Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management (Oct 2020)

Consultation on draft scope
Stakeholder comments table

21 June 2018 to 26 July 2018

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
#MEAction UK	General	General	NICE question: 1 "*Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?*" Currently the main interventions recommended by NICE for ME are graded exercise therapy (GET) and cognitive behavioural therapy (CBT), which focus on increasing activity through shifting thoughts of illness to thoughts of wellness. These interventions are ineffective, harmful and scientifically untenable, as we discussed in detail in our 2017 response. These interventions have received the bulk of UK ME research funding to date. Despite a considerable body of research, GET/CBT have proven ineffective at producing objective improvement (Stouten, 2017). Ineffective treatment is, by definition, not cost-effective: it is a waste of public resources. #MEAction demands an immediate end to the use of GET and CBT An interim warning must be added to the current guidelines, covering the time until the new guideline is published, stating that GET and CBT should not be used and can be harmful to people with ME. Furthermore, this message must be disseminated to all general practitioners and health and social care professionals, including in the Department of Work and Pensions (DWP). The GET/CBT approach should not be the future of ME treatment. Pacing, using the energy envelope theory, is the management strategy most favoured by people with ME (Geraghty, 2017; Kirke, 2017) as well as by expert clinicians esteemed in the patient community (VanNess et al, 2018). It is also recommended by the new CDC guidance:	Thank you for your comments and suggestions. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. The evidence for these interventions will be reviewed using parameters such as the population group included as you describe. The GRADE method allows for the downgrading of any study assessing for the areas you outline. This includes the use of blinding in assessment of outcomes, which means more subjective outcomes are downgraded.

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			"...physical and mental exertion can aggravate symptoms and debilitate patients. An important strategy for patients to learn is how to manage their activities to avoid triggering post-exertional malaise (PEM). This... requires that patients learn to "listen to their bodies" to be aware of their individual exertional limits, aiming to remain as active as possible without exceeding them" (Centers for Disease Control, 2018). Pacing matches the reality of the disease and the experience of people with ME, ensuring they do not worsen their illness and are active within their limitations. It's a technique similar to that used by patients with cancer, MS and other energy-limiting illnesses, rather than a behavioural intervention. Heart rate monitoring can aid pacing.	Thank you for information you provide on patient surveys of response to treatment and current thinking regarding diagnostic criteria. **Pacing** We agree that pacing needs to be included as an intervention in the guideline. **Definitions and symptoms of ME/CFS** The use of the term ME/CFS in the scope does not pre-judge the terminology or title of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the recommendations for distinct groups identified. We have clarified that fatigue is not necessarily the appropriate term and that other symptoms occur and included reference to post exertional fatigue and deterioration of symptoms. **Methods** The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more

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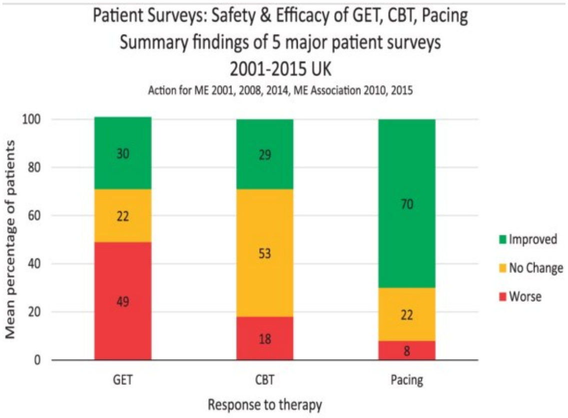
			Collectively, patient survey samples have been much larger than trials. People with ME report this pattern of response (Kirke, 2017):  Thus pacing is the best form of practice in relation to cost; it is cheap and the most effective management strategy. Individuals advocating CBT and GET as treatments have expressly stated that patients communicating with one another is associated with worse outcomes (Collings & Newton, 2014). Yet patients who are moderate to severe require more social support than those healthy	robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes, which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. In addition, the guideline will address information, education and support for health and social care professionals.

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			enough to leave the house or engage in work, and are therefore more likely to be part of an online or in-person support group. A recommendation to stay away from others with the disease does not serve the patient in any way, though it does serve those who wish to promote a controversial therapy without patients learning of common adverse outcomes. We recommend peer support as a low cost way to support patients. ME is very expensive to the UK economy at an estimated cost of £3.3bn per year (Hunter, 2017). Around 250,000 people have ME in the UK, 87% of whom are unable to work (Kingdon, 2018). The committee should keep these figures in mind, as well as patients' quality of life, which on average is lower than that of many other debilitating diseases including multiple sclerosis, diabetes, rheumatoid arthritis and many cancers (Hvidberg, 2015). The best way to save money immediately would be to discontinue the ineffective and harmful treatment of GET/CBT and to introduce effective management strategies in order to stop long term deterioration and to give people with ME the best chance for improvement.	

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			In the long run, the UK will save billions in direct medical and public benefits costs and in the indirect costs of lost productivity by investing in biomedical research. Only by increasing this investment in research can we discover effective treatments, prompt meaningful, objective improvement, and enable more patients to return to work and contribute to their families and communities. By ending the use of harmful treatments and investing in research, the UK will ultimately save money and reap the rewards of hundreds of thousands of individuals' unrealized potential when a treatment is found. The failure to invest millions into finding effective treatments has already cost us untold billions. A Summary of Our Thoughts on the Scope and New Guidelines In order to write improved guidelines, it is crucial to more accurately define ME to discern which evidence is relevant to consider. Previously, studies of fatigue have been judged to be relevant to ME, but we would like to see the retirement of all studies using the Oxford criteria, the sole requirement of which is fatigue of new onset that lasts more than six months (Sharpe et al.,1991). Studies that use the Oxford criteria include patients with many other fatiguing illnesses (Baranuik, 2017). Research	

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			indicates that post-exertional malaise is unique to ME; this has led US health institutions such as the CDC, NIH, and NAM to make an ME diagnosis a positive one, and to describe ME as an 'illness' rather than a syndrome (Institute of Medicine, 2015). Although previously misunderstood, ME's core symptom profile is now established: post-exertional malaise -- not fatigue -- is the cardinal symptom of ME. This is why so many ME patients dislike the name CFS. The lived experience of ME is not well-characterised as 'fatigue', but rather as exertion intolerance, the underlying physiology of which is starting to be much better understood including: a reduced anaerobic threshold, errors in energy metabolism (Fluge and Mella, 2016; Armstrong et al., 2015, Naviaux, et a 2016), and exercise studies that show, among other abnormalities, reduced blood flow to the brain and heart (Neary et al., 2008; Peterson et al., 1994), reduced oxygen uptake in hemoglobin (Miller et al., 2015), reduced oxygen utilization (Snell et al., 2013, Vermeulen & Vermeulen, 2014), and abnormal gene expression (Light et al., 2009) that cannot be explained by deconditioning. Other core aspects of ME include orthostatic intolerance, cognitive impairment, pain, substantial loss of functioning in activities of everyday	

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			life, and unrefreshing sleep. (Further symptoms of ME are discussed below.) Many of these symptoms can be addressed through commonly available treatments that are relatively cheap to deliver and can improve quality of life. There are interventions suitable for common symptoms: ● Post-exertional malaise: pacing; breaking large activities into smaller ones with rest in between ● Orthostatic intolerance: drugs that increase blood volume; beta-blockers ● Pain: bodywork; pain medications ● Sleep: prescription or over-the-counter sleep medication ● Concentration and memory: ADHD medication and other mild stimulants NICE must understand that evidence from research studies that use objective outcomes must take precedence over studies that use subjective questionnaires especially where patient experience and subjective results appear to contradict each other. The quality of trial designs must be considered when weighing evidence.	

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			The new guidelines must also explicitly address the stigma people with ME experience in healthcare settings, which is in part a *result* of the current guidelines. The NICE guidelines will have international impact in terms of the meaning-making and cultural position of this illness and could help counter stigma faced by people with ME. The medical profession is currently faced with many unknowns in dealing with ME: health professionals need to react with openness, honesty and in full partnership with people with ME in the management of their illness. It should be noted that pacing, as is commonly understood by people with ME, is not the same as the 'Adaptive Pacing Therapy' (APT) arm of the PACE trial. Pacing recommends a patient be active when they are able, and rest when they are not.	
#MEAction UK	General	General	This list is by no means exhaustive, but we would feel reassured to know the committee are interrogating the evidence with critical questions in mind such as: ● Are there also published critiques of this research? Do they point out protocol irregularities? ● Was the trial protocol pre-published and do the quoted results match that protocol? ● Does this study properly define ME, including post-exertional malaise in the criteria? Or is it a less well-defined criteria that could include many other diseases and disorders?	Thank you for your comment. The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system**.** The methods do not

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			● Does this trial involve encouraging participants to think differently about their condition and then measure physical health improvement purely by subjective questionnaire, thus encouraging a response bias? ● Did the study drop or downgrade objective measures without sufficient explanation? Or did it choose subjective outcomes when objective measures were feasible, such as pedometers, benefit claiming, or days off school/work? ● Is there a discrepancy between patient surveys and trial data? ● Do people with ME find this treatment or intervention acceptable and tolerable? Have dropout rates been properly assessed? Studies show that participant dropout rate is 50% higher for CBT than usual care (Laws, 2017). This must be taken into account.	depend on conclusions of authors but are based on an interrogation of the data. The areas assessed include appropriateness of the population group and how they were recruited, dropout rates, the use of blinding in assessment of outcomes, which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. Patients' experiences of interventions will also be taken into account when the committee make decisions about the treatments.
#MEAction UK	General	General	A note on evidence hierarchy and GRADE We are aware that clinical guidelines are often formed using an evidence hierarchy and that NICE uses the GRADE system to assess the quality of evidence for an intervention. The most well known systematic reviews using GRADE are by Cochrane. A general critique has been that "the Cochrane Collaboration may cause harm by giving credibility to biased studies of vested interests through otherwise respected systematic review" (Ioannidis, 2016). Cochrane CFS reviews have been specifically criticised for reviewers themselves having undisclosed commercial and	Thank you for your comment. The guideline will not be using existing Cochrane reviews but will review the evidence directly. The GRADE method allows for the downgrading of any study described as an RCT by assessing for the areas you outline.

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			academic interests. GET and CBT studies, though often framed as high level evidence, lack quality and rigour. There are important limitations to these trials related to blinding, design flaws, risk of bias and the indirectness of patients as outlined above. Further, these trials are randomised, but they're not adequately controlled, even if described as an 'RCT', as the therapies are not concealed (O'Dowd et al, 2006). For CBT trials, non-specific benefits of therapy groups is a confounding issue.	
#MEAction UK	General	General	**References:** Action for ME. 2014. Time to deliver: initial findings of Action for ME's 2014 survey. https://www.actionforme.org.uk/uploads/pdfs/me-time-to-deliver-survey-report.pdf (Accessed 15 July 2018). Agency for Healthcare Research and Quality. 2014. Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-fatigue_research.pdf (Accessed 16 July 2018). Armstrong, C.W., McGregor, N.R., Lewis, D.P., Butt, H.L., & Gooley, P.R. 2015. Metabolic profiling reveals anomalous energy metabolism and oxidative stress pathways in chronic fatigue syndrome patients. *Metabolomics*, 11 (6): 1626-1639.	Thank you for these references.

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Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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Action for ME	General	General	Action for M.E. surveyed people with M.E. and people who care for a person with M.E., asking for their opinions on each section of this scope, to help ensure that we were accurately representing the views of people affected by M.E. when responding to this consultation. We received responses from over 260 people, and any quotes included in this submission are taken from this survey. Our answers are informed by the opinions and experiences shared by this group of people, as well as our wider interactions with people with M.E. through our Information and Support Services and social media. Considering the whole scope, 74% of patients who responded to our survey felt that at least some changes were needed. Of these, 50% felt the scope was mostly fit for purpose but felt some changes were needed; 20% felt that some parts of the scope were fit for purpose but	Thank you for your comment and the outline of responses from your survey.

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			that a lot of changes were needed; 4% felt that the scope was not at all fit for purpose. We have outlined the key themes that patients highlighted to us in the following comments.	
Association of British Neurologists	General	General	The ABN have been invited to submit comments on the draft scope. We note the contents of the Notes from the Stakeholder engagement workshop on 16 January 2018 (dated 24 May 2018). We agree with comments regarding the need for taking patients symptoms seriously, providing access to early positive diagnosis and evidence based treatment. We also agree with comments about considering comorbidities and the need for tailored approach to management because ME/CFS is such a heterogeneous condition. We do have some reservations about negative and unbalanced comments in the document regarding the role of cognitive behavioural therapy (CBT) and graded exercise therapy (GET) as evidenced based treatment. We understand that feelings run high, often because of poor or unacceptable experiences of patients with health professionals, and also that these treatments are not suitable or helpful for all people. We hope that the individual experiences of patients are properly heard and acknowledged during this process. However, we believe it is important in this process that the scientific	Thank you for your comment. The notes from the stakeholder engagement meeting are intended as a record of the meeting only. We acknowledge that the principles of CBT and GET are used in other conditions. The guideline will follow the methods set out in the NICE guidelines manual.. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.

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			evidence is not distorted and seen in its proper context. The principles of CBT and GET for example are both helpful in managing fatigue in neurological conditions such as MS where they are generally welcomed by patients (for example -J. Pöttgen, et al, Randomised controlled trial of a self-guided online fatigue intervention in multiple sclerosis, J. Neurol. Neurosurg. Psychiatry. (2018) jnnp-2017-317463.). We expect and look forward to a NICE guideline that will rigorously and objectively appraise the evidence for treatment as well as reflect the diversity of experience, good and bad, of patients suffering from ME/CFS.	
Blue Ribbon for the Awareness of ME (BRAME)	General	General	Strongly believe that the term ME/CFS should no longer be used. Stakeholders at both workshops have strongly conveyed that they believe the term CFS should no longer be used – it should be Myalgic Encephalomyelitis (ME). "It is more appropriate and correct to use the term Myalgic Encephalomyelitis (ME) because it indicates an underlying pathophysiology." ME International Consensus Criteria 2011 (Carruthers et al). Myalgic Encephalopathy is not recognised The term CFS has created confusion with other fatigue states and has led to inappropriate management and treatment, and much broader criteria, capturing a broader group with possible CFS. Research, which has been based on this broader criteria, such as the Oxford criteria – or similar – as in some recent research, and the reported findings, has	Thank you for your comment and this information. The use of the term ME/CFS in the scope does not pre-judge the terminology of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.

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			been unhelpful to those living with ME, as they are not studying those with the condition ME and therefore the results should not be extrapolated and used. As I highlighted at the time of the last Guideline Group the Oxford criteria, and research based on it, has no place in being linked to ME The ME International Consensus Criteria (ME ICC) (2011) enables a far more accurate means of diagnosing people with ME and creates a more homogenous group.	
Blue Ribbon for the Awareness of ME (BRAME)	General	General	People with ME require a good quality ME service for people of all ages with ME. The specialist ME service – as we have repeatedly highlighted over the past 20 years – should initially be set up in each region, with outreach clinics more locally – the ME service should have a good quality and detailed service specification and be consultant-led, by someone who has a true understanding and knowledge of ME, with a specialist nurse and multi-disciplinary team, which sees patients (with an early referral) to confirm diagnosis, offer expert care and advice for the patient and carer(s), GP and other HPs. The ME service should be able to offer on-going care and management, especially for the severely affected and more complex and vulnerable patients. Ideally it would be a prescribing and a referral service, and also be able to write letters on behalf of patients for work, school/college, DWP etc. Hopefully NICE will recognise and acknowledge the national inequality of care for people with ME, and paucity of NHS services.	Thank you for your comment and outline of an ME specialist service.

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			A good quality, accurate, and truly informative new Guideline on ME could be helpful to patient groups to go to their local commissioners to show them what services they should be providing for people with ME.	
British Dietetic Association	general	general	We are disappointed by the lack of recognition for diet and nutrition in this guideline scope. There is no mention of nutrition assessment as part of heath assessment, or general wellbeing in the multidisciplinary pathway, only a brief mention of supplementation rather than assessing nutritional wellbeing. As mentioned above, dietetic assessment and advice is both a cost effective and clinically beneficial way of assisting this group. Compromised nutritional status has the potential to have a significant effect on wellbeing and quality of life. Support is therefore needed to clarify myths and ensure safe nutritional intakes whilst preventing unnecessary restrictions. Weight management is also useful as weight gain or significant loss can add to a patient's fatigue.	Thank you for your comment. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.
British Dietetic Association	general	general	We know so little about the dietary adequacy in CFS/ME patients, that it should not be dismissed, it may have roles in the causal pathway, via immune system, microflora and metabolic pathways. We would like to see included in this guideline, a wider role for diet and nutrition in the treatment and support of this patient group.	Thank you for your comment. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.
Buckinghamshire Healthcare NHS Trust	general	general	Poor medical education on this topic has been a barrier to identification, diagnosis and appropriate care. A confident and early diagnosis based on medical history would facilitate the identification, diagnosis and care of these patients. Major costs are implicated in multiple 'second opinions' delayed diagnosis or unnecessary investigations. The cost saving recommendation would be to appoint a professional committee member	Thank you for your comment. NICE guidelines do not have a specific remit for education of healthcare professionals. Once a guideline is completed the implementation does involve development of CPD with royal colleges and other groups.

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			who could focus on 'medical education'. This individual would be able to identify current shortfalls in education on this topic and champion the new guidelines, incorporating them into CPD learning for practitioners and the medical school curriculum.	
Buckinghamshire Healthcare NHS Trust	general	general	Social care services should not routinely be involved with these cases.	Thank you for your comment. Some of the services needed by people with ME/CFS and their carers do require the involvement of local social service departments e.g. if a person requires home care or adaptations. Carer's assessment are also available via social service departments.
Buckinghamshire Healthcare NHS Trust	general	general	For paediatric cases an attempt should be made for the consultant paediatrician to make a definitive yes/no diagnosis of ME/CFS on first presentation (usually >/=3 months post initial virus/onset), this should lead directly to MDT care involving: Home visit, relevant investigations, school/home tutor input and therapist care as required.	Thank you for these suggestions.
Buckinghamshire Healthcare NHS Trust	general	general	Relating to disability, equality and diversity. Consideration can be demonstrated by offering longer appointment times, especially for 'new' patients due to the complex multisystem nature of the disorder and cognitive and memory difficulties on the part of the patient. Information should also be offered in large print. Doctors should be taught to consider this diagnosis for minority groups including; men, pregnant women, elderly and black and minority ethnic groups. Early and clear communication, allowing time to rule out other differential diagnosis, and commitment to early and confident diagnosis of ME/CFS would reduce patient/family distress and save costs.	Thank you for these suggestions. The guideline will address information, education and support for health and social care professionals and this will help to raise awareness supporting diagnosis. We have included these groups under the equality considerations section in the scope.

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Buckinghamshire Healthcare NHS Trust	general	general	This is a heterogeneous and multifactorial illness. A flexible approach and an acknowledgement of the importance of patient experience, including the use of patient surveys and patient feedback regarding treatment, is required. Management should be adapted on a case-by case basis, with the individual patient at the centre of care.	Thank you for your comment.
Christians with ME, CFS, Fibro and their Carers	General	General	Thank you for the decision to review the NICE guideline on ME/CFS, it is our belief that this guideline needs this review to ensure sound treatment of people with ME/CFS. The draft scope for this review is very good and so the comments that we have are limited due to the excellent scope that has been produced. The following comments are made:	Thank you for your positive comments.
Christians with ME, CFS, Fibro and their Carers	General	General	Proposed additional area: Information, education and support for employers and providers of education to enable people with suspected and diagnosed ME/CFS to continue to study and work. What information, education and support do employers, occupational health teams and providers of education need to support people with ME/CFS to enable them to continue to study and work?	Thank you for your comment. NICE guidelines have remit for NHS and social care services only. We can however include recommendations about appropriate advice and support for access to education and work. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Coeliac UK	General	General	Dietary management is not listed within the draft scope of the updated guideline. The current NICE guideline for CFS/ME (CG53) highlight that people with CFS/ME often find exclusion diets helpful, despite the fact that they are not generally recommended. Dietary management	Thank you for your comment. NICE has existing guidelines on 'Nutrition support for adults' and 'Coeliac disease' and we will cross refer to these guidelines. We do intend to examine diet and have

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			(including serological testing to rule out coeliac disease before gluten is excluded from the diet) should be included within the new guideline to eliminate coeliac disease and to ensure that healthcare professionals are equipped to provide advice and support, such as referral to a dietitian for patients who wish to undertake an exclusion diet.	added diet as an example of the areas included in section 3.5.
Forward ME	General	General	The use of the term 'chronic fatigue syndrome', whilst used historically in research documents, fails to convey the multi-systemic nature of the illness and should be made redundant. The Myalgic Encephalomyelitis: International Consensus Criteria. [Carruthers *et al* July 2011] explains that "it is more appropriate and correct to use the term 'myalgic encephalomyelitis' (ME) because it indicates underlying pathophysiology". Patients refer to themselves as 'having ME'. In contrast, the term 'chronic fatigue syndrome' has fuelled the conflation of ME with fatigue syndrome (chronic fatigue rooted in psychosocial factors). This has historically bedevilled understanding, care and progress- particularly in the UK – with catastrophic consequences for ME patients. This confusion has been further fostered by the overly broad 'CFS' criteria, particularly the 'Oxford' research definition, which the US National Institute for Health has called to be retired as it could "impair progress and cause harm". (Green 2015). For these reasons we are strongly of the view that: • The term 'Chronic Fatigue Syndrome' should be made redundant, with the guideline in development focussing specifically on the needs of people with ME.	Thank you for your comment. As you indicate the term chronic fatigue syndrome has been used historically and the criteria used to include people in studies is contested. These are areas the committee will consider including which study populations are appropriate to include. The use of the term ME/CFS in the scope does not pre-judge the terminology of the final guideline. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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			The reported findings of research studies recruiting based on the 'Oxford' criteria (or similar) should not be considered relevant to this patient group.	
Healthwatch Bolton	General	General	A strong opening statement, acknowledging the WHO classification, and the pathophysiological nature of the illness, should be included. The recent Centre for Disease Control document said, "ME/CFS is a biological illness, not a psychological disorder. Patients with ME/CFS are neither malingering nor seeking secondary gain. These patients have multiple pathophysiological changes that affect multiple systems".	Thank you for your comment. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing statements such as those from the Centre for Disease Control will be used to inform the committee.
Healthwatch Bolton	General	General	Severely affected patients need and deserve treatment. They are often abandoned, sometimes for decades, as they are unable to attend appointments. They need to be able to access treatment by domiciliary visits, and consultations by phone, email or Skype if appropriate. Any treatment suggested for this group of patients needs to be extremely carefully approached, given the increased risk of harm. Visits and admissions to hospital present particularly serious challenges. Social services need to be made aware of the particular challenges faced by people severely affected .	Thank you for bringing the needs of these patients to our attention and for suggesting how these needs should be met. Special consideration will be given to people with severe symptoms throughout the guideline.
Healthwatch Bolton	General	General	Children and adolescents: current guideline urges particular caution in applying GET and CBT in children, yet children's clinics regularly use these interventions without informing children and families of the risks. Diagnosis: children and families should be listened to and believed. Doctors should not choose whether they believe ME exists or whether children can be affected. There is no lower age limit. Management: children should not be forced to undertake any part of a management programme. All aspects of risk and harm should be	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. Thank you also for outlining potential practical areas that help children and their families.

