line 14 in section 3.6 (page 9) of the draft scope to "adverse effects, dependence and withdrawal".	Thank you for your comment. The scope of this update includes a review of pharmacological management of osteoarthritis, and we anticipate that this will include opioids. Safety and adverse events will be considered. The list of outcomes in 3.6 is meant to be a broad indication of the outcomes we cover in the guideline. Specific outcomes will be defined by review questions when we agree the review question protocols. See also the NICE guideline on safe prescribing and withdrawal management currently in development: https://www.nice.org.uk/guidance/indevelopment/gid-ng10141
Reckitt Benckiser UK Limited	4	21	The draft scope is covering "all settings where NHS healthcare is provided or commissioned". It should be explicit that this includes community pharmacies. The NHS is driving a self- care agenda. Pharmacists are an integral part of providing health education and advice to patients with long- term conditions such as osteoarthritis.	Thank you for your comment. Community pharmacies are covered within 'all settings'. We intentionally do not list every setting separately as this could lead to unintended exclusions.
Reckitt Benckiser UK Limited	5	8	Given that some patients may not present to their GP with osteoarthritis or present only infrequently, these patients may be self-treating or treating with the support of a pharmacist. As a result, it is important the pharmacological management section includes distinct over-the-counter	Thank you for your comment. The committee will decide on what pharmacological comparisons to review when the review question protocols are set.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			(OTC) treatment options/recommendations. This is of particular importance given the self-care agenda, GP appointment waiting times and the increasing role pharmacists are likely to play in helping to manage patients with longer term conditions. The inclusion of these OTC treatment options will still fall within licensed indications, as a number include 'non-serious arthritic pain' or similar as a licensed indication.	
Royal College of General Practitioners	General	General	The committee should consider making recommendations for people with multimorbidity. Comorbidity is increasing common for people with osteoarthritis.	Thank you for your comment. We are aware of the complex issues related to care provision for people with multiple health needs. The multimorbidity guideline aims to provide recommendations related to this, including recommendations to support treatment decisions for people with multimorbidities (https://www.nice.org.uk/guidance/ng56). In relation to conditions that may be comorbid to (or associated with) osteoarthritis, the guideline committee will consider these groups when each evidence review protocol is drafted. For each evidence review, the committee will consider appropriate population stratifications or subgroups, in order to determine whether sub-populations in those with osteoarthritis should be separated within the analysis of each evidence review (for example, separating the evidence for people with comorbid

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				conditions). Where appropriate this may result in different recommendations for subgroups within the osteoarthritis population, although recommendations are always intended to be interpreted with normal clinical judgement (for example, knowing when an exercise intervention may be contraindicated in a patient). Furthermore, as part of normal clinical judgement the BNF should always be used alongside NICE guidance when making medication decisions and cautions and contraindications should be taken into account.
Royal College of General Practitioners	3	1 and 21	Patients frequently present to their General Practitioner requesting an opinion about the usefulness and safety of complementary therapy in osteoarthritis. An evidence-based position statement from NICE about the efficacy/safety of complementary therapies would aid shared decision-making with patients	Thank you for your comment. We have focused the update on the interventions for which there is likely to be evidence rather than cover every potential intervention. This is based on the recommendations in the 2017 surveillance report for this guideline: https://www.nice.org.uk/guidance/cg177/evidence
Royal College of General Practitioners	3	6	Electrotherapy is not a standard therapy in osteoarthritis; we would like to query why electrotherapy is included in the draft scope, but not other forms of complementary therapy?	Thank you for your comment. We have focused the update on the interventions for which there is likely to be evidence rather than cover every potential intervention. This is based on the recommendations in the 2017 surveillance report for this guideline: https://www.nice.org.uk/guidance/cg177/evidence The report identified a new evidence base for electrotherapy to support its potential use. It is therefore included in the scope so that we can review

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the evidence in order to make recommendations.
Royal College of General Practitioners	4	6	The committee should consider expanding on the options of management depending on the patient's circumstances.. For example, it is likely that treatment effects and options for an otherwise fit & well 40 year old ex-rugby player would be very different to a frail 75 year old person.	Thank you for your comment. For each evidence review the committee pre-specify population stratifications and subgroups, in order to determine variations in treatment effects and consequently whether recommendations should differ between populations.
Royal College of General Practitioners	5	8	We think that it is important that the pharmacological interventions reviewed within the guideline should reflect combinations used in routine practice.	Thank you for your comment. The combinations of pharmacological treatments will be discussed by the committee when the review question protocol is agreed.
Royal College of General Practitioners	7	1	Could the scope please include the question: "Are there any tools which help clinicians diagnose osteoarthritis earlier in the disease process? What is the clinical and cost effectiveness of these tools?"	Thank you for your comment. The guideline will cover the benefit of imaging for the diagnosis of guideline. The guideline focuses on people in whom osteoarthritis is suspected and therefore will not cover when to suspect osteoarthritis.
Royal College of General Practitioners	8	4	3.5.2.1 – Does providing this information improve clinical or cost effectiveness?	Thank you for your comment. This question is not designed to assess the effectiveness of information (recommendations related to information provision will be based on qualitative evidence if it is identified).
Royal College of General Practitioners	9	6	We would ask that impact on occupation/work is included as a main outcome of the guideline; the impact on the patient's ability to work can be associated with quality of life.	Thank you for your comment. Outcomes will be finalised by the committee for each question when developing the review protocols during guideline development. When considering outcomes, we avoid looking at outcomes that specifically refer to work, as

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				this could discriminate against those who do not work. A similar outcome that is often used is instead 'return to daily activity'. We agree that such impacts are likely to be reflected in quality of life outcomes, which is listed in the scope.
Royal College of Nursing	General	General	The Royal College of Nursing (RCN) welcomes the NICE draft guidelines on Osteoarthritis: care and management. The RCN invited members who work with Osteoarthritis to review the draft guidelines on its behalf. The comments below reflect the views of our reviewers.	Thank you for your comments. We have responded to each in turn.
Royal College of Nursing	General	General	No mention of mechanical aids such as braces/taping	Thank you for your comment. Please see question 3.3 within the draft scope, which intends to assess the clinical and cost effectiveness of devices for the management of osteoarthritis. The question wording has been amended to make clear that this covers bracing and taping. Braces and taping will be considered by the committee for inclusion as part of this review.
Royal College of Nursing	General	General	Not aware of any parts of the scope which would benefit from changes to improve equality and diversity, or of any innovative approached which should be included for consideration	Thank you for your comment.
The Society and College of	8	1-2 and 25-	The Society and College of Radiographers suggests particular attention is given to imaging those at the lower age range considered within this scope (16-18) in	Thank you for your comment. Any recommendations made related to imaging will also take into account any legislation associated with them. We have co-