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			discussed in order to make informed choices. Post exertional deterioration can be long term, even permanent. Great caution is required for any intervention, as mildly affected patients can easily be worsened to moderate or severe. Children should not be separated or removed from parents, especially under care orders, for any part of management. Families should not have restricted access to the child. Children should not be managed in psychological/psychiatric settings or tier 4 units. There should not be any prior expectation or goal setting for increases in activity. School attendance should not be used as a measure of clinic success. Exposure to light and noise to try to normalise is akin to torture. Children should be allowed to rest and recuperate. Children should be offered counselling to help them adjust to and manage their long term debilitating illness if (and only if) they want it. Sleep "hygiene" of waking child early, getting dressed, not allowing naps, is ineffective and harmful. Worsening should not be blamed on lack of engagement. Failure to recover should not blamed on the child or family maintaining an illness mode. Professionals should be aware that ME can persist for many years and may be lifelong. Children should not be told they should have recovered after 2 years and therefore cannot have ME. Clinics should be aware of genetic predisposition, that multiple family members can be affected: children should not told they are copying a sibling or parent. The Lightning Process should not be used and is unethical. Affirmation is given to the child that it will be of benefit to them. They are told recovery stories. They are required to believe them. They are told they can control their illness and outcomes. That having ME leaves them in pit of despair	Special consideration will be given to children and young people throughout the guideline and addressed in every review question. The guideline will address diagnosis and management in children and the recommendations should allow for review of existing practices.

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			which they can climb out of by positive thinking. They are not to say they are in pain or feel ill, as this is negative. Instead they are told to say they are "doing" pain or "doing" illness (so can stop if they really want to). Failure to improve can therefore feel like a personal failing, not trying or not wanting to recover. There should be a method of reporting harm from all interventions to an external, independent body which can collate data. Clinics should not change an ME diagnosis to a psychiatric one if a child has low mood, which is secondary and understandable reaction to chronic illness. Comorbidities should be investigated, including endocrine conditions, auto immunity, POTS, EDS, fibromyalgia. Further testing should be recommended, including virology, serology, genetics, metabolites and vitamins. Regular monitoring of vit D. Children should be allowed aids such as wheelchairs, easy turn taps, ear defenders, dark glasses. Massage and hot and cold compresses may aid pain management in addition to pharmacological interventions. Dietary management and food intolerance should be considered. Greater transparency is needed to shed light on what children and families are being told about ME and management strategies. Families should be signposted to charities such as Tymes Trust and local support groups. Domicilary visitssnd Skype could be used to facilitate consultation and care. Welfare benefits, care packages and assistance should be supported.	

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			Education: some children are unable to participate in any education. Appropriate education should be provided to suit the child so as not to cause deterioration and facilitate a balance of social activity and home life. The use of virtual education or home provision may be essential. Short lessons with rest breaks will help manage rnergy. Cognitive exertion is very demanding of energy, snd great care is needed not to cause deterioration. Noise, light and smell jntensity needs to be connsidered within an educationsl setting. Uniform and shoes can be painful. Travelling to and wiithin school is exhausting and has to be carefully managed. Children may not look ill and should not be disbelieved, ccalled lazy or a school refuser. A child may present as well then deteriorate later or at home. PEM is a defining characteristic and needs careful consideration when trying to maintain education.. Teachers, education welfare officers, school nurses should be aware of ME and how it may affect the child in order not to may them worse. School absences should not be treated as abuse/ neglect on the part of parents, but as essential for recovery. Use of laptops, time-out cards, rest rooms, reduced timetables, are all useful. Exam provision: quiet room, extra time, rest breaks, one exam per day, exam in the afternoon, exam at home, may all be used. Quality of life: importance of rest and recovery. Children should be given every opportunity to happy. They should believed and not have to constantly justify or explain their illness repeatedly . They should be listened to. They should be allowed play and socialise without feeling guilty about not being in full time school. Families should not be accused of FII or subjected harmful and stressful child protection investigation by	

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			disbelieving and ignorant professionals. Children should not be constantly having to srt targets and goals.iAs children improve they will naturally want to do more basedd on previous experience. They should be nursed, supported and loved as ill children, and given the respect and understanding they deserve, and helped to adjust to such a disabling and debilitating illness, which can have such a life altering effect.	
Hope 4 ME Fibro Northern Ireland	General	General	**Specific question from NICE on this scope:** **"Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?"** Current guidance suggests CBT & GET are the most effective treatments. Both these therapies involve the significant cost of sending the patient to sessions with a specialist, and the result may, at best, only be a moderate improvement in functioning. Either therapy can also cause harm by persuading the patient to discount their symptoms. For many patients this has resulted in such harm, that they have had the course of their illness permanently worsened. This is not cost effective. **Rest is Best.** It would seem to us, that the best, and most economic, solution to this paradox would be to simply give new patients (after appropriate screening for other conditions) a period of prescribed rest. This might mean that, as soon as ME is suspected, a sick line for up to 6 weeks is written (or a shorter line offered, that can be updated by phone if required). Thus, the patient immediately starts a period of	Thank you for your suggestions. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53.It is important to review the clinical and cost effectiveness of GET/CBT and other treatments to identify the specific populations that treatments may benefit and or harm. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.. We have included a question on appropriate measures when ME/CFS is suspected which may include rest as you describe. Heart rate monitoring will also be considered by the committee.

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			convalescence. The hope is that natural healing will avert the progression of the disease and allow the patient to self-heal. We think it is important to trust that patients are aiming to recover, and that this longer rest period will not be sought in as a means of evading work. It should also not be expected that this rest will necessarily be a curative process. If there has been no improvement after the six-week period of rest, it might then be appropriate to discuss with the patient how to adapt to a reduced lifestyle, and to offer counselling, and other support such as disability aids. Whilst no effective treatment for ME exists, and whilst the patient is remains unable to function due to the illness, no "rehabilitative" strategies should be considered. Many patients report that attempting to resume their previous lifestyle has lead to a permanent decline in their physical state. Rather the patient should be supported with the required assistance to obtain: appropriate benefits, insurance payouts, mobility aids and lifestyle adjustment advice. **We would also like to suggest that Heart Rate (HR) monitoring** of daily life activities is a useful practice, that can help patients to pace themselves. Heart rate monitoring was suggested in the old CG53 guideline but only for patients well on the way to recovery. We think it can help patients (except those with the the most extreme severity) to moderate what they attempt, and it will encourage appropriate rest	

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			periods when heart rate becomes elevated. The Workwell foundation suggested keeping HR below 60% of age calculated maximum heartrate. A number of our members have reported that HR monitoring has helped them to prevent further decline. A few have had a small degree of improvement which they attribute to heart rate monitoring.	
Hope 4 ME Fibro Northern Ireland	General	General	**Take account of issues relating to treatment and care, or improving health and wellbeing, which are important for people affected by the guideline?** We would like to point out again that it is important to our members that treatments on offer do not cause inadvertent harm. With that in mind we suggest: a) Immediate removal of CBT & GET from the treatment recommendations: The current therapies of CBT & GET are based on an outdated premise that ME patients are simply deconditioned, and over-sensitive to bodily symptoms. These therapies are also reported as harmful by a large percentage of patients. (See charity surveys from MEA and AfME) The urgent removal of these therapies is an issue of great importance for people affected by this guideline. We recommend that the scoping document ask that the new committee investigate these therapies immediately after convening for the first time.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all people with ME/CFS and reduce any

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			b) Investigate whether Anti-Depressants are less helpful than **suggested**. It has come to our attention that patients who are NOT feeling depressed are being asked to take anti-depressants because of a supposed benefit for ME. We suspect the reasoning is rather different and that these drugs are being prescribed on the basis that it is assumed that depression is the cause of the ME symptoms. Patients are also reporting that they are having extreme difficulty coming off these drugs once they have started. We suggest that the anti-depressants should not therefore be offered to patients when they present with ME. Should secondary depression occur then a new assessment can take place.	stigma. The guideline will address information, education and support for health and social care professionals. Anti-depressants are commonly used in clinical practice for conditions other than mood. They are commonly used for treatment of neuropathic pain, to help with sleep, and to treat chronic headache. There is evidence for use of anti-depressants in these areas and their use in pain and headache are covered in other NICE guidelines. We agree that appropriate assessment of mental state should take place to inform prescribing.
Hope 4 ME Fibro Northern Ireland	General	General	**Include medicines, procedures and other treatments or options for care (such as advice about lifestyle changes) that may be important for people affected by the guideline?** Alongside a) **Rest** and b) **Heart Rate monitoring** (see point #21 above) we would also like to suggest: c) **That the care of the most severely ill should be given prominence in the new guideline.** A medical advisor to our group described these patients as equivalent to “a bed-bound quadriplegic” in their care needs.	Thank you for these suggestions. The aim of the guideline is to address needs across the spectrum of severity including the needs of those most severely affected. The technical team will ensure the areas you raise are brought to the attention of the committee. Thank you also for outlining potential practical areas that help people with severe ME/CFS. Special consideration will be given to people with severe

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			Examples of the extra care required could include: tube-feeding; sound and light proofing of living spaces; hoists; 24hour care; home visits and more if required. Currently the most severely affected ME patients have great difficulty accessing care. d) **Moderately affected patients should not be discouraged from using mobility aids.** Our members have often reported to us that their GP has told them not to use a wheelchair or mobility scooter as they will "become dependent". Yet without mobility aids patients can become unable to leave their homes. We feel that appropriate support when discussing mobility aids would help patients to be more independent, thus reducing isolation and hopelessness. e) **Dietary changes have helped some of our members.** It seems that after ME onset, that some patients develop dietary intolerances eg to gluten. It would be useful if GPs could be supportive when a patient suggests that certain foods are now disagreeing with their digestive system. f) **Drug intolerances**. Patients often report that they react badly to new drugs. It might be useful for GPs to be aware that gradual introduction to a new drug is a good precaution. g) **That, in the absence of realistic treatments,** patients should be supported as they seek less conventional therapies. Thus, patients should be able to avail of nursing services such as having blood drawn	ME/CFS throughout the guideline in each review question. We hope that the guideline will help healthcare professionals to understand the nature of patient's problems including requirement for aids if necessary. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5. Thank you for this suggestion about drug intolerances. It is not within the remit of a NICE guideline to recommend that people should be supported to access treatments not available on the NHS.

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			to send for private tests. They should also not be criticised for attempting to find private treatments outside of the NHS. Patients should also be supported in seeking the benefits they require.	
Hope 4 ME Fibro Northern Ireland	General	General	**Include treatments or other interventions that are currently used, but may not be effective, acceptable or tolerable to people using services?** As already stated, it is our view that the currently offered treatments of CBT and GET, and the generalised advice from some GPs to "think positively" and "exercise more" are inappropriate. Also, as already mentioned, anti-depressants may not be appropriate.	Thank you for these comments.
Hope 4 ME Fibro Northern Ireland	General	General	**Promote equality of opportunity regardless of age, disability, sex, gender identity, ethnicity, religion and belief, sexual orientation and socioeconomic status?** We have noticed that patients who are of higher socioeconomic status (eg people working in a professional capacity,or attending University) have a better chance of being taken seriously by their GP. It is unfortunate that those of lower socioeconomic status (eg unemployed, or employed in a series of short term, or part time jobs) have a greater difficulty being heard by their GP.	Thank you for your comment and observations. The evidence and recommendations will be considered in line with NICE commitment to equality in relation to groups sharing the Equality Act's protected characteristics but also health inequalities arising from socioeconomic factors and other circumstances.

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			There seems to be an implicit assumption that those of lower socioeconomic status are more likely to be malingering or seeking benefits by exaggerating their physical impairments. Another bias we have noted is that those who are overweight or obese, are generally given less respect when they make observations about their physical health. They are often told that losing weight will reverse ME, when in fact there is no evidence to support this. The scope should ensure that these issues are considered, so that the guideline can advise GPs to set aside discriminatory biases when making an assessment of the patient's condition.	
Hope 4 ME Fibro Northern Ireland	General	General	**Identify other major projects related to this topic (such as promotional campaigns) that should be used when developing the guideline?** **Media**: In recent years there have been a plethora of media articles suggesting that ME patients could recover if only they could "think positively" and "exercise more". This has had a devastating effect on the patient/practitioner relationship. Many health care practitioners are swayed by this inaccurate media portrayal of ME patients. **A promotional campaign to reframe ME as a serious and debilitating organic disease**, would therefore seem appropriate. It is	Thank you for your comments. The guideline committee will develop research recommendations informed by the reviews of evidence. NICE has existing process where it informs the National Institute for Health Research of research recommendations prioritised during guideline development. Once the guideline is completed plans to disseminate and publicise the guideline will be developed.

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			important that this campaign is directed not only at the general public, but also at all Health Care Practitioners. **Research:** Research into treatments for ME has been hampered over the past years by a lack of funding, and a tendency for UK funders to favour subjective studies based on psychosocial therapies. If NICE has any influence, then this needs to change. **A campaign to promote increased funding for biomedical research into the physiology of ME should therefore be launched.**	
Invest in ME Research			Invest in ME Research has requested that NICE remove CBT and GET as recommendations from the existing guidelines - immediately CBT and GET should have no place in any new guidelines and there is no need for them to be considered yet again.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee.

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				Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.
Invest in ME Research	**General**	General	NICE must decide to withdraw the existing CFS/ME guideline or at least add an addendum to remove CBT and GET (including directive activity management that aims to increase activity) as recommended treatments now instead of waiting until the new guideline is in place. This would then obviate the need to discuss CBT and GET for new guidelines – saving both time and energy of all. Professor Mark Baker has already accepted that the existing NICE guidelines will be torn up so this can happen now. Otherwise NICE must accept that they are responsible for any deleterious effects caused by leaving CBT and GET in place during the development of these new guidelines and be held directly accountable for any future damage caused by NICE recommendations.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.
Invest in ME Research	**General**	General	Will NICE agree to ensure that any new guidelines for ME will not include "nuances" that seem only to be apparent to Professor Mark Baker or others in NICE – but have been totally undetected by doctors, consultants, healthcare workers, patients, carers and the vast number of insurance providers who renege on their legal contracts with patients?	Thank you for your comment. The guideline committee will work with NICE editors to ensure the recommendations are clear.

Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management (Oct 2020)

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Invest in ME Research	**General**	General	As suggested in our response to the existing NICE guidelines some years ago we would suggest that a lawyer be added to all consultations to protect and safeguard the welfare and future of the patient.	Thank you for this suggestion. Organisations that fulfil the criteria listed on NICE website can take part in consultations. https://www.nice.org.uk/get-involved/stakeholder-registrationthat
Invest in ME Research	**General**	General	The NICE the Developing NICE guidelines: the manual 1.4 Key principles for developing guidelines it states – "Once published, all NICE guidance is regularly checked, and updated in light of new evidence if necessary." We might suggest that, as the previous (current) guidelines were so flawed and ineffective, that this checking of new guidelines for ME ought to be reviewed more frequently than normal. Patients cannot have another eleven years of negligence.	Thank you. NICE guidelines are reviewed for update every 2 years. The history of review of the current guideline can be found here https://www.nice.org.uk/guidance/cg53/history.
Invest in ME Research	**General**	General	At the start of the document NICE state that they would like to hear views on these questions (actually only one): 1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline? We would like to see ME patients treated with respect and honesty and more consultants being trained in ME so that GPs have experts to refer to or consult with.	Thank you for your comment. NICE has developed a guideline on Patient experience which already includes the importance of respect for patients. We will cross refer to this guidance. NICE does not have a remit for training of health care professionals but the guideline will address information, education and support for health and social care professionals. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma

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			ME patients need to be monitored regularly like all other chronic illness patients. This would save money and time and energy (and lives) by avoiding recommendations based on self-interest, flawed psychological theories and junk research.	The guideline will address the monitoring and review of people with ME/CFS.
LocalME	**General**	General	CG 53 did not serve, nor did it achieve delivery of service for the ME/CFS population. Even welcome recommendations did not translate into practice. The guidance was pilloried and despised by the public, highjacked, used and abused by some professionals, who are perceived to have used the process to deliver a political ideology of welfare to work and benefit reform and to serve the Insurance industry, by whom they were also employed. It is incumbent on NICE this time, not to make a bad situation worse, but to achieve it's core objective of improving the quality of life for people with ME/CFS and their families. We are encouraged by the appointment of the chair and vice chair who bring highly relevant experience, relevant expertise and a welcome breath of fresh air to this process. We hope they are able to challenge and change the entrenched views which pervade the difficult world of ME/CFS which patients and their families are subjected to. This is especially so for the 25% Severely Affected (SA), many who are children.	Thank you for your comment and observations on the implementation of CG53. The situation for children has been highlighted in stakeholder workshop and in the consultation. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline. People with severe symptoms are also included in the scope as a group requiring specific consideration. Both groups will considered separately in every review question. The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using

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			If the situation is bad for adults, nowhere is situation more dire than that for children and their families experiencing service neglect and false allegations of harm via Fabricated and Induced Illness (FII). Immense damage is being done to children by public authorities and it has to stop. A reviewed and clear guidance document from NICE could do much to correct this iniquity. Some hospitals Foundation Trusts paediatric departments seem to have their own "bolt on/ "pop up" ME/CFS clinics"; non funded/non commissioned structures within general paediatrics. These operate below the radarand are effectively publicly unaccountable. Many are "untrained" in the complexity of ME/CFS and demonstrate a lack of understanding of this condition. This results in service users "going underground" in an attempt to stop the harm, and potential for harm, these inappropriate management and treatments are known to have caused. It is hoped that the NICE Guidance for children will advise against this arrangement. It is not uncommon for Local Authority, education and Academy staff to make rules up as they go along for sick children. Children and young people who are entitled to appropriate Special Educational Needs specialist educational Alternative Provision (SEND) and to multi agency Education and Health Care Plans. The approach taken currently in education is contrary to obligations under the Children and Families Act 2014. This situation was highlighted recently in our area, Suffolk by Ofsted and the Care Quality Commission combined critical report2	GRADE system. The methods do not depend on conclusions of authors but are based on an interrogation of the data. The areas assessed include appropriateness of the population group and how they were recruited, dropout rates, the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. Patients' experiences of interventions will also be taken into account when the committee make decisions about the treatments. As you point out NICE guidelines are only one part of the wider process. We hope that the new guideline will improve services and commissioning and the ability to hold services to account.

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			following their inspection of Suffolk County Council's Special Educational Needs specialist educational Alternative Provision -SEND provision. It is vital for a good NICE guidance to reach these local government agencies. The question remains as to whether, in the current climate of fragmentation within the health and statutory services, will NICE be able to influence change? One key issue is the absence of proper "post market surveillance" of service delivery when things go wrong and harms ensue. This is unacceptable and we hope the Guideline Development will be able to address this issue in its recommendations. Next comes the knotty issue of the "evidence choice" which should drive the guideline development. Much of the problem last time round centred on NICE's choice and review of evidence Centre for Reviews and Dissemination - University of York, and Cochrane Review). The starting point *this* time should be the real lived patient experience. Much weight should be given to this. Acceptable data to explore the patient experience exists. The complexity and the real world patient experience of ME/CFS patients is increasingly enshrined in ME/CFS Service Providers Outcomes, survey data and annual audits delivered to commissioners as part of the contractual obligations. Interrogation of this data and evidence would reveal the current parlous state of services to all, but to severely affected and children in particular.	