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Radiographers		27	accordance with regulation 12 (8) (a) of the Ionising Radiation (Medical Exposure) Regulations 2017	opted a radiologist to advise the committee in this area.
University Hospitals Birmingham	1	20	Sentence ending in 'mostly affecting the knee, hip, hand and foot joints' Reference this statement; what about the spine being commonly affected	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	1	22	Sentence ending in 'flare-ups are common'; reference this statement.	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	1	22	Sentence ending in 'flare-ups are common'; I would not use the terminology flare-ups for describing transient worsening of OA symptoms, since this can lead to confusion with inflammatory arthritis, which can co-exist with OA occasionally; stick to worsening of osteoarthritis symptoms.	Thank you for your comment. No other terminology has been suggested instead of 'flare-up' of symptoms, and the term flare-up appears to be commonly used in the literature.
University Hospitals Birmingham	1	24	Sentence ending in 'people who are obese'; reference this statement	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	2	2	Sentence ending in 'quality of life and health outcomes'; reference this statement	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and is not part of the guideline.
University Hospitals Birmingham	2	6	Sentence ending in 'prescriptions and adjustments to the home'; reference this statement	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	2	9	'multimorbidity' isn't a commonly recognised terminology; suggest change to multiple co-morbidities	Thank you for your comment. We have updated this to state "Many people with osteoarthritis have multiple long-term conditions".
University Hospitals Birmingham	2	Paragraph starting line 11	This whole paragraph sounds like speculation, rather than clear statements with supporting evidence; suggest remove this	Thank you for your comment. This is based on a report by Arthritis Research UK and emphasises the issue of multimorbidity for some people with osteoarthritis. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	2	22	Sentence starting with 'This may be because of common myths' ; OA prevalence does increase with age, hence stating that joint pain is part of normal ageing is a myth can be confusing, and misleading, since pain from osteoarthritis is more likely to be more common as people get older. Suggest remove this part of the sentence.	Thank you for your comment. This paragraph is to emphasise that some people may not present because they believe that joint pain is part of normal ageing. We agree that it is not a normal part of ageing. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				the guideline.
University Hospitals Birmingham	2	23	Reference this statement; is useful to have evidence to support claims like this	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	2	29	'osteoarthritis flare-up'; 'flare-up' is a confusing term; I would not use the terminology flare-ups for describing transient worsening of OA symptoms, since this can lead to confusion with inflammatory arthritis, which can co-exist with OA occasionally; stick to worsening of osteoarthritis symptoms instead of the words 'flare-up'	Thank you for your comment. No other terminology has been suggested instead of 'flare-up' of symptoms, and the term flare-up appears to be commonly used in the literature.
University Hospitals Birmingham	3	2	Sentence ending with 'people with osteoarthritis'; suggest give examples of the multidisciplinary professionals providing care for people with osteoarthritis, to better indicate breadth of professionals involved	Thank you for your comment. The purpose of this section is to give a general overview of the area and provide background information and context. It is not intended to be an authoritative source of information and is not part of the guideline.
University Hospitals Birmingham	5	6	'electrotherapy; from the literature in osteoarthritis, this refers to 'transcutaneous electrical nerve stimulation (TENS)'; suggest you use this term instead, as it will be easier for clinicians searching the guidelines to seek the guidance regarding this when using the NICE guideline	Thank you for your comment. The term 'electrotherapy' has been used in order to incorporate the range of electrotherapy interventions that exist, which include but are not limited to TENS.
Versus	General	Gene	Versus Arthritis welcomes the opportunity to comment on	Thank you for your comment.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Arthritis		ral	the National Institute for Health and Care Excellence's (NICE) Guideline scope for the Osteoarthritis: care and management guideline, which will update CG177.[12] [1] NICE (2019) Guideline scope – Osteoarthritis: care and management. Accessed here: https://www.nice.org.uk/guidance/GID-NG10127/documents/draft-scope	
Versus Arthritis	General	General	Arthritis and related musculoskeletal conditions affect 17.8 million people in the UK and are the single biggest cause of pain and disability in the UK.[iii] Osteoarthritis is the most common form of arthritis affecting 8.75 million people over 45 years of age in the UK.[iv] Physical activity is a recommended core treatment for osteoarthritis by NICE.[v] [iii] Versus Arthritis (2018) State of Musculoskeletal Health 2018. Accessed here: https://www.arthritisresearchuk.org/~/media/Files/Data%20and%20stats/State%20of%20MSK/PHS-08_StateOfMSKReport.ashx?la=en [iv] Versus Arthritis (2018) State of Musculoskeletal Health 2018. Accessed here: https://www.arthritisresearchuk.org/~/media/Files/Data%20and%20stats/State%20of%20MSK/PHS-08_StateOfMSKReport.ashx?la=en	Thank you for your comment.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			[v] NICE (2015) Osteoarthritis Quality Standard (QS87). Accessed here: https://www.nice.org.uk/guidance/qs87/resources/osteoarthritis-pdf-2098913613253	
Versus Arthritis	General	General	Cumulatively, the healthcare costs of osteoarthritis and rheumatoid arthritis will reach £118.6 billion over the next decade.[vi] Musculoskeletal conditions account for a fifth of all sickness absence and result in the loss of around 30.8 million working days to the UK economy each year.[vii] [vi] York Health Economics (2017). The Cost of Arthritis: Calculation conducted on behalf of Arthritis Research UK. [vii] Office for National Statistics (2017). Sickness Absence Report 2017.	Thank you for your comment.
Versus Arthritis	General	General	This submission responds to the questions contained in the draft scope for the updated NICE guideline on Osteoarthritis: care and management.	Thank you for your comment. We have responded to each comment in turn.