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			This, we say, as patient representatives working with NHS commissioning amounts to a wholesale failure of duty of care by the gatekeepers of pathways of care, the Clinical Commissioning Groups. We urge NICE in it Scoping final draft to consider recommending a mechanism to enable a comprehensive national audit of service provision, recommend continued surveillance, monitoring and review of what is being delivered so any new guideline can be properly embedded. Then there is the other knotty issue of the recently much encouraged and lauded "partnership working" and "service co-production". Fine words, but the reality is somewhat different. **A unique regional opportunity for NICE to appraise.** Patient voluntary groups, charities, and individuals, patients and carers in Norfolk and Suffolk are uniquely placed to provide comment here with 20 years of intensive and continuous "partnership working", "activism", campaigning, "co production" and rabble rousing in the wider public interest under our belt. Some of us would welcome offering this unique journey, related material and understanding to the guideline process to assist the committee in their complex and difficult task. Much of it is recorded electronically and is in the public domain.http://nandsme.blogspot.com/p/the-story-so-far.html In 1985 the Suffolk and Norfolk service was developed by a dedicated doctor, a consultant in acute medicine, a haematologist, Dr Terry Mitchell, who saw and responded to a critical need. His service model was used by the Department of Health to drive the 2004 service	

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			development for a national role out of services funded by them, headed by Clinical Regional Champions of which Terry Mitchell was one. We joined him on his journey in 2005.That journey has revealed some exceptional NHS leaders who have worked with us and also it has revealed a culture of disregard and disrespect by others for the plight of ME/CFS, unworthy of those engaged and working in public service. Our evaluation is that changes within health service of delivery, with its attendant privatisation and fragmentation, are likely to make NICE's task all the harder. NICE and its guidance are but one part of the process- not the end game. NICE and its partner organisations and "Non Government (and arm's length) Departmental Bodies", NHS England, NHS Improvements, NHS Public Health and NHS, Health and Work must work together with the Care Quality Commission to begin to right the Inequality that characterises ME patient care and patient pathways. They must hold Clinical Commissioning Groups and other statutory bodies to account because, as things stand, no one is taking either ownership or responsibility for the mess this is all in.	
London School of Hygiene & Tropical Medicine	general	general	I think that additional questions might be needed to reflect the "specific consideration to children and young people, and people with severe symptoms."	Thank you for your comment. The existing questions are draft questions and we can adjust these as required to ensure we cover the needs of the groups included as needing specific consideration. These two groups will be considered separately in each review question.

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ME Research UK	general	general	What mechanisms will be built into the guideline process to allow for the incorporation of new information as it becomes available? This is especially important in ME/CFS where ongoing biomedical research will continue to add to the knowledge base and help identify potential treatments. A pre-programmed review process could assess the applicability of new advice and treatments from national and international sources.	Thank you for your comment. The guideline development process includes a search for new evidence before consultation of the draft guidance.
ME Research UK	general	general	Access to the NHS and other services is currently difficult, if not impossible, for severe sufferers of ME/CFS, and consequently there is a lack of data on these individuals. The collection of patient statistics needs to be addressed in order to determine more accurately the extent of the illness, and the range of patient severity and incapacity levels, and to provide a baseline reference for the assessment of treatment outcomes.	Thank you for this information. The guideline research recommendations can include recommendation for basic epidemiological research if this is prioritised by the guideline committee.
ME Research UK	general	general	There is likely to be a lack of high quality published evidence on interventions for ME/CFS, partly because the condition is a syndrome with considerable patient heterogeneity. Given this fact, evidence from clinicians should be considered bearing in mind the spectrum of patients which any one clinician will come across, as well as the variations in diagnostic criteria and non-standard outcome measures used. Such evidence should be viewed and incorporated with care.	Thank you for your suggestion. The NICE process allows for the inclusion of expert testimony if this is likely to add to existing evidence.
NHS England	General	General	What is the role of neurologists/neuropsychiatrists 1) At the diagnostic phase? 2) Follow-up/management? The role of the neurologist/neuropsychiatrist should be significant at the diagnostic phase but less at follow up and during management, unless at a disease specific clinic.	Thank you for this suggestion.

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NHS England	General	General	Not all patients fall nicely into ME/CFS diagnosis, therefore a list of symptoms that should be reviewed should be included.	Thank you for this suggestion.
NHS England	General	General	Many of these patients have difficulty to attend the surgery; therefore consideration should be given regarding housebound patient and the use of community services doing part or all of the assessment.	Thank you for outlining potential practical areas that help people with severe ME/CFS. Special consideration will be given to people with severe ME/CFS throughout the guideline..
NHS England	General	General	Early diagnosis is often difficult and other diagnosis may be more likely early on, this should be reflected in the document.	Thank you for your comment. The detail of possible discriminating factors for diagnosis and alternate diagnoses will be considered by the guideline committee.
Parents of children with ME/CFS Support Group	General	General	'Parents of children with ME/CFS Support Group' is a national support group with a closed Facebook group comprising of 1001 members (20th July 2018) who self-identify as a parent of one or more children with ME/CFS. Some members also have a diagnosis of ME/CFS themselves. We welcome the opportunity to provide our experience and knowledge to the development of new guideline for ME/CFS.	Thank you for this information. We do intend to include a call for evidence in the guideline.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		Currently children in England where there are ME clinics, can be effectively pressurised to agree to treatment that they do not want or feel comfortable with in order to remain under specialist care and access the support required with education (home education, reduced timetables at school, special exam arrangements). On paper they have a choice, in reality they do not. Hospital education, for example, can only be provided if prescribed by a paediatrician. Patients who do not improve can be held responsible for their failure to improve. In the case of children, parents can be blamed for their child remaining ill.	Thank you for outlining some of the problems faced by children and their carers. We are aware of the concerns that people with ME/CFS have and agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments**.**

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		It is important that the arrangements for patients to take part in the consultation take into account the disabling nature of this illness. Mildly or moderately affected patients who may be well enough to attend meetings may require two nights of accommodation and taxis for transport. Wheelchair access, rest breaks and a space to lie down may be required. Individuals may require specific adaptations. Carers attending to represent patients may require the cost of nursing/carer cover to be included in their expenses. The moderately and severely and very severely ill who cannot travel far should be enabled to contribute as their experience may be very different to those able to travel to clinics and access care. Contribution via email, by teleconference or by proxy could be options.	Thank you for your comment. The guideline centre and NICE are considering a variety of ways to involve patients to ensure the widest involvement and testimony is possible.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		Regarding obtaining input from children and parents into the guideline review: There would be concerns about recruiting children and parents only via the specialist clinics – or, at least, it would need careful consideration how best to do this to avoid bias. Based on patient experience, it seems that the specialist paediatric clinics can patient-blame when children do not improve. Suggestions made to patients include that a child's problems were psychosomatic or that the child was not prepared to engage and take the steps necessary to improve. Clinics have been keen to discharge children when the clinic is unable to do any more to help them, even if the patient has deteriorated under their care. Parents can have to make the case for children remaining on the clinic books if they need clinic support for access to special education arrangements.	Thank you for these suggestions for how best to include experiences of children and their carers. We are considering how this best can be done. The information about distribution of clinics is useful.

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			It is of concern that, if children and parents are mainly recruited from the paediatric clinics to contribute to the guideline review, patients who have not found the sleep management and graded approach to exercise/activity helpful may not be fairly represented as many will have been discharged still sick. There could easily be a bias toward patients who have begun to improve and hence remained under treatment. A further concern is that, as the support of the clinics is so vital for education arrangements, parents can be very reluctant to rock the boat and express concerns to the clinics. Will children and parents feel able to make critical contributions to the guideline review? It will be important that they feel safe and are encouraged to do so if their experience has not been positive. Can they be allowed to contribute anonymously? There are online support groups and forums for parents and children. Approaches could maybe be made to parents and children through these to help ensure a more balanced input? It is important the children with ME and their parents who live outside England, where there are no ME clinics, be included.	
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		Could an early "Call for evidence from stakeholders" (Developing NICE guidelines: the manual section 5.5) be made in a form to facilitate response from the severely ill/their carers as a way to embody patient expertise into an "eligible" and strong piece of evidence?	Thank you for your comment. We understand the need to be sensitive to both timing and format of responses for any call for evidence.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		A warning should be added to the current NICE guidelines regarding reported harms for CBT and GET. Patients should be informed of these reported harms before being given the option of whether to commence with these treatments. A mechanism should be put in place to report harms from treatment and management approaches for ME/CFS.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		**Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?** Skype, email and telephone consultations. Encouraging patients to seek support from local ME/CFS support groups. Mechanisms to support these groups which are often run by people who are ill themselves.	Thank you for these suggestions.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		The draft guidance (year 2020) will be only put out for feedback for 6 weeks. This should be extended with the time for several iterations if necessary.	Thank you for your comment. The guideline is currently scheduled for a standard consultation period. Further consultation can be planned if required.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		Where research or points can be referenced, citation notes should be used with a referenced appendix	Thank you for your comment. NICE guidelines are published in a number of different formats ranging from recommendations alone to more detailed information on study details and analysis.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	General		Throughout the document definitions need to be clear. The term post exertional malaise PEM or 'payback' is not even used in the scoping document. It needs to be defined adequately. It is not sufficient to say it is a worsening of symptoms. Current NICE guidelines would allow worsening of a headache and fatigue as PEM. A definition applicable to ME/CFS needs to be included.	Thank you for your comment and information. The guideline will include definitions of terms used. We have altered the scope to make reference to post exertional malaise and deterioration of symptoms more explicit.

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Primary Care Rheumatology Society	General	General	The Primary Care Rheumatology Society endorses the development of this guideline for CFS/ME. Patients with the condition present at all levels within the health and care system, so national guidelines to help with identification, diagnosis and management are welcome.	Thank you for your comment.
Primary Care Rheumatology Society	General	General	The scope identified is limited to CFS/ME and the Primary Care Rheumatology Society wonders why there is not an extension to include Fibromyalgia. The prevalence of CFS/ME is identified as 0.2% but the prevalence of fibromyalgia is much higher, and poses a huge burden in Primary care and we believe there is an overlap between the conditions. The prevalence of Fibromyalgia is estimated at 5.4% (Prevalence of chronic pain in the UK: a systematic review and meta-analysis of population studies A Fayaz1, P Croft2, R M Langford3, L J Donaldson4, G T Jon. https://bmjopen.bmj.com/content/6/6/e010364)	Thank you for your comment. The outline for the guideline is for ME/CFS and does not include fibromyalgia. This link describes the prioritisation for NICE topics and how they are chosen for development. https://www.nice.org.uk/about/what-we-do/our-programmes/topic-selection
Primary Care Rheumatology Society	General	General	Would the guideline committee please make clear recommendations on the role of specialist referral centres for ME/CFS? There are very few centres in the country and patients cannot always travel or be referred to these centres. There is therefore wide variation in diagnosis and management of the condition at various tiers in the NHS. We feel this is unhelpful and does not provide best possible care to this group of patients,	Thank you for this suggestion. The guideline scope does not include formal reviews relating to organisation of services. Our experience is that there is seldom robust evidence to inform such recommendations. We have included a draft question regarding the personnel required to be involved in care and this and the reviews on interventions may allow us to inform this area.
Royal College of General Practitioners	General	General	This is an important guideline. People describe that their symptoms are sometimes not believed, that obtaining a diagnosis or label for their symptoms is difficult, and that once diagnosed, people are offered management that they do not find acceptable. The diagnosis can be challenging for General practitioners and Primary care Clinicians with a	Thank you for your comment.

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			lack of specialist generalist support in secondary care. The transition from child and young person's care to adult specialist services can create gaps and barriers in care pathways	
Royal College of Paediatrics & Child Health	General	General	This review is timely, particularly because of changing definitions, overlap with chronic pain syndromes and variation in diagnostic criteria at different stages of life. i.e. childhood, adolescence, young adult, then elderly.	Thank you for your comment.
Royal College of Pathologists	General	General	The RCPath would be specifically interested in commenting on any laboratory tests recommended in the draft guidance.	Thank you for your comment.
Royal College of Psychiatrists	General		This is an important guideline and it will be essential to be guided by the evidence base, whilst taking all views into account.	Thank you for your comment.
Royal College of Psychiatrists	General		Co-morbid depression and anxiety are high in ME/CFS and the rates of suicide are increased compared to the general population. It is essential that a biopsychosocial approach is taken so the mental health needs of those suffering from ME/CFS are addressed. We take the view that a mind-body split is unhelpful and can prevent patients accessing the care they need. This applies to all long term conditions, including ME/CFS. Regarding suicide see: Mortality of people with chronic fatigue syndrome: a retrospective cohort study in England and Wales from the South London and Maudsley NHS Foundation Trust Biomedical Research Centre (SLaM BRC) Clinical	Thank you for your comment and this reference. The guideline will include cross-reference to other NICE guidance for the mental health of people with chronic conditions.

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			Record Interactive Search (CRIS) Register. Roberts, E., Wessely, S., Chalder, T., Chang, C. and Hotopf, M. Lancet. Volume 387, No. 10028, p1638–1643, 16 April 2016	
Royal College of Psychiatrists	General		The choice of diagnostic criteria for ME/CFS should favour inclusivity and clinical feasibility to ensure the guidance is of practical use for health professionals and does not inadvertently exclude groups of patients.	Thank you for your comment and suggestion of need to include a broad group of people.
Royal United Hospitals Bath NHS Foundation Trust		general	Assessors for Disability benefits need to be trained in the manifestations of ME/CFS, particularly for Disability Living Allowance and Personal Independence Payments. For example, a 'blue badge' may help a family to access 'normal' activities with other family members, and prevent isolation for young people.	Thank you for your comment and suggestions of non-medical interventions that may be helpful to patients and their families.
South London & Maudsley NHS Foundation Trust	General	General	This is an important guideline and it will be essential to be guided by the evidence base, whilst taking all views into account.	Thank you for your comment.
South London & Maudsley NHS Foundation Trust	General	General	This response mirrors the Royal College of Psychiatrists response and was completed by the same person. We want to highlight this for transparency but we felt it important that our Trust also submitted a response.	Thank you for your comment.

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South London & Maudsley NHS Foundation Trust	General	General	Co-morbid depression and anxiety are high in ME/CFS and the rates of suicide are increased compared to the general population. It is essential that a biopsychosocial approach is taken so the mental health needs of those suffering from ME/CFS are addressed. We take the view that a mind-body split is unhelpful and can prevent patients accessing the care they need. This applies to all long term conditions, including ME/CFS. Regarding suicide see: Mortality of people with chronic fatigue syndrome: a retrospective cohort study in England and Wales from the South London and Maudsley NHS Foundation Trust Biomedical Research Centre (SLaM BRC) Clinical Record Interactive Search (CRIS) Register. Roberts, E., Wessely, S., Chalder, T., Chang, C. and Hotopf, M. Lancet. Volume 387, No. 10028, p1638–1643, 16 April 2016	Thank you for your comment and this reference. The guideline will include cross-reference to other NICE guidance for the mental health of people with chronic conditions.
South London & Maudsley NHS Foundation Trust	General	General	The choice of diagnostic criteria for ME/CFS should favour inclusivity and clinical feasibility to ensure the guidance is of practical use for health professionals and does not inadvertently exclude groups of patients.	Thank you for your comment and suggestion of need to include a broad group of people.
Stonebird	**General**	General	This Scope is disturbingly very different from the previous draft scope. It has ignored, for example, most of what we recommended as a Stakeholder previously in conjunction with the 25% ME Group; it is hard to imagine that this Scope is a reflection of the concerns that the ME Community has been expressing throughout the consultation period so far.	Thank you for your comment. **Representation of severe ME** The scope does, under section 3.1, list the population who are included in the guideline and this makes

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			The Scope certainly does not reflect what we would expect it to, after so much input, nor does it represent Severe ME at all, which is not recognised as a distinct group in the document; how then can people with Severe ME be confident that their illness is understood, recognised or that any recommendation will be safe? Fundamentally this Scope is about a heterogeneous group of people primarily with Fatigue sill, not the WHO classified neurological disease, Myalgic Encephalomyelitis; it is certainly not about Severe ME. Unless it addresses the following issues we fear that the new Guideline, like its predecessor CG53, will once again be a fatigue-focused document that, without defining the illness, will continue to ignore the full symptoms, physical experience and need, ultimately endangering or ignoring patients. The listed main outcomes, at the end of the doument, are of particular concern as they are so limited in scope and do not appear to address the illness or challenge the fundamental perception that it is primarily a fatigue illness. **1. In line with its obligations under the AGREE11 instrument, NICE must specify the population (patients, public, etc.) to whom the guideline is meant to apply.**	specific mention of people with severe ME/CFS as a distinct group requiring special consideration. The scope is intended to outline the areas included in the guideline and it is important that it does not pre-judge the work of the committee. We have altered section 1 following stakeholder comments. However this section is intended only to 'set the scene' for the guideline. As you indicate a variety of terms with different meanings have been in use. These are areas the committee will need to consider including which study populations are appropriate to include. The use of the term ME/CFS in the scope or the term encephalopathy does not pre-judge the terminology of the final guideline. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. **Outcomes**The main outcome section in 3.6 is a draft list of outcomes to include in evidence reviews and this list will be adapted and added to by the committee.

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			It must be specifically described. The Scope cannot possibly answer its own question : *In whom should ME/CFS be suspected?* without identifying what "ME/CFS" means. The Scope is fundamentally flawed precisely because it fails to define what it means by "ME/CFS". It also continues to use the term encephalopathy, despite the fact that this is not a properly recognized, acknowledged name for the disease. The Scope should surely explicitly state that the World Health Organisation's mandatory International Classification of Diseases categorises ME as neurological under ICD 10-G93.3. ME, an organic neurological disease can be fatal . "CFS", on the other hand, defined through the now discredited Oxford Criteria, which are no longer used in the USA, and the CDC/Fukuda Criteria, describes no distinct patient group. The label "ME/CFS" is not formally acknowledged or classified by the WHO; it has no ICD Code. The WHO ICD-10 code as used in UK, Australia, Europe and other countries, has 'CFS' in the index only, indexed to G93.3; 'CFS' does not appear in the Tabular list, i.e. the main body of the classification listings, at that code. In ICD-10 'CFS' is not the same as 'Fatigue syndrome,' which is classified at F48.0 Neurasthenia under "Mental and behavioural disorders "	

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			This distinction is not made in the Scope, except to state that "*ME/CFS is heterogeneous and multifactorial and people experience the illness differently.*"In other words a disparate, vague group people ranging from those suffering from unexplained "chronic fatigue" to those with Severe/Very Severe ME suffering profound, massive multi-system physical dysfunction lasting for decades. In order to protect patients it must also clearly state that the National Institute for Health and Care Excellence (NICE) does not list ME as a functional somatic disorder. The Scope must also clarify and state that ME is not "fatigue syndrome" (F48.0) and that the term Chronic Fatigue Syndrome specifically means "chronic fatigue syndrome" (G93.3), making it clear that ME/CFS refers to the neurological disorder WHO ICD-10 G93.3, not "fatigue syndrome" F48. This is particularly important given how the ICD codes F44, F45 and F48 are currently being used as 'catch-all' codes in situations where clinicians feel there is an element of MUS affecting the patient and their management.	**Aetiology** NICE guidelines do not generally review aetiology, pathology and biological research. A guideline is not intended as a definitive account of all aspects of a condition. These areas can be discussed when helpful for diagnosis and management.

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			What is missing here is a statement that ME is currently incurable and there is no universal treatment. **2. The aetiology, pathology and biological research that provides explanation for ME symptoms and their underlying metabolic mechanisms should be included in the Scope.** The Scope acknowledges that " *the lack of understanding of the aetiology of the condition has contributed to a number of different symptom-based definitions being used in research and in clinical care*" yet the aetiology and pathogenesis of ME, as in the 2007 Guideline, still lie outside the Scope's remit. How can the Scope ensure that the GDC use the safest definitions? The Scope needs to clarify the cause, signs, symptoms of Myalgic Encephalomyelitis as part of defining the disease for the GDG, to do this they must take into account the published biomedical evidence, over 7000 papers, that it ignored in the drafting of CG53. Clarification of symptoms, inclusive of ME, is required so that they are nor mistakenly disregarded as "co-morbid" nor ignored if they are co-morbid.	We have removed the word 'distressing' from section 1. The definition to use will be discussed by the committee and we do not want to impose a definition at this point in development. We expect that the guideline once developed will provide information on

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			What rational reason can there be for omitting aetiology and pathogenesis or the full symptom experience? How can the GDG possibly know what disease and information to look at without this clarity? **3. The Scope should not rely on any opinion - based, blanket summary statements about aetiology and pathology. Aetiology and pathology need to be included in the evidence review. At its core it should rely upon a specific definition of this multi-systemic neurological disease, which NICE so far has failed to present.** Will NICE remove the word "distressing" from the Scope to describe ME, as this is associated with the definition/diagnostic criteria of MUS ? It would be better to replace this with acquired serious chronic, complex mutisystemic disease, as defined by the ICC criteria. The Scope should list the full symptoms experience by people with ME, including the symptoms experienced by people with a Severe diagnosis, who will have a wider range of symptoms, than those minimal symptoms so far recognised by NICE, including paralysis and the profound hypersensitivities: light, touch, sound, movement, motion, chemical and perfume sensitivity.	common symptoms. The symptoms listed in section 1 are not intended as psychosocial minimisation. **Pain** The Main outcomes section lists outcomes we will search for in evidence reviews. The inclusion of pain in this list is because it allows this outcome to be assessed in interventions for the management of ME as a whole. We have changed the wording in section 3.3 to clarify our intention not to include management of other conditions rather than symptoms some of which may be integral to ME/CFS. We have altered section 1 following stakeholder comment to indicate concerns about use of term fatigue and preference for malaise and have put more emphasis on post exertional malaise and deterioration of symptoms. There is no plan to use Delphi consensus methodology. The NICE guidelines manual outlines how evidence is used. The committee will be taking

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			The only symptoms apart from fatigue that the Scope refers to are "*chronic pain, disordered sleep, digestive problems and cognitive difficulties*, this is a typical psychosocial minimization. It is not clear how the Scope will provide an outcome for pain, as stated in its main outcomes, given it also says that neuropathic pain in adults has separate guidance and chronic pain assessment and management is being developed and so will not be covered under these guidelines. This is a huge omission and also a large contradiction. We feel pain should be adressed as a whole within the ME Guidance to ensure it is understood in context. **4. The terms PEM/PENE, the cardinal symptom of ME, as described in the ICC Criteria, should be referred to in the Scope, not just debilitating fatigue, particularly after exertion. "Fatigue" is not a full enough or correct term to cover the actual physical experience, following exertion, in Myalgic Encephalomyelitis.** Furthermore, muscle fatigue also should be recognised as a specific symptom, so that it can be better investigated. The Scope should provide a specific definition for PEM/PENE as provided in the ICC which includes delayed onset and inability to perform at the same level of exertion over consecutive days, corresponding with biological research on the impaired energy metabolism and aerobic systems in ME, the cardiac abnormalities that have serious implications	patient experience into account when making recommendations. Other guidelines will not be referred to without consideration of their relevance to the population in this guideline. The guidelines listed are an indication of those considered likely to be related to this guideline.

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			for GET and are a contraindication of aerobic exercise. It is vital that the Scope acknowledges the severity of PENE in Severe ME particularly, especially in regard to "Activity Managment" as referred to CG53, to ensure it is not recommended, using elements of CBT and GET. **5. The Delphi Consensus methodology, where recommendations are based on opinion, not evidence should not be used in the drafting of the new Guidelines, because they will be totally reliant on the makeup of the GDG and the predominant attitudes that individuals hold towards ME, which can vary widely depending on what they represent - the psychosocial construct or a biomedical approach.** CG53, for example, made the extremely dangerous recommendation that people with Severe ME be offered Graded Activity Management, on the basis of consensus not evidence. The Scope needs to clarify what exactly does it mean by "evidence" when there is so little evidence available, especially in Severe ME. Will it be taking into account patient surveys and patient experiences, especially people with Severe ME? **6. Other NICE guidelines should not be automatically extrapolated to patients with ME, especially where there is no or little evidence of benefits or safety.**	**Interests** Stakeholders are not currently asked to declare interests. The committee including those providing expert testimony are required to declare interests according to the NICE policy. **Quality standards** The development of quality standard is a separate process from guideline development. This link describes the prioritisation for NICE topics and how they are chosen for development. https://www.nice.org.uk/about/what-we-do/our-programmes/topic-selection

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			Safety is of high relevance here because the person with ME and particularly the person with a Severe diagnosis is at risk of serious harm and deterioration and unimaginable suffering, without comprehension and consideration of the true nature of the disease. We would like to see a RISK assessment ensured before any recommendation and a specific acknowledgment that the slightest wrong action or interaction, for a person with Severe ME, is catastrophic and long term damage can ensue that cannot easily, if ever, be put right again. This is an extremely serious point. This includes recommendations on how to care for people. The unique nature of ME , particularly the post-exertional impact and deterioration, make other NICE Guidelines not necessarily transferable or appropriate. All aspects of ME should be included directly in the scope because of this. It is dangerous to not recognise the acquired multi-system dysfunction, the serious drug sensitivity, the metabolic disruption, the cardiac abnormalities, the reduced cerebral blood flow as well as the many possible biomarkers of ME. The Scope should also clarify NICE's position on its two sets of references regarding "CFS/ME" in Improving Access to Psychological Therapies and the Guideline on "suspected neurological conditions" both of which include references to chronic fatigue syndrome as being a "functional" symptom or disorder, this is contradictory. This is another reason not to include CFS in the title of this Guideline.	As mentioned above people with severe ME are included in the guideline as a group requiring specific consideration. Please see the comments above on outcomes.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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			7. Will Stakeholders and the GDG membership be expected to declare all Conflicts of Interest, including insurance, pharma and corporations taking over provision of health and social care services as integrated services /integrated care systems ACOs? **8. A quality standard, defining the absolute minimum to ensure safe and effective practice, needs to be developed for this Guideline, to prevent patients being diagnosed, mistreated or mislabeled as having non organic MUS in the IAPT LTC MUS pathway.** It beggars belief that for the last 30 years the UK medical profession has taken seriously the claim, by psychiatry, without any basis, that the WHO classified neurological disease Myalgic Encephalomyelitis (ME) is a "Somatoform" disorder, inclusing MUS; this wrong must surely be addressed by NICE in this Scope, in these Guidelines to ensure patient safety. **9. We are concerned that although treatments are not being considered by the Scope, therapies promoted as treatments may yet be wrongly included under management.**	

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			Most methods of management are not safe for they demand interaction and cognitive effort that especially in Severe ME, cannot safely be sustained. Many people do not understand the enormous danger of deterioration in ME or for how far or for how long people can deteriorate. Cognitive activity, within the cognitive dysfunction of ME can lead to PENE. This needs to be recognised. **10. People want real change and specific acknowledgment in the Guidance that the psychosocial paradigm will be no longer be allowed to dominate and misinterpret ME. This is a concern that we feel has not been fully addressed by the Scope.** We are extremely concerned that the minimal outcomes identified at the end of the Scope, with their limited focus on sleep, fatigue and pain rather than full symptom recognition, full symptom alleviation, support and the appropriate meeting of the needs of homebound people who cannot attend hospital settings, fail people with ME yet again. The focus on fatigue as opposed to PENE and muscle fatigue is yet again inaccurate, unhelpful and leaves the Scope vulnerable to the continued inappropriate inclusion of people with mental health conditions, alongside poorly diagnosed other illnesses, including undiagnosed or unrecognised rare diseases, under a heterogeneous	

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			umbrella term of ME/CFS that will yet again not help people with neurological ME or anyone get the right intervention, diagnosis and support.	
The 25% ME Group	General	General	It is essential to learn from the experience of developing Clinical Guideline 53. The publication of this guideline did nothing to avoid promulgating the obfuscation of the neurological disorder M.E. as recognised by the World Health Organisation (ICD-10 G93.3). Time, money and effort was spent producing guidelines for a non-specific cohort of fatigued patients subsumed under the misnomer 'CFS/ME'. This tactic was doomed to lead to unsatisfactory results for people with M.E. The difficulties inherent in approaching a non specific cohort of patients were flagged up as long ago as January 2002, in *A Report of the CFS/ME Working Group: Report to the Chief Medical Officer of an Independent Working Group* (Department of Health publication): "The CMO assembled the Working Group to report on CFS/ME. Many correspondents with the Group noted that the term CFS/ME covered subgroups of patients who might have different aetiology, symptom complexes, or response to various treatments." "Some patients with CFS/ME might not respond, or might even respond adversely, to certain treatments found effective in other patients. … In view of concerns raised over patients' experience, the question of whether differential treatment response represents some distinct difference in disease merits carefully planned research."	Thank you for your comment. The intention is that the guideline will provide increased clarity and appropriate recommendations for people.

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			The Report highlights the need for resolution of this issue as a "key message": *"One highly heterogeneous disease might exist that encompasses CFS/ME or several related* pathophysiological *entities may exist; these distinct hypotheses should be studied."* The Report also acknowledges: *"These possibilities complicate the consideration of aetiology and pathogenesis, as they do other aspects of the condition."*	
The Young Sufferers of ME Trust	General	General	Shared Decision Making: Families have reported to us: • they do not receive information about any proposed treatment plan • there are no shared decision making conversations where a family gets the opportunity to express their wishes, concerns and preferences. • they are told that children need in-patient care but there is no information available on the planned care/treatment, despite several requests from families. • in-patient care is often referred to as "intensive rehabilitation" with no further information on the proposed treatment plan, or the pros and cons of this approach. • Families feel coerced into agreeing to either outpatient or inpatient care and treatment as there are suggestions that social services will be involved if they refuse.	Thank you for your comment and this information about family experiences.

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			A treatment plan should be made available to each family. This treatment plan should list the evidence base for all proposed treatments plus any potential side effects (perhaps in the form of a Patient Decision Aid). There should be clear information on a family's rights to withdraw and a clear process by which they can complain should they feel their rights are being ignored.	
VIRAS	general	general	VIRAS group members are qualified in science and research and include healthcare professionals from varied disciplines as well as carers for and patients with M.E. and Lyme disease. We are stakeholders for the NICE guidelines for Lyme disease and we welcome the opportunity to provide our expertise to the development of new guidelines for M.E.	Thank you for this information.
VIRAS	general	general	The SCOPE omits to put M.E. and CFS in context. The history of the diseases is relevant and vital to understanding how serious neuro-immune diseases have been trivialised in mainstream and medical media, and how it came about that the first NICE guideline for "CFS/ME" was influenced by vested interests which created and perpetuated discrimination against patients. The historical and political	Thank you for your comment. The guideline scope sets out the areas a guideline will cover and does not

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			context is essential information for the guideline committee and this should be stated in the Scope. The undue influences on the first guideline must be recognised. The pool of literature about M.E. and CFS has been tainted by decades of futile psychosocial theories of phobia, hysteria and hypochondria, and equally futile notions about deconditioning, fatigue and exercise. Notwithstanding consistent failure to prove any of these theories, they have been spun and disseminated so effectively that they have indoctrinated the thinking of some medical professionals, the media and the public. The 2007 NICE guideline for 'CFS/ME' failed to identify and take into account the unproven nature and irrationality of these theories, or the vested interests of those who promoted them. As a result, an effect of the guideline was to confirm the opinions of those whose purpose was to psychologise patients, discredit their accounts of their symptoms and disqualify them as medical patients. This situation has facilitated the suppression of research, withholding and withdrawal of medical support, state benefits and in some cases, the support of the patient's own families, partners, friends and colleagues. It would be a conceit to believe that NICE or its committee are above all this and that the past could, or should, simply be erased - that a blank-slate on which to write a world-class guideline for M.E. and CFS is possible in this contaminated environment. Therefore the prejudice and	provide summary of historical and political context for the condition the guideline covers. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made.

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			discrimination against M.E. and CFS patients must be recognised so that these can be dealt with if and when they impinge. This is the correct way to avoid repeating past mistakes. There are around 1,500 documents on the NICE website which include the phrase: "Evidence Based". Yet it should be understood that NICE procedures permit 'evidence' to be drawn from virtually any source. The recently published NICE guideline for Lyme Disease (NG95), provides 12 major items of information and recommendations: "Based on the experience and opinion of the Guideline Committee", three major items: "Based on very low quality evidence" and just one: "Based on moderate to very low quality evidence". That covers virtually the entire guideline. The result is an opinion-based guideline bereft of evidence and which represents nothing more than opinions. (https://www.bmj.com/content/361/bmj.k1261) Therefore, when assumptions, opinions and theories substitute as 'evidence', their value, veracity and the vested interests of their origins must be critically interrogated from every angle. This can only be undertaken with a good understanding of the context and the history of M.E.	
VIRAS	general	general	VIRAS would like to thank NICE and the stakeholders who contributed to designing and writing the draft scope. It has clearly required a lot of work and much of it looks very good.	Thank you for your positive comment.

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			The main problem we have is that NICE do not appear to have decided what disease the scope is for. The exact same mistake resulted in some failures of the 2007 guideline. This decision must be made before any more work is undertaken and we request to be informed. VIRAS never intended to be associated with a guideline for 'fatigue' and if NICE proceed on that basis we will oppose it. Multiple sclerosis patients are not expected to tolerate guidance which incorporates patients who only have fatigue. Neither are lupus, myasthenia gravis, Sjogren's and Parkinson's patients. Patients with M.E. or CFS should not be expected to tolerate it either, and if NICE intend that they should – then that will be discrimination which VIRAS will challenge by every available means.	The wording has been changed following consultation on scope. The changes include recognition of the difficulty around the term fatigue and the presence of other symptoms.
Welsh Association of ME & CFS Support	General	General	The Welsh Association of ME & CFS would like to thank you for the opportunity of commenting on this scoping document. We hope our comments are constructive in nature and will prove helpful in the forthcoming guideline process.	Thank you for your comment.
LocalME		16-25	The main outcomes listed are nearly all subjective judgements. Why not measure return to work/education on a full or part-time basis or joining civil society for example? Adverse effects and the impact of treatment or management strategy should be added to the main outcomes to be assessed. Coroner's reporting of deaths from ME and with possible failures by statutory services implicated; failure to provide early appropriate	Thank you for your comment. The list is for outcomes that are likely to be found in studies and does not include all outcomes likely to be of interest to people ME/CFS. Neither is the list intended to be exhaustive and we will include other measures including objective measures where possible. We have also added adverse reactions to the current list.

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			diagnosis, appropriate specialist services and safe interventions based on sound guidance.	
The ME Association	1-2	15-27 & 1-28	The MEA is pleased to see that the new guideline will be addressing a number of key issues of concern to the ME/CFS patient community. These relate to: nomenclature definition late diagnosis and misdiagnosis lack of appropriate or even potentially harmful advice on management, especially in relation to the current recommendations for behavioural treatments that are either ineffective (ie CBT) or potentially harmful (ie GET) as far as the underlying disease process is concerned the inadequate response from government departments in relation to the funding of biomedical research and provision of NHS services for a disease that causes a very large economic loss to the UK economy.	Thank you for your comment. The guideline will address nomenclature, diagnosis and appropriate advice on management. The guideline can also make research recommendations in areas the guideline has examined.
Action for ME	6-7	Page 6 line 7 – page 7 line 14	In our survey, a significant minority (36%) felt that changes were needed to the section 'Key issues and draft questions'. The information people affected by M.E. felt was missing was varied, but commonly centred on aspects of treatment and management for which there is not yet a robust evidence base. Given the lack of treatment, people with M.E. frequently contribute to online forums and can provide management suggestions based on what has worked for them. This includes the use of medication that is not specifically licensed for M.E., but help with individual symptoms. While	Thank you for your comment and suggestion. We do intend to include a call for evidence in the guideline to address the issues you raise. The scope however does not usually include information on methods that will be used in the guideline.

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			NICE will be considering robust research evidence on M.E. treatments, this condition is in a unique position in that there is no consensus on what can be beneficial to patients, and there has been no research investment to evidence the techniques commonly used by patients, such as pacing. To best serve people with M.E., there needs to be some mechanism in place by which patient evidence can inform the NICE guideline and be given significant weighting in relation to other forms of evidence. Therefore, one addition to this section should address the consideration of patient evidence on treatment and management methods. It may be that this cannot be used as the basis for formal NICE recommendations, but could enable healthcare professionals to recognise the variety of symptom management methods that could be utilised, and to therefore respond flexibly to the needs of a patient. One person with M.E. told us they "*have suffered for 30 years and have neither found an effective strategy or management technique that can indicate when I'm going to fall off a cliff edge*".	
Action for ME	1-2	Page 1 line 14 – page 2 line 28	In Action for M.E.'s survey, 47% of respondents felt that improvements needed to be made to the section 'Why the guideline is needed'. While this section does describe some of the ways in which people can be affected, patients felt that it does not adequately address the serious nature of M.E. People with M.E. commented:	Thank you for your comments. We have altered this section and included reference to the fluctuating nature of the condition, variation in symptom severity and post exertional malaise.

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			"*Life with M.E. is not just severely disrupted, normal life as previously known is completely impossible. You are unable to do everyday things that most people take for granted i.e. having a bath when you want to, washing your hair, taking a walk, go shopping, enjoying cooking and many, many more things*". "*This disease is utterly disabling, the effect on quality of life is devastating, I feel this section downplays the severity of symptoms and how completely life-changing they are*". Patients commonly suggested three key ways to ensure that this is addressed. Therefore, Action for M.E. recommends: - More detail is included on the variation in M.E., particularly symptom severity - The fluctuating nature of the condition is described - Post-exertional malaise is listed as the hallmark symptom of M.E. We have included more detail on each of these points in the following three comments (numbers 3-5).	
Royal College of General Practitioners	6/7		Important to identify the support needs of people with CFS/ME, their families and carers.	Thank you for your comment. This area is already included in the guideline.
Blue Ribbon for the	6/7	3.5 section	Overall we are pleased with what changes and additions that have been made in this section	Thank you for your comment.

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Awareness of ME (BRAME)				
Action for ME	1	19-25	It would be a more accurate depiction of the impact of the condition if this section included more detail on the varied experiences that patients have, namely in symptom severity. By highlighting those who are severely affected, and detailing the ways in which the condition impacts on them, it would accurately describe the need for the guideline. A person who is currently experiencing moderate M.E. symptoms and has had the condition for over 5 years said he didn't think "*it highlights how severe M.E. can be for some people*". Other symptoms experienced by people with M.E. that are not included in this section include severe headaches, nerve pain, orthostatic intolerance, and sensitivity to light, touch and sound. Patients with severe M.E. are frequently either house-bound or bed-bound. It is particularly important to recognise the experiences of those with very severe M.E. who experience symptoms severely and on a continual basis. People who are very severely affected are often unable to live independently, and can require full-time care and support with all aspects of their personal care. They can also require tube-feeding. By including a description of this full spectrum of severity, it will ensure that the scope has accurately and clearly specified the considerable need for this guideline.	Thank you for your comment. We have added further detail to this section.
Action for ME	1	19-25	Additionally, professionals frequently do not understand the fluctuating nature of M.E., which can prohibit the provision of appropriate care and	Thank you for your comment. We have added the fluctuating nature of the condition to this section.

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			support. Therefore, it is important that this section accurately describes the ways in which M.E. symptoms can change over time. One person said: "*The fluctuating severity of the condition is not recognised here. Over 20+ years I have had several extended periods of 'severe' (housebound/bedbound) but also some periods of 'mild'. Even when overall 'moderate' due to careful management, severity can fluctuate significantly over the course of a week/month*". It is necessary to accurately capture the nature of M.E. in this scope, as the basis for the overall NICE guideline. To do so, the fluctuating nature of the condition must be included. It is vital that health professionals, and others involved in the care of people with M.E., are equipped to recognise and respond to the varying symptoms, as this can make a huge difference in the support that the patient receives. For example, a well-informed health care professional can respond flexibly, by recognising a flare-up in symptoms and taking steps to prevent any additional exertion.	
The 25% ME Group	1	19-25	This section does not do justice to the severity of this illness. It should be noted that the most severely affected patients are bedbound, tube-fed because they are very weak or have severe gastrointestinal problems and are unable to swallow, and may be unable to speak or to tolerate light, sound or touch.	Thank you for your comment. We have added further detail to this section.
The ME Assocation	1	7 - 13	The ME Association (MEA) welcomes the fact that NICE has accepted that certain parts the current NICE guideline on ME/CFS are not fit for	Thank you for your comment. We recognise the concern about the current recommendations for GET

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			purpose and has been listening to the views of people with ME/CFS, and the charities that represent them, during the process of preparing the scoping document. Having taken part in the stakeholders meeting on May 25th to discuss the previous version of the scope, where we raised a number of concerns and suggestions, we are pleased to note that some – but not all – of these have been accepted. Following publication of the revised scoping document, MEA trustees have reviewed the new content. We have also given our members the opportunity to pass on comments. We continue to have a number of concerns and suggestions for improvement. These are set out below. We must also return to a matter of great concern to the ME patient community and something that has been raised in both correspondence and during the stakeholders meeting on May 25th. This relates to the recommendation in the current NICE guideline that everyone with mild or moderate ME/CFS should be offered a course of CBT and/or GET. As NICE is already well aware: patient evidence indicates that CBT is not an effective form of treatment for ME/CFS, although, as an adjunct to treatment, it may help some people to cope with some aspects of the illness, as it can with some other disabling medical conditions	and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

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			patient evidence indicates that GET often causes a worsening of symptoms or significant period of relapse the basis for recommending these two behaviour-based treatments, where the model of causation involves abnormal illness beliefs and behaviours and deconditioning, is not consistent with current scientific understanding of the pathophysiology of ME/CFS, especially findings relating to defects in energy production at a cellular level serious concerns have been raised by clinicians and researchers about the accuracy of the results relating to outcome from the main clinical trial – The PACE trial - upon which these two approaches are based. Members of parliament, speaking during the recent parliamentary debate on ME/CFS, have also raised the same concerns. It was pointed out during the debate that for NICE to continue providing this recommendation until the new guideline appears in October 2020 places NICE at risk of litigation if people come to harm as a result of being coerced into having these treatments as a condition for obtaining or continuing to receive state or private sickness/insurance benefits. In addition, the CDC in America has recently updated their guidance on the management of ME/CFS. This guidance no longer makes any recommendation regarding the use of GET and issues a clear warning about the use of inappropriate activity management and exercise regimes. The CDC now recommends that people with ME/CFS should	

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			adopt an approach to activity management that is based on the principles of pacing – something that patient evidence consistently reports to be acceptable, safe and effective: From the new CDC guidance: Post-exertional malaise (PEM) is the worsening of symptoms following even minor physical or mental exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or even weeks. PEM can be mitigated by activity management (pacing). The goal is to avoid PEM flare-ups and illness relapses by balancing rest and activity. Patients need to determine their individual limits for mental and physical activity, and plan activity and rest to stay within these limits. Some patients and healthcare providers refer to staying within these limits as staying within the "energy envelope." Limitations may be different for each patient. Keeping individual activity and symptom diaries may be helpful to patients in identifying their personal limitations, especially early on in clinical care. Healthcare providers need to keep in mind that when patients with ME/CFS exceed their individual capacities, PEM and serious deterioration of function may result. In general, patients should not push themselves beyond their capacities as this may exacerbate the symptoms and trigger PEM. When patients experience improvement, activities can be cautiously increased with monitoring for any negative effects. Patients need to be advised about "push and crash" cycles:	

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			patients sometimes respond to having a "good day" by subsequently doing too much to make up for "lost time," and then relapsing. Any activity or exercise plan for people with ME/CFS needs to be carefully designed based on individual presentation with input from each patient. If possible, evaluation by a rehabilitation specialist may be beneficial. For some patients, even daily chores and activities such as cleaning, preparing a meal, or taking a shower can be difficult and may need to be broken down into shorter, less strenuous pieces. While vigorous aerobic exercise can be beneficial for many chronic illnesses, patients with ME/CFS do not tolerate such exercise routines. Standard exercise recommendations for healthy people can be harmful for patients with ME/CFS. Full CDC guidance: https://www.cdc.gov/me-cfs/healthcare-providers/clinical-care-patients-mecfs/index.html We therefore ask NICE to remove this recommendation from the current guideline. Or to issue some form of written warning to all health professionals about the use of these two treatments.	
Welsh Association of ME & CFS Support	1	19-25	WAMES finds the description of the illness to be unacceptable as it is misleading and lacking key pieces of information, which is likely to perpetuate the difficulties GPs and others have in using the current guideline to accurately identify and diagnose the	Thank you for your comment. Following stakeholder consultation we have changed the wording of this section. The changes include reference to the fluctuating nature of the condition and the severity of

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			condition. Fatigue is not the main characteristic of ME, the post-exertional response is. No mention is made of the fluctuating nature and the comparatively poor Quality of Life experienced. We propose an alternative wording: *ME/CFS is a chronic and potentially highly disabling disorder causing considerable disruption to daily life, relationships, work and education. People with ME have been found to experience poorer quality of life of than other chronic illnesses e.g. MS, serious depression. This is magnified by the isolation, misunderstanding, stigma and disbelief many face from family members, friends, health and social care professionals, benefits assessors etc.* *The illness appears to be triggered by events such as viral illness, reactions to medication, toxic poisoning. A wide range of symptoms can be experienced, which fluctuate over the course of the illness. Key symptoms can include unrefreshing sleep, flu-like malaise, pain, extreme exhaustion/weakness/fatigability, orthostatic intolerance, digestive and cognitive dysfunction, but the main characteristic of ME/CFS is the deterioration of symptoms following minor physical or mental exertion, which is often delayed by a day or more and takes longer than normal to recover from. This has been called many names including Post-exertional malaise (PEM) or Post exertional Neuro immune Exhaustion (PENE), Systemic exertion intolerance. Only a small percentage of*	symptoms. We have clarified the issues in relation to the term fatigue and included reference to post exertional malaise and deterioration of symptoms.