Versus Arthritis	8	4-6	We welcome the amendment to this question from the original draft scope. However, we believe that an additional question could be added to help develop the evidence base to establish best practice in information provision for osteoarthritis (OA). Consistency of information for people with osteoarthritis is important for successful self-management of the condition, taking into account that their needs will differ depending on what stage of the pathway they are (pre-diagnosis,	Thank you for your comment. This question is not designed to assess the effectiveness of information. Recommendations related to information provision will therefore be based on qualitative evidence if it is identified.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			diagnosis, managing or struggling with their condition).	
Versus Arthritis	8	8-10	This question could be developed further by asking for evidence about what stage of the pathway that patients derive the most clinical benefit from interventions like exercise, weight management and education. In the original scope, there was a reference to clinical and cost effectiveness of these interventions before surgery (question 4.2) that should be reinstated: "What is the clinical and cost effectiveness of weight loss and/or exercise before surgery in adults with OA?"	Thank you for your comment. The original question was intended to investigate whether advice to lose weight or exercise before surgery was appropriate, rather than to assess the effectiveness of these interventions in managing osteoarthritis. This has now been split into separate questions: one for weight loss, one for exercise therapy and one for treatment packages (including combinations of treatments). There are also 2 further questions (8.1 and 8.2) investigating when people should be referred for surgery and whether any factors such as BMI are associated with benefits or harms after surgery.
Versus Arthritis	8	13-14	We support the amendment from the original draft scope in April which provides clarity to the question. This strengthens the recommendation from the 2014 guideline, which stated that "Assistive devices (for example, walking sticks and tap turners) should be considered as adjuncts to core treatments for people with osteoarthritis who have specific problems with activities of daily living. If needed, seek expert advice in this context (for example, from occupational therapists or Disability Equipment Assessment Centres)."	Thank you for your comment and for providing the reference related to aids. As a result of stakeholder comments this question has been amended to focus on devices (such as supports, splints and braces). Assistive devices will not be included. Question 2.1 of the scope intends to assess what information is useful for people with osteoarthritis.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			However, NICE should also consider how information around aids and devices can be standardised to help provide clarity to people with osteoarthritis about the costs and benefits of different aids and devices and their cost effectiveness. Versus Arthritis has included a number of recommendations on aids in our recent policy report.[13] [viii] Versus Arthritis (2019) Adapted Homes, Empowered Lives. Accessed here: https://www.versusarthritis.org/media/12929/adapted-homes-empowered-lives-report.pdf	
Versus Arthritis	8	24	The original draft scope included a reference to optimum frequency of follow-up and review, and this should be reinstated in the draft scope. In the 2014 NICE guideline on Osteoarthritis, it is recommended that an annual review is considered for any person with one or more of the following: troublesome joint pain; more than one joint with symptoms; more than one comorbidity; and those who take regular medication for their osteoarthritis.[ix]	Thank you for your comment. Based on stakeholder feedback it was determined that there was variation in practice and limited advice related to follow up and review for people with osteoarthritis, including the frequency of contact. The committee will consider the need for advice on frequency when refining this review question and protocol.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			It is important to assess the evidence base around annual reviews and follow-up for people with OA in these groups, as well as what type of follow-up, continued support, assessment and review has the most clinical and cost effectiveness. This will help to establish best practice around interventions for people with OA in the long term and in follow up to surgery. Versus Arthritis' State of MSK Health 2018 highlighted the prevalence of people with osteoarthritis who also have another comorbidity.[x] By the year 2025 the number of people living with one or more serious long-term conditions in the UK will increase by nearly 1 million, rising from 8.2 million to 9.1 million.[xi] Pain and functional limitations of arthritis make it harder to cope with multimorbidity, causing fatigue and depression. Four out of five people with osteoarthritis have at least one other long-term condition such as hypertension, cardiovascular disease (CVD) or depression.[xii] [ix] NICE (2014) Osteoarthritis: care and management. Accessed here: https://www.nice.org.uk/guidance/cg177/resources/osteoarthritis-care-and-management-pdf-35109757272517 [x] Versus Arthritis (2018) State of Musculoskeletal Health	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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			2018. Accessed here: https://www.arthritisresearchuk.org/~/media/Files/Data%20and%20stats/State%20of%20MSK/PHS-08_StateOfMSKReport.ashx?la=en [xi] Versus Arthritis (2018) State of Musculoskeletal Health 2018. Accessed here: https://www.arthritisresearchuk.org/~/media/Files/Data%20and%20stats/State%20of%20MSK/PHS-08_StateOfMSKReport.ashx?la=en [xii] Versus Arthritis (2018) State of Musculoskeletal Health 2018. Accessed here: https://www.arthritisresearchuk.org/~/media/Files/Data%20and%20stats/State%20of%20MSK/PHS-08_StateOfMSKReport.ashx?la=en	
Versus Arthritis	8	32-33	In addition to this question it would be helpful to include a question focusing on the optimal time period for referral for possible joint replacement surgery, given the evidence collated by Professor Sir Harry Burns (former Chief Medical Officer) in his independent review of waiting times in Scotland shows that outcomes of joint replacement surgery after waiting for more than 18 weeks become gradually worse the longer a patient has waited.[xiii] One study completed by Garbuz found that waiting for joint replacements for longer than six months 'was linked to a 50% decrease in functional outcome' and 'that delaying	Thank you for your comment. To make clear that optimal timing of referral for surgery is being covered, we have rephrased question 8.1 to read: 'When should people with osteoarthritis be referred for possible joint replacement surgery, and what factors should this be based on?"