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			people have been found to have fully recovered, though this is more likely for younger people.	
Buckinghamshire Healthcare NHS Trust	1	19-23	Fatigue is not always the presenting 'characterising symptom', ME/CFS may present as recurrent infections, headaches, neurological symptoms, malaise or a significant reduction in pre-morbid functioning. A longer list incorporating well recognised diagnostic terminology for common symptoms could be used here: post-exertional malaise, unrefreshing sleep, cognitive impairment, orthostatic intolerance. These are much more sensitive and specific for diagnosis of ME/CFS than fatigue, lack of complaint of fatigue should not result in a false negative diagnosis.	Thank you for your comment. We have altered this section following stakeholder consultation to clarify that fatigue is not necessarily the appropriate term and that other symptoms occur.
Forward ME	1	19 - 23	There is a need for a clear and robust description of the unique clinical profile that ME presents – if not here in the scope, then certainly in the final version of the guideline. It should be noted that this does not hinge on 'fatigue' as such but does entail the cardinal feature of Post Exertional Malaise (PEM). PEM is unique to ME and prevents confusion with other causes of chronic fatigue. The latest update of the CDC website (12.7.19) advises: "Post exertional malaise (PEM) is the worsening of symptom following even minor exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or even weeks." However, Post Exertional deterioration can be even more long-lasting, as the Institute of Medicine	Thank you for your comment. This section is not intended to provide a description of complete clinical profiles which we would expect to be part of the final guideline.

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			Report acknowledges: "PEM is unpredictable in duration, potentially lasting hours, days, weeks or even months." https://www.ncbi. Nih.gov/books/NBK284902/ (under heading 'PEM', references provided)	
The ME Association	1	15-18	Re Nomenclature: We welcome the decision to use the composite term ME/CFS in the new guideline and hope that NICE will acknowledge that chronic fatigue syndrome (CFS) is not a suitable alternative name for this illness. CFS fails to reflect the fact that this is a serious and complex multisystem disease. The use of this name also encourages physicians to use CFS as a diagnostic label for anyone with unexplained chronic fatigue. It is akin to naming dementia as a chronic forgetfulness syndrome. Many of the current diagnostic criteria in use fail to recognise that post-exertional malaise/symptom exacerbation is a key diagnostic feature of ME – so a diagnosis of CFS does not necessarily equate to a diagnosis of ME. The MEA believes that the term CFS is not acceptable and should be removed from common usage.	Thank you for your comment.
Forward ME	1	23-25	This is a most severe illness in terms of impact on the patient, as indicated by multiple quality of life/sickness impact studies. For example, US infectious diseases specialist Philip Peterson and team employed the 'Medical Outcome Study' to measure physical suffering, with a maximum score of 100 representing best health. 'CFS' patients in Peterson's clinic scored, on average, 16. Presenting findings, Peterson said *"We really haven't seen anything like it with respect to the other medical illnesses"* adding that he needed to engage an artist to redesign the morbidity	Thank you for your comment and this information.

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			graph for the slide presented, since no other category of patients scored so low. SOURCE: Hillary Johnson; Osler's Web 1996; Peterson published as Peterson PK, Schenck CH, Sherman R. *Chronic fatigue Syndrome in Minnesota. Minnesota Med 1991; 74: 21-26.* A Danish study found that ME patients on average had a lower quality of life than patients with multiple sclerosis, diabetes, stroke and multiple forms of cancer. SOURCE: http://journals.plos.org/plosone/article?id=10.1371/journal.pone0132421. it should be noted that the most severely affected patients are bedbound, tube-fed because they are very weak or have severe gastrointestinal problems and are unable to swallow, unable to speak or to tolerate light, sound or touch. Regarding prognosis, there is no age group for whom 'complete recovery 'is the norm. Indeed, we are not aware of a single documented case of recovery to the point where life is not at all restricted by this illness. To cite published findings, a systematic review of 14 studies found: • A median full recovery rate during follow-up periods of 7% • That only a minority of participants had improved at all over the study period – the median proportion of patients who improved during follow-up being 39.5% SOURCE: Carruthers. B *et al Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols* Journal of Chronic Fatigue Syndrome, Vol 11(1) 2003, pp7 – 115.	

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Respect for ME	1	23-25	I suggest removing 'although this can vary depending on the age of onset'. There is no convincing evidence that younger patients are any less disabled or more likely to recover than adults. Similarly, since ME causes immune dysfunction and cardiovascular dysfunction, there is likely an increase in all-cause mortality (Jason et al., 2006; McManimen et al., 2016). The guideline must acknowledge that death can occur in some patients.	Thank you for your comment. We have removed this sentence.
The 25% ME Group	1	7-9	The most fundamental issue in terms of securing safe and relevant care for people with M.E. is that the forthcoming guideline is relevant to the diagnosis and management <u>*of M.E. patients*</u>. In almost any other area of healthcare this can be taken for granted: a guideline to inform the diagnosis, care and treatment of patients with Parkinson's disease will set out the results of deliberations relevant to Parkinson's disease; a guideline to be applied to patients with prostate cancer will set out the results of deliberations relevant to prostate cancer. Yet when it comes to the care and treatment of people with M.E. the fulfilment of this most basic of preconditions cannot be assumed. Notably, M.E. is routinely conflated with psychosocial / psychosomatic chronic fatigue - to the detriment of M.E. patients. It is therefore essential that the guideline equips professionals to identify M.E. patients, as a prerequisite to meaningful efforts to address M.E. patient need, while protecting from harm / inappropriate advice or intervention.	Thank you for your comment. The use of the term ME/CFS in the scope does not pre-judge the terminology or title of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the recommendations for distinct groups identified.

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The 25% ME Group	1	16-18	Far from being overly exclusive, existing criteria tend to be broadly inclusive of a heterogeneous group. Warnings about the dangers flowing from this have been sounded for many years. See, for example, ScotME submission to the Gibson Parliamentary Enquiry - '*Heterogeneity of CFS/ME - the dangers of failure to sub group' (2005)*: citing the 2002 CMO's working group report (see comment 1), this flags up the difficulties inherent in a situation whereby "varied needs, degrees of disability and confounding conditions [are] subsumed under the broad diagnostic banner of CFS as currently defined in the UK, yet a 'one size fits all' approach to treatment has been adopted". It is vital that robust guidance is provided to practitioners to facilitate a positive diagnosis of M.E. (not a 'dustbin' diagnosis - *i.e.* a diagnosis of exclusion) and to distinguish patients with M.E. from patients with other physical disorders, and also from patients with a mental or behavioural disorder. This is essential because of the specific care needs of people with M.E.	Thank you for your comment. The intention is that the guideline provide clarity around diagnosis and appropriate recommendations.
The ME Association	1	23-25	The effect on everyday life should also refer to the fact that several studies of functional impairment in ME/CFS have shown that the effect on the level of disability and well being can be as great, or greater, than for many other serious medical conditions, including cancer and heart disease.	Thank you for your comment. We have reworded this sentence to reflect the severe disruption that people with ME/CFS and their families and carers can experience.
Action for ME	1	19-20	As well as highlighting severe M.E. and the fluctuating symptoms of the condition, another way to improve this section would be naming post-exertional malaise (PEM) as the hallmark symptom of M.E., and describe	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the

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			the impact of PEM. 'Post-exertional malaise' means that the body does not recover normally after expending energy, and can have an impact on many or all of the symptoms that a person with M.E. has. The International Consensus Criteria for M.E. uses the term 'post-exertional neuroimmune exhaustion' to refer to PEM and says "*this cardinal feature is a pathological inability to produce sufficient energy on demand with prominent symptoms primarily in the neuroimmune regions*" [Carruthers et al. (2011), Myalgic Encephalomyelitis: International Consensus Criteria, p. 329]. Recognising this feature ensures an accurate portrayal of what living with M.E. is like for those with the condition. Someone with M.E. commented that the description included in the scope needed to focus on PEM rather than fatigue because while "*fatigue occurs in many illnesses [PEM] is what makes M.E. unique*". It would be beneficial to demonstrate how this particular feature affects people with the condition, as this provides clarity as to how additional activities, physical or cognitive, can worsen symptom severity and even cause a long-term deterioration in their condition. One person with M.E. told us they felt the "*impact of post-exertional malaise isn't sufficiently addressed. The effect on daily living and quality of life should be stressed further*".	appropriate term and to include reference to post exertional malaise and deterioration of symptoms.
Forward ME	1	26 - 27	This statement is far too vague and negative – plausible hypotheses as to the underlying cause have emerged through decades of biomedical research and a wide range of physical abnormalities have been documented. Granted, this information has not been drawn together to produce an incisive and conclusive picture of the reasons behind the	Thank you for your comment. We have reworded this sentence to indicate that the causes are not clear rather than unknown.

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			onset and persistence of ME in each and every case. However, it would be misleading to imply that we do not have, at a minimum, some very strong clues as to the cause.	
Hope 4 ME Fibro Northern Ireland	1	19-20	**The word "fatigue"** despite being prefixed by "extreme and debilitating" is not a good word to describe ME. ME patients, are not simply experiencing fatigue, but instead they find they cannot function due to a plethora of disabling symptoms that occur, both as they try to perform normal daily tasks, and for an extended period afterwards. This is very different to "fatigue". **ME patients feel "ill"** rather than tired or fatigued. In the same way that individuals off work with 'flu would not say they were "tired", so ME patients likewise do not regard their condition as primarily one of "tiredness" or "fatigue". To be clear, our group feels that the word "fatigue" entirely misrepresents the condition. **Descriptors** that could replace the word "fatigue" could include: Lack of physical and cognitive stamina; Failure to function; Incapacity; Bodily weakness; 'Flu-like symptoms; Inability to sustain effort; or even Rapid fatiguability. As a symptom, "fatigue" is much too common to be useful as a primary disease description.	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms.

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			Suggestion for improving the sentence spanning lines 19 & 20: **"ME is a disabling illness characterised by an extreme and debilitating lack of physical and cognitive stamina, particularly after exertion."**	
Hope 4 ME Fibro Northern Ireland	1	22 - 23	**Common symptoms:** We would like to suggest that the following symptoms are added: **Add:** Post exertional exacerbation of all symptoms; noise and light sensitivity; muscle fatiguability; postural orthostatic intolerance; alcohol intolerance; and co-ordination issues.	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.
Invest in ME Research	1	19-20	**ME/CFS is a disabling and distressing illness characterised by extreme and debilitating fatigue, particularly after exertion** Instead of this we would prefer that NICE Use the phrase from the 2015 US Institute Of Medicine (now renamed National Academy of Medicine**)** report – "ME/CFS is a serious, chronic, complex, systemic disease that often can profoundly affect the lives of patients." The original NICE statement generalises this disease and is already setting up this review to fail.	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms.

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			NICE has already allowed significant damage to be done by its invalid guidelines that have been left in place for far too long. NICE should recognise this as a disease.	
Invest in ME Research	1	20-21	Clinically, ME/CFS is heterogeneous and multifactorial and people experience the illness differently. This sentence needs to be added following the above statement – and remembered "However, the hallmark symptom of post exertional malaise must be present for a diagnosis of ME/CFS to be made."	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms.
Respect for ME	1	19-20	'distressing' is an unfortunate word choice here. Given the problems some patient groups have highlighted with diagnoses like 'bodily distress disorder' and 'bodily distress syndrome', it is unwise to use this term in the guideline. It is unnecessary anyway, since the scope also mentions that it is 'debilitating' and 'disabling'. The description here relies on 'fatigue' rather than PEM. The use of an overly broad definition of ME or CFS in studies results in the inclusion of 'patients who may have had an alternate fatiguing illness' (Agency for Healthcare Research and Quality, 2014). One description we prefer is: 'ME/CFS is a multisystem condition that appears associated with a combination of genetic, cellular and systemic metabolic deficits in aerobic metabolism. The hallmark clinical feature of ME/CFS is post	Thank you for your comment. Distressing has been removed. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.

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			exertional malaise (PEM), which involves a constellation of extensively disabling ... signs and symptoms in response to exertion.' (Davenport et al., 2018). The International Consensus Criteria and Canadian Consensus Criteria also provide strong descriptions of ME. Note also the recent update (12.7.18) of the CDC website: "For some patients, even daily chores and activities such as cleaning, preparing a meal, or taking a shower can be difficult and may need to be broken down into shorter, less strenuous pieces. While vigorous aerobic exercise can be beneficial for may chronic illnesses, **patients with ME/CFS do not tolerate such exercise routines.** Standard exercise recommendations for healthy people can be harmful for patients with ME/CFS." (Their bold.) This section should also describe severe and very severe patients. These patients are poorly understood so it is necessary to determine some of the symptoms that may define severe/very severe ME: new and severe intolerances (including to medicines, foods, perfumes, sound and even light) that can make treatment difficult; inability to speak or swallow that may be initially mistaken for elective mutism or an eating disorder; extreme pain, which includes migraines and stomach pain; paralysis and seizure-like episodes; extreme orthostatic intolerance that means the patient cannot sit up in bed; and long-lasting or seemingly permanent symptoms, which in turn make it difficult to identify PEM.	

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Respect for ME	1	26 - 27	Though evidence is certainly far from conclusive, there are clues in the evidence base (brain, mitochondrial, immune, gut and hormonal abnormalities, for instance) that should be recognised.	Thank you for your comment. We have reworded this sentence to indicate that the causes are not clear rather than unknown.
Royal United Hospitals Bath NHS Foundation Trust	1	23-24	We question whether the statement that for "most people complete recovery is unusual" is supported by the current research evidence we have available to us. Recovery from ME/CFS is complex to define and research studies into interventions for ME/CFS have shown that recovery is possible for some people, both from an objective assessment and subjective perspective (e.g. Nijhof et al 2012). Although some people do suffer for a long time, statements saying that recovery is unusual, could lead young people who suffer with ME/CFS to believe that recovery is not possible, when for them it may be.	Thank you for your comment. We have deleted this sentence.
The 25% ME Group	1	10-11	In view of the outcome of the previous process of guideline development, we must emphasise that adherence to 'NICE' methods and processes is not a sufficient condition to ensure that the final product is fit for purpose in application to M.E. patients. For explication on this point we would direct 'NICE' to relevant written submissions to the Health Select Committee Enquiry relating to aspects of the operation of 'NICE' (2007). The Select Committee sought views on several issues, including: why NICE's decisions are increasingly being challenged; whether public confidence in the Institute is waning, and if so why; NICE's evaluation process. The 25% ME Group made a submission to this enquiry. Pertinent submissions were also lodged by ScotME and by the ME Association. All can be read in the published report of written evidence:	Thank you for your comment. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We intend to include a call for evidence in the guideline to address the issues you raise. The guideline will address information, education and support for health and social care professionals.

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			s https://publications.parliament.uk/pa/cm200607/cmselect/cmhealth/503/503ii.pdf See also submissions to NICE from 2017 consultation on CG53 replacement. To elucidate the validity of broadening the evidence base, see the 2008 Harvean oration by Sir Michael Rawlins, then chair of NICE. An article based on this speech was published as: Rawlins M. *De Testimonio: on the evidence for decisions about the use of therapeutic interventions.* Clinical Medicine (the Journal of the Royal College of Physicians) 2008; 8: 579-88. Quote: "The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an uncomfortable pedestal for while the technique has advantages it also has disadvantages. Observational studies have defects but they also have merit. Decision makers need to assess and appraise all the available evidence irrespective as to whether it has been derived from RCTs or observational studies; and the strengths and weaknesses of each need to be understood if reasonable and reliable conclusions are to be drawn. Nor, in reaching these conclusions, is there any shame in accepting that judgements are required about the 'fitness for purpose' of the components of the evidence base. On the contrary, judgements are an essential ingredient of most aspects of the decision-making process." Suggest taking in evidence cases of M.E. patients where the response of NHS and/or social services (or the lack of it), has been problematic, with serious adverse outcomes. This would serve to (i) ground the guideline in	

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			how and why existing practice needs to change and (ii) help gauge the utility of fresh guidance in terms of pointing towards securing an appropriate - and not harmful - service response. We have become acutely aware that professional mindset is a huge problem - tends to remain firmly set in the face of observed patient response to present NHS approach (variously - lack of improvement, deterioration, continued very low plateau for those patients who can't attempt what is being advised); no cognisance of harm; outcome is more of the same, no matter how much the patient is struggling / being set back; blame the patient. This does underline the clear need for makes robust guidance,that is congruent with M.E. patient reality.	
The 25% ME Group	1	20-21	Delete this sentence. It is essential instead to recognise core features that delineate the unique clinical profile of M.E. It should be noted that this does not hinge on 'fatigue' as such but does entail the cardinal feature of Post Exertional Malaise (PEM). This can be done while acknowledging that some variation can and does occur. However, simply emphasising 'heterogeneous', 'multifactorial' and 'different illness experience' in isolation from the core features is a recipe for continued diagnostic mess and iatrogenic harm to M.E. patients.	Thank you for your comment. This sentence has been reworded.
The 25% ME Group	1	22-23	Listing symptoms which commonly occur is no substitute for recognising that a distinctive clinical profile exists (see comment above).	Thank you for your comment and information. This section has been reworded. One of the tasks for guideline development will be to consider diagnostic criteria and the use of the term 'ME/CFS' in the scope

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			The presentation of symptoms in abstraction from identified areas of pathogenesis is also problematic. This was recognised as long ago as 2003, with the publication of Carruthers, B *et al. Myalgic Encephalomyelitis / Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols* in the Journal of Chronic Fatigue Syndrome, Vol. 11 (1) 2003, pp7-115; and the accompanying editorial (pp 1-6), which advise: • the clinician should not be confused that fatigue (or myalgia or the other symptoms that occur with increased frequency with fatigue) is an entity in its own right but is a common symptom of underlying disease [p2-3] • We present a systematic clinical working case definition that encourages a diagnosis based on characteristic patterns of symptom clusters, which reflect specific areas of pathogenesis. [p7-8] • We hope that the clinical working case definition will encourage a consideration of the ongoing interrelationships of each patient's symptoms and their coherence into a syndrome of related symptoms sharing a complex pathogenesis rather than presenting a 'laundry list' of seemingly unrelated symptoms. [p10] We believe this will sharpen the distinction between ME/CFS and other medical conditions that may be confused with it in the absence of a definite laboratory test for ME/CFS. [p10]	does not imply acceptance of any particular definition or meaning and does not pre-judge the terminology of the completed guideline.
The ME Association	1	22-23	Re the common symptoms list: this omits three key diagnostic feature of ME/CFS – activity induced fatigue (mental and physical), post-exertional malaise and symptom exacerbation, and fluctuation of symptoms	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post

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			(although the latter feature may not apply to those at the severe end of the clinical spectrum). Post-exertional malaise (PEM) is the worsening of symptoms following even minor physical or mental exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or even weeks.	exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.
Blue Ribbon for the Awareness of ME (BRAME)	1	23/25	There is no mention here of how 25% of people with ME are severely affected and are house/bedbound for the majority or all of the time needing 24/7 care and may be tube-fed, unable to speak and are unable to tolerate light, sound, smells and are sensitive to the lightest touch. ME can have a fluctuating nature which is usually between the different severity levels.	Thank you for your care. This section has been reworded to include reference to 24 hour care.
Blue Ribbon for the Awareness of ME (BRAME)	1	19/20	Whilst the fatigue experienced is a unique characteristic of ME, the illness is far more complex, and to be diagnosed with ME a person also has to have neurological, immune, gastro-intestinal, genitourinary, energy metabolism/ion transportation impairments. The 'extreme and debilitating fatigue, particularly after exertion' is a core and unique characteristic of ME which differentiates it from other causes of chronic fatigue and the guideline needs to have a clear definition of PENE – 'Post Exertional Neuroimmune Exhaustion – this cardinal feature is the pathological inability to produce sufficient energy on demand with prominent symptoms in the neuroimmune regions. Exhaustion may occur immediately after the activity or be delayed by hours or days' ME ICC 2011 (Carruthers et al)	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.

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			And PEM – Post Exertional Malaise – the latest update of the Centre of Disease Control (CDC) website (13.7.18) states – "Post Exertional Malaise (PEM) is the worsening of symptoms following even minor physical or mental exertion, with symptoms typically worsening 12-48 hours after activity and lasting for days or even weeks" However, Post Exertional deterioration can be even more long-lasting, as the Institute of Medicine Report acknowledges "PEM is unpredictable in duration, potentially lasting hours, days, weeks or even months" https://www.ncbi.Nih.gov/books/NBK284902/ (under heading 'PEM' references provided)	
Science for ME	1	19/20	"illness characterised by extreme and debilitating fatigue, particularly after exertion." – Many patients consider ME/CFS to be characterised by a range of symptoms associated with feeling ill. But more importantly by PEM (Post Exertional Malaise) that is an increase the range and severity of symptoms and disability (not just fatigue) following exertion (including a delayed effect). Using a description based on PEM is central to the Institute of Medicine (now the Academy of Medicine) report and description. http://www.nationalacademies.org/hmd/Reports/2015/ME-CFS.aspx It would be good to revise the description to include a clear description of this very important aspect of ME/CFS.	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.

<table>
<tr><th>Stakeholder</th><th>Page no.</th><th>Line no.</th><th>Comments
Please insert each new comment in a new row</th><th>Developer’s response
Please respond to each comment</th></tr>
<tr><td>LocalME</td><td>1</td><td>23/24</td><td>“For most people with ME/CFS, everyday life is severely disrupted, and for some, who are bed bound and tube fed, without proper on going monitoring and specialist palliative intensive care, the situation can be life threatening.”

It is important for a base line functionality to be established. (see suggested use of list below)

Functionality should be closely monitored, using *objective* measures, e.g. actometers, heart rate monitors etc, not just subjective ones easily biased to please the person asking; any decline recorded with interventions and treatment monitored so that any improvement be seen, as improvement can be subtle but -Improvement isn't necessarily incremental as condition can fluctuate and also can hit a glass ceiling. NICE should consider a recommendation that a specialist ME nurse who could do home visits (as MS patients have on offer) would be a desirable and cost effective solution.

GPs should confer with patient/carer/parent to determine current level of functionality

<table>
<tr><td>SEVERITY</td><td>MILD</td><td>MODERATE</td><td>SEVERE</td><td>VERY SERVERE</td><td>CRITICAL ACUTE NEED</td></tr>
<tr><td>NB ME/CFS is a</td><td>Mild, mobile, self care,</td><td>Reduced mobility,</td><td>Minimal daily tasks</td><td>Unable to mobilise or</td><td>May need emergenc</td></tr>
</table>
</td><td>Thank you for your comments and this information. There is a question about the different models of multidisciplinary care in the scope that will include team composition.</td></tr>
</table>

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			fluctuating and variable condition. Patient may experience considerable variability and fall between two or more categories	light domestic duties with difficulty. May be in education /work but taking days off (and/ or be part time) education and work Involvement to the detriment of social, family and leisure activities, will use weekend to rest and recover,	restricted in all activities of daily, not working or in mainstream education. Peaks and troughs of activity, sleep disrupted and sleeping on daytime, night sleep quality poor or disturbed	only, severe cognitive difficulties (brain fog), wheel chair dependant for mobility, rarely leaves house, significant worsening of symptoms following any activity, mental or physical.	to carry out any daily tasks of daily living, prone, bed bound majority of the time, unable to to tolerate /sound- and light sensitive (due to sensory overload) Possible tube fed. Possibly in need of intensive or palliative care approach.	domiciliary an/ or intensive care nursing with consultant overview and support, Consultant nurse to advise a multi disciplinary team. Possibly in need of intensive or palliative care approach. Possible tube fed. Likely to need specialist	

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			Continuing Health Care Assessment and or specialist nursing home care. All display (**Post Exertional Malaise (PEM)** **(Post Exertional Malaise (PEM)** (**Post Exertional Malaise (PEM)** (**Post Exertional Malaise (PEM)** **(Post Exertional Malaise (PEM** **(Post Exertional Malaise (PEM** It needs to be made very clear that patients can move between these categories and may become more severe : patients often relapse rapidly or show improvement slowly and at different times. Doctors have refused home visits on the grounds that patient was able to attend surgery before. Patients often feel doctors don't see or understand the severity of the symptoms –patients are often only able to see a doctor on a good day and the doctors don't see the subsequent symptom increase (PEM) and that patients may take a long time to recover from a simple visit to the	

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			doctor. Doctors also do not see the many other bad days. Hence it is important to communicate the levels of disability. There is no mention within the NICE Scope of severe, life threatening presentations of Me, found even in children or end of life, palliative or intensive care need with extreme presentations of ME. GPs who have refused home visits need to be made aware of the risk. Domiciliary home visits, formally made by consultants who coordinated multi disciplinary teams with nurses for severe ME cases, many who are tube fed and on Hickman lines, need to be reinstated if patients lives are not to be put at risk. There is a need to take into account the fact that other conditions, where increasing activity is prescribed for rehab, is potentiality harmful and likely to exacerbate ME patients symptoms who suffer PEM. Attempts for **"Vocational rehabilitation"** - advised by HCP, Occupational Health Advisors, DWP HCP or Social Care REABLEMENT advisors, must be approached with considerable caution; especially by patient's GPs, or by Health Care and Benefits advisers for the DWP, as it is clear from the following statement (which takes no account of the difficulties of those with ME), serious harms can be done to patients with ME. The dangers of "PEM" and critical relapse need spelling out. T**he Council for Work and Health** to **All Party Parliamentary Group on Occupational Safety and Health**	

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			"Vocational rehabilitation" is a good investment. Keeping people at work and off benefits and reducing sickness absence is of significant benefit to the national economy." Likewise the concerns raised by the 25% Group advocate Helen Brownlie and others to the NICE consultation on NG 74 Intermediate care including reablement guidelines last year. (This Guideline is now adopted). Concerns were raised in public by LocalME members at the NICE ME Engagement meeting January 2018 to Professor Mark Baker.	
Science for ME	1	23/24	"For most people with ME/CFS, everyday life is severely disrupted". It would be useful to describe the different levels of severity. Patients range from mild to more severe where they can be house bound, wheel chair bound or even bed-bound. Some patients who are very severe have an extremely low level of function. For example, from: http://www.meresearch.org.uk/our-research/completed-studies/severe-cfs-review/" "Case studies reported that in extreme presentations very severe CFS/ME individuals may be confined to bed, requiring reduced light and noise exposure." Patients often feel doctors don't see or understand the severity of the symptoms –patients are often only able to see a doctor on a good day and the doctors don't see the subsequent symptom increase (PEM) and that	Thank you for your comments and information. This section has been reworded to include reference to different levels of severity. The guideline will address information, education and support for health and social care professionals

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			patients may take a long time to recover from a simple visit to the doctor. Doctors also do not see the many other bad days. Hence it is important to communicate the levels of disability. In the US the FDA produced a document summarizing the patient experience https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm368806.pdf	
Blue Ribbon for the Awareness of ME (BRAME)	1	24/25	Any improvement is not dependent on age and more dependent on a patient seeing a health professional when they first become ill who suspects the possibility of ME, who then gives the correct advice, and sensitive and well-informed management in the early stages of the illness, which offers a possible improved prognosis – despite this, the illness may still take hold, and the person may still go on to become more ill or even severely affected by ME, but this would have still been tempered by the correct advice and support in the early stages.	Thank you for your comment. This sentence has been removed.
Support for ME	1	26/27	Vaccinations are another possible trigger that should be considered. Our son was given the BCG vaccine (unnecessarily) and developed ME/CFS as a result of the vaccine's side effects. We are also aware of others who have developed ME/CFS after a vaccination.	Thank you for your comment. We are aware there are other potential triggers. This is not intended to be exhaustive and is an example of a possible trigger.
Invest in ME Research	1	5	**Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management**	Thank you for your comment and this suggestion. The inclusion of both encehhalomyelitis and encephalomyopathy in the current title scope does not

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			We have never accepted why the term encephalopathy was introduced. The European ME Alliance (a grouping patient organisations and charities from 14 European countries) uses ME/CFS to tally with the Canadian Consensus Criteria which are increasingly used by researchers. ME stands for myalgic encephalomyelitis. NICE should use this also and be consistent.	pre-judge the terminology of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.
Stonebird	1	5	**P1 line 5 'encephalopathy, chronic fatigue syndrome'** We have already suggested that this term is inappropriate. Encephalopathy has no formal recognition with the WHO. And should not be used. The correct term is Myalgic Encephalomyelitis, which is specifically a neurological disease. The literature is complicated by the use of different terms, such as CFS, CFS/ME, ME/CFS or increasingly CF (Chronic Fatigue), all meaning different things to different people. Even if a person uses the word "ME", it is not necessarily referring to the original disease Myalgic Encephalomyelitis, for it depends on which definition they choose to recognise. This awful state of confusion has not been helped by calling ME, incorrectly and without any substantiation, Myalgic Encephalopathy As stated in the general comment, if NICE continues to use the term Chronic Fatigue Syndrome, it needs better specification under G.93.3	Thank you for your comment. We agree that the literature is complicated by the use of different terms. The inclusion of the term chronic fatigue syndrome and both encehhalomyelitis and encephalomyopathy in the current title scope does not pre-judge the terminology of the final guideline.

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			to ensure it is not wrongly interpreted as F. 48 fatigue syndrome, a mental health condition.	
Stonebird	1	6	**P1 line 6 'diagnosis and management'** People with ME want treatments not just management. The Scope of this document will not bring the hoped for change in provision for ME.	Thank you for your comment. The scope includes questions on the clinical and cost-effectiveness of pharmacological and non-pharmacological interventions for people with ME/CFS.
Hope 4 ME Fibro Northern Ireland	1	4,5	**"Chronic Fatigue Syndrome" is a misnomer,** that has caused harm to ME patients. "Chronic Fatigue Syndrome" as a name, gives the impression of simple ongoing tiredness. As a result, medical professionals are tempted to use the label too widely, and this neither helps the wrongly diagnosed individuals, nor those with a severe and complex presentation of ME. In short, the name Chronic Fatigue Syndrome causes the disease to be widely regarded as non-serious. In addition, the World Health Organisation (WHO) has a listing of Chronic Fatigue (ICD10-F48.0) and separately a listing of ME (ICD10-G93.3). The WHO recognises CF and ME as two separate entities, and we fear that maintaining the CFS name will perpetuate this problematical confusion. **Therefore, we propose that the "Chronic Fatigue Syndrome" appendage to the name Myalgic Encephalomyelitis should be dropped entirely.**	Thank you for your comment. The inclusion of the term chronic fatigue syndrome and both encephalomyelitis and encephalomyopathy in the current title scope does not pre-judge the terminology of the final guideline We have reworded the section 'why the guideline is needed' to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms.

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			Likewise "encephalopathy" as a variation on the ME name is unnecessary. "Myalgic Encephalopathy" was suggested at one point as a compromise, but it has not been well received by patients, and is not widely used in literature. Further the argument that the name Myalgic Encephalomyelitis does not perfectly equate with the disease presentation falls flat when considering other historic names, such as Malaria (which literally means "bad air"). **A return to the name "Myalgic Encephalomyelitis"** by NICE would be a positive step because: a) Patients would appreciate this, b) NICE would be giving a strong message to the patient population that the disease is now being taken seriously and c) It would remove any doubt about this guide being applicable to patients presenting with simple long-term fatigue of unknown origin. *NOTE: For simplicity and clarity, the abbreviation ME will be used in this response to refer to the condition for which this guideline is being developed.*	
LocalME	1	14 and general	**Why the guideline is needed-** overall, the 2007 CG 53 not fit for purpose.	Thank you for your comments and information. Supporting GPs The guideline will address information, education and support for health and social care professionals.

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			Localme responded to the 2017 NIhCE consultation on review of CG53, outlining their main concerns which will need to be addressed; • **the lack of quality** in the existing guidelines, which adversely impact on medical practice, including the failure of GP education for ME and CFS, this failure and its attendant adverse knock on adverse effects within Local Government agencies -community health, social care and education- rendering CG53, overall, not fit for purpose. • the resulting **lack of public confidence** in NICE and NHS ME and CFS Service provision. We were told that these guidelines were going to be rewritten by the Director of Guideline development Professor Mark Baker, and we would start again. This appears from the Scoping draft not to have happened. • as was stated in 2017 in the public consultation when **NICE internal committee suggested there was no need for review,** there is, in our view, both a moral and a legal imperative for NICE to review and get the guideline right this time.	Replacing CG53 The old guideline will be replaced by this one and we will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. Diagnostic guidance The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing statements such as the Canadian International Consensus Primer will be used to inform the committee. The guideline committee The committee composition has been carefully considered in light of the comments made in this

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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			- **new legislation since the 2007** guideline adoption, *strengthens* the need for NICE to have a better understanding of the **legal** obligations and legal compliance issues surrounding patient care; recent case law now places clear requirements of the Duty of Care on both public and private health and social care bodies. - **the failure to use an effective <u>diagnostic</u> guidance and criteria** (specifically one like the **Canadian International Consensus Primer**)-which is highly regarded by both academics, medics and patients – and which adequately captures the unique and distinctive presentation of ME and CFS- a condition which fails to fit into the NICE preconceived "mould" and guideline development process. - the need for a different and more effective balance for those recruited to the Guideline Development Group, in the light of the previous controversy over CG53, - **NICE to be less prescriptive in their criteria f**or identifying and determining "eligibility" of the evidence base for developing a revised guideline; be more embracing of patient "outcomes" and patient	consultation and at the stakeholder workshop. We believe the committee is balanced with professionals from different disciplines and we have recruited five lay members. Evidence base The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We intend to include a call for evidence in the guideline to address the issues you raise.

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			experience, as captured within NHS ME and CFS Service outcomes, Key Performance Indicators and Annual Change Audits. NICE must be provided with a proper audit of commissioning of services. Commissioning and outcomes data should be provided by partners Non Government Departmental Bodies, **NHS England and NHS Improvements** to assist NICE with their task. **NHS Public Health** data and Needs Assessments could help NICE's task. • **NICE guidance should prevent harm**; much more weight should be attributed by NICE to the NHS service patient survey experiences, complaints and suggested "harms" of inappropriate management approaches. "Harms" and adverse impacts particularly from Graded Exercise (GET) need to be taken seriously. • **previous NICE recommendations** which patient welcomed, such as heart rate monitoring (and its associate links to POTs and OI) now, some 11 years on, should be better understood and this expertise delivered to those patients in need by NHS ME and CFS Services- not as a "co morbidity", but as a common presentation within ME symptomology.	

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			- the almost total lack of services for the 30% of the most severely affected patients constitutes a breach of **the United Nations Convention on the Rights of Persons with Disabilities.** In addition, the **Equality and Human Rights Act** requires that policies (and Guidance) on people must take into account "protected characteristics";of which ME is specified within the Equalities Act literature. the above also relate to the **p**aucity of appropriate services and management for children and young people. Families with children with ME and CFS are being treated like "harming parents" **Fabricated and Induced Illness (FII)** and "mother blame". Being subject to legal action against them by local Government statutory agencies is also a Human Rights issue.	
The 25% ME Group	1	14	This is a rather bland and 'bloodless' rationale for change. In view of the lives - and deaths - of people with severe M.E. occurring over the last 11 years (*i.e.* since CG53 was published), with many truly unacceptable encounters with health and care services, a much more urgently worded section might be expected.	Thank you for your comment. This section has been reworded in light of the stakeholder comments.
Healthwatch Bolton	1	15	We welcome the term ME/CFS so as not to confuse it with chronic fatigue or other post-viral states.	Thank you for your comment.
Invest in ME Research	1	15	**This guideline scope uses the term 'ME/CFS' but this is one of a number of names that have been used to describe this illness. It is**	Thank you for your comment. We agree that the literature is complicated by the use of different terms. The inclusion of the term chronic fatigue syndrome in

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			recognised that there are people who need care but who may not meet existing clinical or research criteria It is important that NICE do not include all possible fatigue states into a suspected myalgic encephalomyelitis (ME) diagnosis. Especially NICE should be aware that in addition to the conditions mentioned here burnout and excessive physical exertion (overtraining) are often included under the ME/CFS umbrella despite them being coded separately in the WHO ICD 11 classification in parent sections 22 (Factors influencing health status or contact with health services) and 24 (Injury, poisoning or certain other consequences of external causes). PVFS/ME/CFS are in the parent section 8 (Diseases of the nervous system). It is important for NICE to mention the need for careful screening of the patient's history before giving the patient an ME diagnosis and even then patients need to be monitored regularly to see if something else or treatable has been missed. As there are very few ME consultants in the UK then NICE guidance needs to be as specific as possible to help GPs diagnose ME patients correctly or GPs to be able to refer to a consultant that can confirm the diagnosis or not.	the current title scope does not pre-judge the terminology of the final guideline

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Parents of children with ME/CFS Support Group	1	15	The draft scope uses the name ME/CFS. We would prefer the illness to be solely called ME, as chronic fatigue is just one aspect of illness and does not accurately reflect the multi-systemic nature of ME symptoms. However we understand that many ME sufferers have been diagnosed with CFS in recent years, and so reluctantly accept ME/CFS.	Thank you for your comment. We agree that the literature is complicated by the use of different terms. The inclusion of the term chronic fatigue syndrome in the current title scope does not pre-judge the terminology of the final guideline
VIRAS	1	15	"This guideline scope uses the term 'ME/CFS' but this is one of a number of names that have been used to describe this illness." Why was this name chosen? The 2007 NICE guideline was for 'CFS/ME', a term which well informed patients and doctors immediately recognise as being the construct used to define patients with 'chronic fatigue', which subsumes patients with myalgic encephalomyelitis (M.E.) as well as those with critically defined chronic fatigue syndrome (CFS). 'CFS/ME' is a contrived heterogeneous diagnosis which produces wholesale misdiagnosis and obstructs the care of patients and research into their illness. One only has to read the 2007 guideline to confirm this. Therefore for many years, patients and physicians who take M.E. seriously, and consider it to be a recognisable and diagnosable condition, have used the term 'ME/CFS'. This defines patients who are diagnosed by strict criteria for M.E., which is classified by the World Health Organisation, International Classification of Diseases under G93.3, 'neurological conditions'. It also includes patients who would meet the same criteria, but who have had a 'CFS' diagnosis foisted upon them.	Thank you for your comment. We agree that the literature is complicated by the use of different terms. The inclusion of the term chronic fatigue syndrome and both encephalomyelitis and encephalomyopathy in the current title scope does not pre-judge the terminology of the final guideline.

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			That NICE have hijacked the term 'ME/CFS' for their own use appears to be a callous deception. It diverts attention away from the fact that numerous aspects of the draft scope show that NICE are actually preparing another guideline for 'CFS/ME', or in plain terms, for 'fatigue'. If NICE are not clear about who and what they are preparing a guideline for, or alternatively, have named the topic of their guideline only for the sake of appearances, then they should not go any further without becomming familiar with the history of vested interests and the corruption which surrounds 'CFS/ME'.	
#MEAction UK	1	16	"It is recognised that there are people who need care but who may not meet existing clinical or research criteria." Although no diagnostic criteria are perfect, ME is a positive diagnosis and these guidelines should not attempt to cover everyone who has fatigue, which is a non-specific symptom of many conditions.	Thank you for your comment. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise. We have reworded this section to clarify that fatigue is not necessarily the appropriate term in this context and to include reference to post exertional malaise.
Respect for ME	1	16	'It is recognised that there are people who need care but who may not meet existing clinical or research criteria.' Of course every patient deserves treatment, but it is unwise to assume that a broader group of patients has the same needs as people with ME. If a diagnosis of ME cannot be reached, patients deserve the right to explore other avenues. Doctors will continue to use their clinical judgement anyway when it comes to patients who do not fit the criteria. Therefore this statement adds nothing but encourages a lack of proper investigation and	Thank you for your comment and information. This sentence has been removed.

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			perpetuates the problem of ME as a 'wastebasket diagnosis'. It is perhaps also useful to mention what ME is **not**, including burnout, depression, neurasthenia and overtraining syndrome. Patients with those conditions would be better served by their own guidelines. The one exception, perhaps, is where patients do not meet the six-month requirement for symptoms. In these instances, patients should be diagnosed with post-viral fatigue syndrome (PVFS) with advice to take adequate rest to avoid later developing ME.	
VIRAS	1	16	"… It is recognised that there are people who need care but who may not meet existing clinical or research criteria." Who are these patients that 'need care', by whom are they 'recognised' and what has this got to do with patients with M.E. and CFS? Does this refer to people who have 'fatigue' but who do not have post-exertional malaise (PEM) or Post-Exertional Neuroimmune Exhaustion (PENE) and therefore: DO NOT HAVE M.E. OR CFS? Are NICE suggesting that these people who need care will not receive any unless they get an M.E. or CFS MISDIAGNOSIS and are covered by a NICE guideline? What is the evidence that there are people who 'need' but are not getting necessary medical or social care because they don't meet ME/CFS criteria? Is it NICE's intention that this phantom population should be incorporated into an unrelated guideline in development and subsumed into the ranks of M.E. and CFS patients, and that NICE are prepared to redefine 'ME/CFS' for this purpose?	Thank you for your comment and information. This sentence has been removed.