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			treatment may result in deterioration that may not be recoverable after surgery.' [14] Additional studies in the review showed that 'each additional month waiting for treatment was associated with an 8% decrease in the odds of better than expected functional outcome.'[xv] Furthermore, the review found that functional capacity gain was poorer for patients who waited longer the six months for surgery, and that patients on extended waiting times had increased pain and disability compared to those with shorter waits.[xvi] [xiii] Harry Burns; Scottish Government (2018) Independent Review into Waiting Times Targets. Accessed here: https://www2.gov.scot/Topics/Health/Quality-Improvement-Performance/Review-Targets-Indicators [xiv] Harry Burns; Scottish Government (2018) Independent Review into Waiting Times Targets. Accessed here: https://www2.gov.scot/Topics/Health/Quality-Improvement-Performance/Review-Targets-Indicators [xv] Harry Burns; Scottish Government (2018) Independent Review into Waiting Times Targets. Accessed here: https://www2.gov.scot/Topics/Health/Quality-Improvement-	

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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			Performance/Review-Targets-Indicators [xvi] Harry Burns; Scottish Government (2018) Independent Review into Waiting Times Targets. Accessed here: https://www2.gov.scot/Topics/Health/Quality-Improvement-Performance/Review-Targets-Indicators	
Versus Arthritis	9	1-3	A significant majority of first time (primary) joint replacements were carried out in patients with osteoarthritis: 90% of primary hip replacements, 98% of primary knee replacements and 54% of primary shoulder replacements.[xvii] Previous NICE guidelines on Osteoarthritis have included recommendations that patient-specific factors (including age, sex, smoking, obesity and comorbidities) should not be barriers to referral for joint replacement surgery. It is crucial that NICE retains and strengthens these recommendations in the updated guideline on Osteoarthritis so that clinical guidelines can be used to hold Clinical Commissioning Group (CCGs) and providers accountable for any attempts to restrict access on non-clinical factors. Evidence from the Royal College of Surgeons[xviii] and other organisations over the last few years have shown that CCGs have been restricting access to joint replacement surgery on the basis of non-clinical factors such as BMI thresholds. The results of a Freedom of Information (FOI)	Thank you for your comments. The list was not intended to be exhaustive, and the factors included will be discussed with the committee when developing the review protocol. You are correct that we are not intending to cover the effectiveness of joint replacement itself as this is being covered by the joint replacement guideline in development. However, this osteoarthritis guideline update will look at who should be referred for joint replacement surgery and whether particular factors predict the success of surgery. In order to determine whether particular patient factors predict this, it has to be determined whether surgery is more or less successful in a particular group of people that have the factor of interest. Surgical outcomes therefore need to be measured to determine this. However, the wording of the question is a draft and may be amended further when the guideline committee define the clinical question and protocol fully.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			request carried out by the ABHI indicated that a majority of CCGs have formalised these restrictions through their commissioning policies, despite the evidence-based guidance from NICE. [xvii] National Joint Registry (2018) 15th Annual Report. Accessed here: https://www.hqip.org.uk/wp-content/uploads/2018/11/NJR-15th-Annual-Report-2018.pdf [xviii] Royal College of Surgeons (2016). Smokers and overweight patients: Soft targets for NHS savings? Accessed here: https://www.rcseng.ac.uk/-/media/files/rcs/library-and-publications/non-journal-publications/smokers-and-overweight-patients--soft-targets-for-nhs-savings.pdf	
Versus Arthritis	9	6-14	We believe that work should be added as one of the main outcomes for developing evidence around the updated guideline. The economic impact of musculoskeletal conditions on the UK workforce is significant, accounting for a fifth of all sickness absence and result in the loss of around 28.2 million working days to the UK economy each year.[xix] [xix] Office for National Statistics (2017). Sickness Absence Report 2017.	Thank you for your comment. Outcomes will be finalised by the committee for each question when developing the review protocols during guideline development. When considering outcomes, we avoid looking at outcomes that specifically refer to work, as this could discriminate against those who do not work. A similar outcome that is often used is return to daily activity. The impact on work is likely to be reflected in quality of life outcomes, which is included in the list of main outcomes in the scope and reflected in economic considerations.
Zimmer Biomet	9	1	Zimmer Biomet particularly welcomes the investigation of the impact of patient factors on the outcome of joint	Thank you for your comment.

Osteoarthritis: care and management (update)

Consultation on draft scope
Stakeholder comments table

1 May 2019 – 31 May 2019

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			replacements. There are many apparently arbitrary and inconsistent restrictions to access to joint replacement at CCG level today. The new guidance will help in correctly identifying the impact of patient factors and ensuring that those who are likely to have an improved quality of life from total joint replacement will not be prevented from doing so.	