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			Exactly what 'care' do NICE think that these subsumed patients will get if they are MISDIAGNOSED with M.E. or CFS? Why do NICE assume that this 'care' will be appropriate to their needs unless NICE have already decided what care will be recommended for ME/CFS? If so, then the treatment and management part of the guideline must be predetermined and the whole guideline development process, including the stakeholder consultation, is a bogus waste of everybody's time and effort. Could this be a case of: 'why not include anyone who feels tired, after all, it's not as if this guideline is about a serious disease – it is not as though NICE would be including patients with a hangover-headache in a migraine guideline or clumsy people who sometimes drop things in a multiple sclerosis guideline. It's only a guideline for M.E. and CFS, so there is no need to be meticulous about it – is there?' Please enlighten us if there is more to this than arbitrarily gathering patients with different illnesses without any scientific or medical justification. We are not aware that it is a function of NICE to redefine the parameters of a disease. What authority and qualifications do NICE have to appoint themselves this role? If NICE intend to define their own set of diagnostic criteria then this should be undertaken and published before the guideline work commences, so that it can be properly peer-reviewed and	

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			validated. The 'peer-review' process of a NICE guideline (stakeholder feedback), is wholly inadequate for the purposes of constructing a new disease definition. Somewhere in the morass of patients that NICE seem intent on helping to create, those with M.E. or well-defined 'CFS', who suffer with the hallmark symptom of PEM, will be swamped by people with fatigue, chronic fatigue, burn-out, a long-lasting infection, sleep disorder, post viral malaise, the malnourished, the anxious and depressed and predictably: THESE AND MANY OTHERS WHO SHOULD BE DIAGNOSED WITH AND TREATED FOR A COMPLETELY DIFFERENT ILLNESS. This is not the way to produce a credible or viable guideline. This bent for inclusiveness might appear to be considerate and kind – but in reality it shows ignorance and discrimination against the very patients that the new guideline is supposed to help. In an approach opposite to NICE's apparent intention to broaden the scope to include all-and-sundry, VIRAS and others were concerned that patients with Lyme disease were being misdiagnosed with M.E. and CFS. We suggested that the NICE guideline for Lyme disease should recommend review and investigation of patients with these diagnoses because of the striking overlap of symptoms. This suggestion was ignored, which in our opinion demonstrates that NICE are quite prepared to accept having misdiagnosed ME/CFS patients who actually have	

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			different, diagnosable and even treatable diseases. This careless approach is a dereliction of NICE's incumbent responsibility. This lax attitude towards the diagnosis of M.E. and CFS, will predictably result in continued or increased, missed and misdiagnosis of patients with different diseases.	
Blue Ribbon for the Awareness of ME (BRAME)	1	17	If people have ME then they should meet the criteria of Myalgic Encephalomyelitis International Consensus Criteria – Carruthers et al 2011	Thank you for your comment. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing criteria such as the International Consensus Criteria will be used to inform the committee.
Healthwatch Bolton	1	17	After "people" insert "with pvfs"	Thank you for your comment. This section has been reworded in light of the stakeholder comments. We are aware of the different terminology and the use of the term ME/CFS in the scope does not pre-judge the terminology or title of the final guideline. This will be one of the tasks of the committee.
Parents of children with ME/CFS Support Group	1	17	There is no agreed, universal, accurate diagnostic criteria for ME/CFS in England. A diagnostic criteria needs to be included in the draft scope for the new guideline so that health professionals can accurately and confidently diagnose the multi-systemic disease that is ME/CFS, and this criteria needs to include Post-Exertional Malaise as a defining characteristic. Patients who are clinically on the borderline of the diagnostic criteria need care and understanding, especially if they have	Thank you for your comment. The diagnosis of ME/CFS has been included as a key area to be addressed by the committee. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use in the guideline.

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			been ill for under 6 months and diagnosed with Post-Viral Fatigue Symptoms as this can often be the beginning of ME.	
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	1	17	The management of people meeting different diagnostic criteria may need to be different. For example, the management of a person with the symptom chronic fatigue, but not experiencing post exertional malaise, may need to be different to the management of someone who experiences post exertional malaise as a defining feature of their illness. What may be safe for the first person may cause harm to the second. It must be clear who the guidance applies to and which (if any) aspects of the final guidance may be unsuitable for those meeting the more stringent ME criteria rather than the looser CFS criteria(s). It is likely that ME/CFS comprises of several different subgroups. Current guidance recommends Cognitive Behaviour Therapy and graded increases in activity, for example through Graded Exercise Therapy, which many patients report being harmful to them.	Thank you for your comment and this information. We understand the concern by patients about the current recommendations for GET and CBT. The evidence for these interventions will be reviewed using parameters such as the population group included as you describe.
#MEAction UK	1	19	We are concerned by a disproportionate focus on 'fatigue', at the expense of more disease-specific language such as: ● exertion intolerance ● energy limitation ● physical and mental stamina impairment ● post-exertional malaise	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.

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			'Exertion' does not just relate to physical activity but also cognitive activity, a domain in which people with ME are substantially impaired. An excessive focus on fatigue and a lack of knowledge of other symptoms leads to both under-diagnosis of people with ME and incorrect diagnosis of ME in people with other fatiguing conditions. A more accurate description of ME is this one from a recent editorial: "ME/CFS is a multisystem condition that appears associated with a combination of genetic, cellular and systemic metabolic deficits in aerobic metabolism. The hallmark clinical feature of ME/CFS is post exertional malaise (PEM), which involves a constellation of extensively disabling... signs and symptoms in response to exertion" (Davenport et al., 2018).	
#MEAction UK	1	19	This section must include information about the clinical picture of severe/very severe ME. People with severe ME need to be much more involved with creating the new guidelines as their needs have been largely ignored. Committee members therefore must have an adequate understanding of these issues to be able to make informed decisions. A suggested description of very severe ME for this section might read thus: 'Symptoms of severe ME include: partial or complete paralysis, unrelenting pain (including abdominal pain when eating), inability to tolerate stimuli (including sound, light and touch), inability to speak or	Thank you for your comment. We have added further detail to this section.

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			swallow, and little to no functional capacity (i.e., being 80-100% disabled according to several different disability/severity scales), and so needing round-the-clock care, including, in some cases, being tube-fed. 'Orthostatic intolerance can be so severe the person cannot sit up in bed and communication and comprehension can be seriously impaired. This level of illness can last for decades, though others may fluctuate in and out of severe states. People with severe and very severe ME currently often have less access to medical care than those with milder symptoms, with many having no medical care at all.' Patient groups like Stonebird and the 25% M.E. Group can provide more detailed information.	
Healthwatch Bolton	1	19	Remove "distressing"	Thank you for your comment. This sentence has been reworded and distressing removed .
Healthwatch Bolton	1	24-5	Remove "although…", etc., or provide evidence to verify.	Thank you for your comment and suggestion. This sentence has been reworded.
Hope 4 ME Fibro Northern Ireland	1	19	**The word "distressing"** is a concern. If ME patients are "distressed" by their illness, this might suggest that ME is linked to the psychiatric construct of Bodily Distress Disorder or similar. We feel it goes without saying that any disabling disease is distressing, and therefore this word is misplaced within the description of ME and can be safely omitted. .	Thank you for your comment. This sentence has been reworded and distressing removed.

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LocalME	1	19	Suggest- ME/CFS is a profoundly disabling condition, Research evidence indicates a far greater significant illness impact on quality of life than similar neurological conditions like MS[1] The UK ME/CFS Biobank for biomedical research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and Multiple Sclerosis. Lacerda, E.M. ; Bowman, E.W. ; Cliff, J.M. ; Kingdon, C.C. ; King, E.C. ; Lee, J.S. ; Clark, T.G. ; Dockrell, H.M. ; Riley, E.M. ; Curran, H. ; Nacul, L. ; 2017Open J Bioresour	Thank you for your comment and suggestion. This section has been reworded to reflect the experience of people with severe ME. However as it not clear that ME/CFS is one condition but is potentially likely to be several different conditions or overlapping conditions we think illness is a more appropriate term.
ME Letterforce	1	19	The word "distressing" needs to be removed as it implies a primarily emotional response The word "fatigue" needs to be removed as it implies that fatigue is the only symptom that worsens after exercise. ME/CFS is a highly disabling neurological disease characterised by post exertional worsening of symptoms. This is not caused by deconditioning or a sensitivity to exercise that can be conquered by gradually increasing exposure. We would encourage the use of a description that is similar to other neurological diseases. As an example the MS Scope reads	Thank you for your comment. This sentence has been reworded and distressing removed.

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[1] The UK ME/CFS Biobank for biomedical research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and Multiple Sclerosis.

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			"MS is a chronic and potentially highly disabling disorder that has considerable personal, social and economic consequences. People with MS live for many years following diagnosis. The condition may have a significant impact on a person's ability to work, as well as an adverse and often highly debilitating effect on quality of life (QoL) of people with MS and their families" This could equally be used for ME.	
Parents of children with ME/CFS Support Group	1	19	We suggest that this clause should read more accurately as 'ME/CFS is a disabling and distressing multi-systemic illness' in order to more accurately portray the serious nature of the illness. The World Health Organisation classifies ME as a 'neurological condition' (International Classification of Diseases, G93.3)	Thank you for your comment. This section has been reworded to include the experience of people with severe ME/CFS..
Parents of children with ME/CFS Support Group	1	19	The draft scope excludes the defining characteristic of ME/CFS, namely post-exertional malaise. A better definition would be 'ME/CFS is ... characterised by significantly reduced physical and mental stamina and functionality, with a defining characteristic of either completely new symptoms or an increase in existing symptoms if a person exceeds their individual activity / energy levels (Post-Exertional Malaise). Exertion could be physical, emotional or cognitive in nature and is often delayed by 24 - 48 hours after the event. There is a wide range of severity from mild reduction in energy/functional ability to extreme reduction in functionality & completely bed-bound, requiring 24-hour nursing care.'	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.
Science for ME	1	19	"ME/CFS is a disabling and distressing illness.."	Thank you for your comment. This section has been reworded.

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			The term "distressing" is incorporated into mental and behavioural diagnoses, including the ICD-11's Bodily distress disorder (BDD), which could inappropriately capture a subset of ME/CFS patients. Diagnosis of BDD will be highly subjective, with the healthcare provider determining whether patient response and attention to symptoms is disproportionate. Therefore, several members feel that it is important not to use phrasing that overlaps with terminology in disorders that incorporate distress at bodily symptoms. Perhaps characterising ME as life-changing would be better as the disability leads to severe restrictions in function to the extent many have to give up work (or reduce working hours) as well as hugely restrict social activities. Severely affected patients struggle with many of the activities of daily living. It is not just function that is lost, patients constantly suffer with symptoms (including pain) all the time. A recent paper from Jason's research group at DePaul University found: "Those individuals with ME or CFS reported significantly more functional limitations and significantly more severe symptoms than those with MS." http://biomedicine.imedpub.com/diff...halomyelitis-and-chronic-fatigue-syndrome.pdf	

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VIRAS	1	19	"ME/CFS is a disabling and distressing illness characterised by extreme and debilitating fatigue, particularly after exertion." Please redraft this sentence to say: "ME/CFS is a disabling and distressing illness characterised and identifiable by Post-Exertional Malaise, which is the exacerbation of symptoms following activity and reported by some patients as extreme and debilitating fatigue" Fatigue is non-specific and common. Post-Exertional Malaise (properly defined as Postexertional neuroimmune exhaustion (PENE) in the Myalgic encephalomyelitis: International Consensus Criteria) is specific and uncommon. If NICE proceed with the guideline on the misguided basis that fatigue, however extreme, characterises ME/CFS, then their investigation and advice will be erroneous. Some of the draft scope content suggests that NICE might commandeer the commission to produce a guideline for 'ME/CFS' and use it to write a guideline for 'fatigue'. If this is so, then they should inform the Department of Health, VIRAS and other stakeholders of this fact immediately and explain why they have misled us and wasted our time and effort under false pretences. Please note: 'Fatigue' is a reduced capacity for work following exertion and which therefore is restored by rest. Everyone experiences 'fatigue',	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms. Autonomic, sensory and motor dysfunction have been added to the list of common symptoms.

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			even extreme fatigue, but this term does not describe nor provide insight into ME/CFS patient's symptoms and does not help to characterise their illness. The Institute of Medicine Report states: "Post-exertional malaise (PEM) "PEM is worsening of a patient's symptoms and function after exposure to physical or cognitive stressors that were normally tolerated before disease onset. Subjective reports of PEM and prolonged recovery are supported by objective evidence in the scientific literature, including failure to normally reproduce exercise test results (2-day cardiopulmonary exercise test) and impaired cognitive function after exertion. There is sufficient evidence that PEM is a primary feature that helps distinguish ME/CFS (SEID) from other conditions." (https://www.nap.edu/resource/19012/MECFScliniciansguide.pdf)	
Healthwatch Bolton	1	20	Remove "after exertion" and insert "after minimal activity (physical or mental), resulting in post exertional neuroimmune exhaustion or PENE, sometimes known as PEM or post exertional malaise".	Thank you for your comment. This section has been reworded and 'after exertion' has been removed.
ME Research UK	1	20	Please consider replacing '*debilitating fatigue, particularly after exertion*' with '*debilitating post-exertional malaise, often accompanied by multiple sensitivities, for example to light, sound or vibration*'	Thank you for your comment. This section has been reworded and 'debilitating fatigue particularly after exertion' has been removed.
Patient Advisory Group to the CMRC	1	20	Post exertional malaise, the exacerbation of many symptoms and the triggering of other symptoms, following physical, cognitive or emotional activity, and sometimes delayed by up to 72 hours, should be included here as the cardinal symptom of this illness. It must be adequately	Thank you for your comment. This section has been reworded and 'debilitating fatigue particularly after exertion' has been removed.

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(CFS/ME Research Collaborative)			defined. This symptom is so much more than simply "fatigue" after exertion. Orthostatic intolerance is also a very common symptom but is not mentioned here. Chemical, light and sound sensitives are common symptoms but are not mentioned.	
VIRAS	1	20	"Clinically, ME/CFS is heterogeneous and multifactorial" NICE cannot claim this unless they also claim to know of at least two known causes of these illnesses. As the draft Scope later specifies that the cause is unknown, this sentence is inaccurate and self-contradictory. The Scope could say: "Physician diagnosed patients with M.E. and CFS include misdiagnosed patients and therefore represent an heterogeneous group. This is due to the present lack of a definitive test, use of inadequate diagnostic criteria, overlooked alternative diagnoses (misdiagnosis), poor knowledge of the disease and a widespread misperception that these illnesses are characterised by fatigue." PLEASE NOTE: In the PACE Trial, 3,158 patients were referred by a doctor for recruitment into the trial. 1,078 of these referrals were rejected because they did not meet the Oxford Criteria for 'CFS', despite this being the weakest and most inclusive criteria, which does not differentiate patients who only have fatigue. Therefore 34% of patients that doctors referred to participate in the research did not meet the laxest and most inclusive criteria for 'CFS'.	Thank you for your comment. This sentence has been removed and we have reworded this section to clarify that fatigue is not necessarily the appropriate term. The use of the term ME/CFS in the scope does not pre-judge the terminology of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.

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			To illustrate how lax the Oxford criteria is, 38% of the patients who were enrolled in the PACE Trial, did not meet the 2003 Reeves et al International criteria for CFS and 44% did not meet the London criteria for M.E. This means that 42% of patients referred by a physician to participate in 'CFS' RESEARCH did not meet International criteria. This demonstrates the shocking level of misdiagnosis which has been going on for years. Using lax diagnostic criteria creates a 'heterogeneous' group of patients not by diagnosis, but by misdiagnosis. This predictably results in care recommendations applicable to some patients which are completely unsuitable for others. It is this impreciseness that resulted in the need for a completely new NICE guideline, because the 2007 guideline had treatment recommendations that are actually useless or harmful to properly diagnosed M.E. patients. In fact if a particular patient gets any benefit from the treatments recommended by NICE – it could be considered evidence that they are misdiagnosed, e.g., because patients cannot think or exercise themselves better from a neurological illness. The perpetuation of heterogeneity contributed to by NICE, produced a guideline which failed doctors and patients. The scope must define what it is studying and what it is not, else it will not empower doctors to make a confident diagnosis and ensure that patients receive the correct information, treatment and management. It is disappointing that the draft scope has failed in this basic requirement.	

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Healthwatch Bolton	1	21	Remove "people experience the illness differently" and insert "symptoms may fluctuate in severity"	Thank you for your comment. This section has been reworded.
Hope 4 ME Fibro Northern Ireland	1	21	**Illness Experiences:** Whilst our group recognises that ME patients may not have a consistent presentation, we are concerned that the statement that ME is*:* "heterogeneous and multifactorial and people experience the illness differently", takes away from any precision in attempting to properly describe the disease. Perhaps replace the sentence concerned with a much shorter one: "**Clinically, ME may not present consistently at onset.**"	Thank you for your comment. This section has been reworded.
ME Letterforce	1	21	The use of "Multifactorial" needs to be reconsidered. We don't know what causes ME. There are some specific triggers for the disease but we don't know if these are single triggers or if this a single trigger plus other factors yet. "Heterogeneous" (as in "diverse in character and content) should be avoided as that gives the impression of a group of patients who may share only a few of a large range of symptoms. Patients must share common symptoms to qualify for a diagnosis of ME/CFS.	Thank you for your comment. This section has been reworded.
VIRAS	1	21	"and people experience the illness differently".	Thank you for your comment. This section has been reworded.

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			What is the purpose of this remark? Are NICE preparing a guideline about patient's subjective "experience" of being ill? This remark is only significant to those who attempt to portray ME/CFS as nothing more than a patient's subjective experience (i.e., their hysterical 'illness beliefs'). Do individuals with multiple sclerosis NOT 'experience the illness differently' from other patients? Do patients with Parkinson's NOT 'experience the illness differently' from other patients?	
#MEAction UK	1	22	The descriptions of symptoms are not accurate. A better description would be: "Other common symptoms include disordered sleep, chronic pain, cognitive impairment, digestive problems, flu-like symptoms, and sensory sensitivity, though there are many symptoms across a range of bodily systems." Cognitive impairment is one of the most disabling factors for many people with ME and should not be excluded. Sensitivity to light and sound are especially prominent in severe and very severe ME and as such should be included. For a more complete clinical picture, please see the Canadian Consensus Criteria (Carruthers, 2003) or the International Consensus Criteria (Carruthers, 2011).	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.

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Blue Ribbon for the Awareness of ME (BRAME)	1	22	Should read 'Core symptoms include ….' should also include here immune dysfunction, cardiovascular, respiratory and energy metabolism impairments	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
Invest in ME Research	1	22	Common symptoms include chronic pain, disordered sleep, digestive problems and cognitive difficulties. Add the word "Other" to the beginning of the sentence as follows – Other common symptoms include chronic pain, disordered sleep, digestive problems and cognitive difficulties.	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
LocalME	1	22	"Common symptoms include chronic pain, disordered sleep, digestive problems and cognitive difficulties" characterised as "brain fog". In addition to these symptoms and PEM (See above comment) other common symptoms include rapid muscle fatiguability and delayed recovery, headache, sore throat, flu-like malaise, sensory overload (light, sound) food and chemical intolerance and sensitivity problems, "allergy "affects up to an estimated 60%, (prescription) drug and alcohol intolerance, cardiac problems, orthostatic intolerance, POTS, deregulated HPA axis, pituitary, adrenal and thyroid insufficiency not identified on NHS tests,	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
ME Letterforce	1	22	The hallmark of ME is post exertional worsening of symptoms and that should be clearly addressed in this section.	Thank you for your comment. We have reworded this section to include reference to post exertional

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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			We would also like to see addressed here, more fully, the severity of the disease that leaves many patients housebound or bedbound and the fluctuating nature of the disease.	worsening of symptoms, severity of the disease and the fluctuating nature of the condition.
Parents of children with ME/CFS Support Group	1	22	The draft scope excludes many of the common symptoms experienced by ME/CFS sufferers. Further common symptoms that need to be included are: orthostatic intolerance, autonomic issues, heavy limbs, restless leg syndrome, swollen glands, soft tissue pain, brain fog, food intolerances, recurring sore throats and sensitivity to light, sound and smell. Digestive problems should be changed to 'gastrointestinal problems not often attributed to other illnesses'	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
Parents of children with ME/CFS Support Group	1	22	The draft scope placed extreme and debilitating fatigue as a defining characteristic on page 1, line 19. We argue that the defining characteristic is Post-Exertional Malaise and therefore extreme and debilitating fatigue should be added to the list of common symptoms here.	Thank you for your comment. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise and deterioration of symptoms
Respect for ME	1	22	Flu-like symptoms, and sensitivities to stimuli and chemicals, are also commonly reported. When comparing symptoms alone, Jason 2016 found that 'flu-like symptoms and tender lymph nodes are the most important symptoms when differentiating these two illnesses [MS and ME]' (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5214344/). This suggests that these symptoms in the immune domain should be noted in the guidelines.	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
Science for ME	1	22	"Common symptoms include chronic pain, disordered sleep, digestive problems and cognitive difficulties"	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We

Stakeholder	**Page no.**	**Line no.**	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
			In addition to these symptoms and PEM (See above comment) other common symptoms include rapid muscle fatiguability and delayed recovery, headache, sore throat, flu-like malaise, sensory (light, sound) sensitivity problems, orthostatic intolerance, (prescription) drug and alcohol intolerance.	have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
VIRAS	1	22	The 'common symptoms' list is quite good, but it should include 'headache' and we suggest that 'cognitive difficulties' sounds trivial and does not describe a symptom. It could be replaced with 'cognitive impairment, which is sometimes described as 'brain fog' and features impaired memory and information processing.	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
Healthwatch Bolton	1	23	Insert "and autonomic dysfunction" after "cognitive difficulties"	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.
ME Letterforce	1	23	The common symptoms should include sore throats, glands and flu like symptoms. It should also include orthostatic intolerance and neurological symptoms	Thank you for your comment. We are aware there are other symptoms and have reworded this section. We have added autonomic, sensory and motor dysfunction to the list of common symptoms. This list is not intended to be definitive and are examples of possible symptoms.

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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
ME Research UK	1	23	Please consider adding the sentence: '*Patients may experience a range of symptoms and comorbidities, some but not necessarily all of which are related to their ME/CFS.*'	Thank you for your suggestion. This section has been extensively reworded in light of stakeholder comments. We think it is clear that people with ME/CFS have comorbidities and experience symptoms that are not necessarily related to their ME/CFS.
Healthwatch Bolton	1	24	Insert "there is profound, prolonged disability" after "disrupted"	Thank you for your comment. This section has been reworded.
Royal College of Psychiatrists	1	24	Recovery, and certainly improvement, are not unusual. See this systematic review which looked at the course of at the course of CF/CFS without treatment / intervention: Cairns R, Hotopf M. A systematic review describing the prognosis of chronic fatigue syndrome. Occup Med (Lond) 2005; 55: 20–31.	Thank you for your comment and the reference. This sentence has been removed.
South London & Maudsley NHS Foundation Trust	1	24	Recovery, and certainly improvement, are not unusual. See this systematic review which looked at the course of at the course of CF/CFS without treatment / intervention: Cairns R, Hotopf M. A systematic review describing the prognosis of chronic fatigue syndrome. Occup Med (Lond) 2005; 55: 20–31.	Thank you for your comment and the reference. This sentence has been removed
#MEAction UK	1	25	Though mortality remains understudied, we suspect ME is underreported as a cause of death in the UK. Since ME causes immune dysfunction and cardiovascular dysfunction, there is likely an increase in all-cause mortality (Jason et al., 2006; McManimen et al., 2016). We suggest	Thank you for your comment.

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			adding the sentence "There is some evidence of an increase in all-cause mortality, with the possibility of death directly caused by ME in the most severely affected."	
Buckinghamshire Healthcare NHS Trust	1	25	Is there epidemiological data for this? 7% median recovery is often quoted from the literature.	Thank you for your comment. This sentence has been removed in the light of stakeholder comments.
ME Research UK	1	25	Please consider adding the sentence: '*ME/CFS can sometimes be so severe that patients become bed-bound for long periods and require additional interventions such as tube feeding. In two cases in the UK, the illness has been cited by a coroner as the cause of death.*'	Thank you for your comment this section has been reworded.
Royal College of Psychiatrists	1	25	Age of onset is one of a number of factors that can influence outcome.	Thank you for your comment. We recognise this is one of a number of factors and in the light of stakeholder comments we have removed this sentence.
South London & Maudsley NHS Foundation Trust	1	25	Age of onset is one of a number of factors that can influence outcome.	We recognise this is one of a number of factors and in the light of stakeholder comments we have removed this sentence.
Invest in ME Research	1	26	The causes of ME/CFS are unknown but there are thought to be many contributing factors. Should read	Thank you for your comment this section has been reworded.

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			The cause(s) of ME/CFS are unknown but there are thought to be many contributing factors.	
LocalME	1	26	"The causes of ME-suggest-The specific causes of ME are unclear and causation could be multiple. e.g. viral, mould, bacterial, infection along with environment and pollution.	Thank you for your comment this section has been reworded.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	1	26	Include - 'currently' unknown.	Thank you for your comment this section has been reworded.
The Ehlers-Danlos Support UK	1	26	Suggest replacing 'the causes… are unknown' with 'there are a number of known causes of ME/CFS-like illness although the causes of ME/CFS itself are unknown'.	Thank you for your comment. We have reworded this sentence to indicate that the causes are not clear rather than unknown.
VIRAS	1	26	"The causes of ME/CFS are unknown but there are thought to be many contributing factors." This could be clearer and it could mislead the committee. As it relates to fundamental information relating to the guideline topic please consider replacing it with:	Thank you for your comment. We have reworded this sentence to indicate that the causes are not clear rather than unknown.

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			"The cause or causes of ME/CFS are unknown. Some risk factors have been reported though none are shown cause the illness. These include: viral infection, stressful life events, vaccination, etc. A risk factor for poorer prognosis is reported to be the severity of the illness. Post-exertional malaise differentiates ME/CFS from chronic fatigue and is associated with a significantly worse prognosis than the latter." (Jason 2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3171164/)	
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	1	27	Post viral fatigue should be noted and distinguished from other types of onset. It might serve as an interim diagnosis prior to a formal diagnosis of ME/CFS.	Thank you for your comment. This is not intended to be exhaustive and is an example of a possible trigger. We have noted that post viral fatigue is one trigger and we are aware there are others.
Stonebird	1	27	**Page 1 line 27 Why is there no mention of Enterovirus despite its historical presentation as the underlying cause of ME, now virtually ignored?**	Thank you for your comment. This is not intended to be exhaustive and is an example of a possible trigger. We have noted that post viral fatigue is one trigger and we are aware there are others.
VIRAS	1	27	"commonly reported trigger". 'Trigger' implies cause-and-effect which in ME/CFS is unsubstantiated. Many illnesses seem to coincide with other factors in patient's lives but this does not establish them as a cause or a factor of their illness. Mention 'commonly reported coinciding factors' if you wish, but do not use a term which could mistakenly be interpreted as attributing a cause.	Thank you for your comment. This section has been reworded to reflect the lack of certainty in causality.

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ME Letterforce	1	15 and 16	Although there have been other names historically for ME this statement should not be included in the SCOPE as it is open to misinterpretation. It also allows ME/CFS to be mistakenly identified as being a modern term for other illnesses or umbrellas of diseases and this is not desirable as there no evidence. We need to define ME/CFS as being a distinct disease and not confuse it with other diseases that include some of the same symptoms or with umbrella terms. We have no evidence that ME and CFS (using all possible criteria's) are the same disease but by including post exertional worsening of symptoms we hope to capture a population of patients who could benefit from this guideline.	Thank you for your comment. The use of the term ME/CFS in the scope does not pre-judge the terminology of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.
LocalME	1	19,20	Suggest - characterised by delayed Post Exertional Malaise, (PEM) and relapse following any physical or mental activity; essentially a disruption of the body's fundamental energy metabolism, at cellular level and affecting all principal bodily systems, heart, brain, gut and endocrine/ hormonal systems.	Thank you for your comment. We have reworded this section and make explicit reference to post exertional malaise.
LocalME	1	16,17, 18	**"***It is recognised that there are people who need care but who may not meet existing clinical or research criteria."* The CG 53 research criteria used should <u>not</u> be used this time. The Canadian International Consensus Primer is well regarded by academics and patients and should be adopted. The issue of appropriate criteria MUST be addressed and corrected on efficacy and cost effectiveness ground**s.** ME is a complex and multisystem condition with neurological, musculoskeletal	Thank you for your comment. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise. Existing criteria such as the International Consensus Criteria will be used to inform the committee.

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			dysfunction, which follows from abnormalities in the nervous, autoimmune, cardiac, immunological, metabolomics, systems and calcium channels, putting the body in a dauer state. Some individuals will only have some of these dysregulations and others with have most with a few having all. All systems difficulties will be compounded by any activity. Ramsay, Light, Newton, Montoya Lipkin, Maureen Hansen, Davies, Sonya Marshall-Gralisnuk, Staines, Naviaux and Mark Van Ness. The criteria issue must be addressed to help NICE meet it's core stated ambitions of *"improving health and wellbeing*"; *"to improve the quality of life" and to "reduce variation of availability and quality of NHS treatments"* for people with CFS/ME by *"setting out the care and treatment options that should be available for them."* NICE must ensure that the <u>correct</u> patient group is identified and that adequate and safe management approaches are recommended for this specific group. 40% wrong diagnosis found are unacceptable. The inclusion of, *"...people who need care but who may not meet existing clinical or research criteria",* has resulted in deflection of the <u>very limited</u> NHS and Social care resources; in particular for those in most need who should have been prioritised; the Severely Affected. Severely Affected (SAs) are 30% of the ME and CFS population most of whom, nationally, are in receipt of virtually no care at all from, Primary, tertiary or	NICE guidelines are only one part of the wider process and NICE does not have a remit for tariff setting. We hope that the new guideline will improve services and

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			secondary NHS and Social care. Support must be given to those with life changing limitations. Bearing in mind the current level of patient tariff, commonly allowed by CCGs and commissioners of about £500-600 per annum. Is NICE aware of this limited resource allocation? NICE should recommend a minimum stand tariff linked to a locally conducted Public Health Needs Assessment for the commissioning of each of the specialist services. The following treatment costs referenced illustrate the extent of the problem. **"***NHS efficiency watchdog, the National Institute for health and Clinical Excellence (Nice)***.** *Nice makes a calculation based on years lived in good health, known as quality-adjusted life years or Qalys. A treatment costing less than £20,000 to £30,000 per Qaly is believed to represent value for money. In the study, CBT given in addition to specialist medical care was found to cost £18,374 per Qaly, GET £23,615 and APT £55,235."* https://www.independent.co.uk/life-style/health-and-families/health-news/two-chronic-fatigue-syndrome-treatments-offer-good-value-8000997.html	commissioning and the ability to hold services to account.
Action for ME	2	23-28	Patients have clearly stated that they do not wish CBT and GET to be included in the final guideline, for example:	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is

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			"*That GET CBT are removed because they do more harm than good and doctors have no accurate way of assessing the very small group who may be helped. Risks massively outweigh the benefits"* "*The current CBT and GET treatments are inappropriate*" Action for M.E. supports NICE's decision to review the evidence relating to M.E. diagnosis and management, particularly given the need to consider the evidence base for CBT/GET that is being increasingly challenged [Wilshere et al. (2018) Rethinking the treatment of chronic fatigue syndrome, Twisk (2017) Dangerous exercise: the detrimental effects of exertion and orthostatic stress in M.E. and chronic fatigue syndrome]. Graded Exercise Therapy in particularly has been shown to cause harm to M.E. patients, with 47% of Action for M.E. survey respondents saying that it made their condition worse [Action for M.E. 2014, Time to deliver]. Therefore, we would only want CBT and GET included in the scope in the circumstances that these treatments are reviewed in light of this research and patient evidence. CBT and GET constitute a significant component of M.E. treatment in the UK as it stands, and it is reasonable that they are included in the considerations of the NICE guideline committee. In reviewing the evidence on these treatments it is vital that NICE listen to patient voice and experience. A number of trials have taken place relating to these treatments, and the methodology and findings of these trials have been challenged and rejected [Wilshere et al. *op. cit*.]. To provide a true and	feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

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			accurate picture of how people with M.E. have been impacted by these treatments, the NICE guideline scope must enable the guideline committee to review all relevant evidence including the experience of patients. Furthermore, given the harms reported by patients, NICE has an ethical obligation to safeguard patients and ensure that no harms are incurred as a result of their recommendations.	
Buckinghamshire Healthcare NHS Trust	2	23-28	Whilst patients should be offered support from a multidisciplinary team, including input and support from therapists, the previous recommendations of cognitive behavioural therapy (CBT) and graded exercise therapy (GET) have been withdrawn.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

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Forward ME	2	23 - 28	Delete this section. It is important to note that the primary reason for the requests for review of the current guideline was because of the evidence of harm caused by GET and the lack of effectiveness of CBT. Note the recent update (12.7.18) of the CDC website: "Any activity plan for people with ME/CFS needs to be carefully designed based on individual presentation with input from each patient. If possible, evaluation by a rehabilitation specialist may be beneficial. For some patients, even daily chores and activities such as cleaning, preparing a meal, or taking a shower can be difficult and may need to be broken down into shorter, less strenuous pieces. While vigorous aerobic exercise can be beneficial for may chronic illnesses, **patients with ME/CFS do not tolerate such exercise routines. S**tandard exercise recommendations for healthy people can be harmful for patients with ME/CFS." (Their bold). The evidence for CBT is weak.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.
Hope 4 ME Fibro Northern Ireland	2	23 - 28	**CG53 Guideline: Cognitive Behavioural Therapy (CBT) and Graded Exercise Therapy (GET)** Our group is pleased to note that the scope states that "The evidence supporting these interventions has been challenged". However, we suggest that the full extent of that challenge should also be recorded. Many highly respected scientists have declared the evidence base	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision

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			supporting these therapies, as effectively worthless due to the profound methodological flaws uncovered: not least the lack of blinding, alongside highly subjective outcome measures. We are pleased that the scope correctly notes that patients are "being pressured to participate in exercise programmes leading to a worsening of symptoms". We believe this resulted from an over-confidence in these therapies, and a failure of the CG25453 guideline to recognise that harm* may be caused. **We suggest that the new guideline should detail the strength of the evidence supporting any treatment recommendations.** This should include: a) a proper description of the harms the treatment may cause, b) the degree of improvement that might on average be expected, and c) the "number needed to treat". This way patients can make a properly informed decision. ***Note:** We are concerned that CBT and GET were introduced without any means of officially recording adverse effects and that numerous charity complaints about therapy harms were dismissed, meaning that CBT & GET still remain as treatment recommendations to this day. Whilst we are pleased to note that the scope says: "There is therefore a need to review the evidence for these and other interventions". We think "critically review" might be more appropriate, because there is much	on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects

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			evidence to explore, both in terms of the complete papers themselves and the various critiques written by others. **Considering the extensive harms from CBT and GET treatment practices reported by patient groups, we suggest that reviewing the place of these therapies in the current CG53 guideline, should be the urgent first task of the new guideline group.** It is our view that these damaging therapies, based on the now completely de-bunked "fear avoidance and deconditioning" hypothesis for ME, should be urgently removed from clinical practice. Supportive counselling (to cope with lifestyle changes) and practical help (such as mobility aids) could be offered until such times as better treatment options become available. **The adage "First do no harm" is paramount.**	to the list of outcomes. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.
Invest in ME Research	2	23-28	The previous NICE guideline (CG53) made recommendations on the use of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The evidence supporting these interventions has been challenged and some people with ME/CFS report being pressured to participate in exercise programmes, leading to a worsening of symptoms. There is therefore a need to review the evidence for these and other interventions. This statement by NICE in this document is quite disingenuous. The challenges to CBT and GET are not new.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or

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			CBT and GET were challenged when the NICE guidelines were formed. In 2007.Invest in ME wrote “There is little unequivocal evidence to show that CBT or GET has good evidence of benefit and much which shows the contrary result. Most of these studies have also used the flawed Oxford criteria for selection of participants in the programme where neurological symptoms of the illness disqualify patients from being included! At this time there is no evidenced-based proof that these therapies are appropriate which has been accepted as rigorous and independent from the psychosocial approach to ME/CFS by some experts.” We also wrote “A recommendation for treatment of ME/CFS in the NICE Guidelines for those who are "mild to moderately affected" are Cognitive Behavioural Therapy (CBT) and GET. In making this recommendation, the Guideline Development Group seem to be ignoring credible evidence that such treatments are potentially dangerous for those who suffer from this illness, particularly in the case of GET. The comments on the management are often worthless as they seem to be dealing with patients suffering from burn-out rather than from a neurological illness. They also seem to be contradictory with a great deal of print sometimes emphasizing the use of psychological therapies such as GET and CBT and at other times stating that the choices are the patients’.”	harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.

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			The flawed and discredited PACE Trial proved that CBT and GET we not effective for treating ME.	
LocalME	2	23-28	There is no mention of life threatening, palliative care needs or end of life care. We agree that the evidence for GET and CBT needs urgent review. In 2015, the Duty of Candour became law. This should now be applied to the reported harms from GET. Patient Experience and charity patient surveys on GET and other matters are vital evidence which NICE must take account of. **NICE being made aware of the harms attributed to GET, have a Duty of Care.** **(Duty of care-** In tort **law**, a **duty of care** is a **legal** obligation which is imposed on an individual (or public body) requiring adherence to a standard of reasonable **care** while performing any acts that could foreseeably harm others.) Recent research has shown marginal, if any improvement, and certainly not cost effective compared with cost burden of those made much worse by it. Patients report suffering relapses from GET. MEA Survey http://www.meassociation.org.uk/wp-content/uploads/2015-ME-Association-Illness-Management-Report-No-decisions-about-me-without-me-30.05.15.pdf	Thank you for your comment. The guideline will address the management of ME/CFS and special consideration will be given to people with severe ME/CFS throughout the guideline 'including any specific end of life needs'. The guideline will cross refer to related NICE guidelines. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee.

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			There is no "yellow card" adverse reaction process for reporting harms and patients attending ME/CFS clinics report that there is no method of recording of harm or a worsening of ME symptoms and no follow up. The evidence for GET/CBT is weak or non-existent. The current guidelines recommend that treatments should be optional but patients report they have been coerced to complete GET/CBT by insurance companies or children pressured through threats of child protection. Given weak evidence for any treatments we believe that the guidelines should make strong statements against forced treatment. Patients offered treatments should be alerted to the reported harms, including the possibility of severe and long-lasting relapse, in order to be able to make informed decisions. Many clinics including our local clinic stipulate that in order to receive care patients must be compliant with their treatment approach. This is contrary to patients being able to withdraw any aspect of treatment without it affecting other aspects of treatment. In other words patients are being forced to access aspects of treatments that they are not happy with in order to access any care at all. **For the reasons outlined above, we need immediate caveat on GET not in 2020**. We need to make our views explicit ; that a strong caveat re GET needs to be issued immediately and well publicised to all doctors, nurses, physiotherapists, Occupational Therapists, CBT therapists etc who may well assume they already know about ME so are unlikely to look at guidelines, and also well publicised in the media to counteract the stigma	Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all

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			many continue to suffer from friends and families accusing them of laziness or playing sick role if unwilling to try GET to get better. This should be routine as part of shared decision-making but it simply does not happen. In addition, the 2006 **NHS Plus (now NHS Health and Work) Guidance on Occupational Health for CFS ME** should be withdrawn. All references to it made by the NICE Technical Surveillance Team in 2017 need to be removed. In the 2006 NHS (PLUS) Guidance on ME was programmed for review in 2011 and has not been revisited. NHS Health and Work, has failed to show due diligence and review. It has failed to evaluate against the recent changes in legislation of the Care Act 2015 and the Duty of Candour 2015. NICE should send a caveat to **Faculty of Occupational Medicine** who are involved with **Occupational Health Guidelines for ME** on behalf of **NHS Health and Work. The Council for Work and Health** to feed into *"The Council for Work and Health Outputs and outcomes as at 31 July 2017 and strategic objectives for 2017 to 2022"* and critically, the DWP who are an "interested party" as is the Insurance Industry. This guidance has a big impact on financial independence for people with ME as it affects ill health retirement and insurance claims **Reference** for this critical organisation for ME patients**;** **http://www.councilforworkandhealth.org.uk/our-work -**The guidance is critical for this organisation since it states. *"**The Council for Work & Health** brings together the professional bodies which represent these*	decisions about treatments. The guideline will address treatments for ME/CFS. We hope that a new guideline with up to date reviews of evidence will improve understanding and the care of all people with ME/CFS.

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			groups to provide an authoritative and representative 'single voice' on health and wellbeing issues. It also provides an opportunity for co-ordinated and integrated working on all issues which impact on health and wellbeing services and facilitates information sharing to promote improvement. "	
The 25% ME Group	2	23-28	We welcome the acknowledgement that such approaches need to be looked at again. Concerns are (i) what is - and is not - considered admissible evidence and (ii) the method whereby this 'evidence' is scrutinised. Parameters set on both when CG53 developed are exactly what got us into the present mess in the first place. We would welcome the opportunity to elaborate on this point and to feed into guideline development process accordingly.	Thank you for your comment. NICE methods for review of evidence are described in the NICE guidelines development manual. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.
Respect for ME	2	13-17	The reference of a 40% misdiagnosis rate here suggests that the criteria should be more and not less discerning. This focus on fatigue is certainly part of the problem. Most international experts now believe that post-exertional malaise (or post-exertional neuroimmune exhaustion) is a more specific and unique marker for diagnosing ME than the presence of chronic fatigue. According to the recently updated CDC website (12.7.19): 'Post exertional malaise (PEM) is the worsening of symptom following even minor exertion, with symptoms typically worsening 12 to	Thank you for your comment. The use of the term ME/CFS in the scope does not pre-judge the terminology of the final guideline. We have reworded this section to clarify that fatigue is not necessarily the appropriate term and to include reference to post exertional malaise. One of the tasks for guideline

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			48 hours after activity and lasting for days or even weeks.' Indeed, the body of evidence around PEM persuaded the Institute of Medicine to conclusively label ME a 'disease', rather than a syndrome'. As the IOM Report acknowledges: 'PEM is unpredictable in duration, potentially lasting hours, days, weeks or even months.' (https://www.ncbi.nih.gov/books/NBK284902)	committee will be to consider diagnostic criteria and the issues you raise.
Royal College of Paediatrics & Child Health	2	13-17	The scope indicates that at a referral centre, '40% of those referred did not have fatigue from CFS, (and several responsible disorders are quoted) and 5.2% did not have clear cause for their symptoms' without reference as to whether the referral centre was a secondary or tertiary centre or to age of those referred. The 2008 CFS/ME guideline recommends general and specific medical investigations "to exclude other causes" before making a diagnosis of CFS/ME. The Review committee should consider whether any medical investigations i.e. blood tests can reliably "exclude" other causes for symptoms which may be non-specific and vary in time, situation and age of onset and presentation- particularly as all investigations have their own sensitivity and specificity.	Thank you for your comment. The guideline includes the diagnosis of ME/CFS and the draft scope questions include the clinical and cost effectiveness of tests in making a diagnosis of ME/CFS.
The 25% ME Group	2	13-17	Insert after "found that 40% did not have CFS" the clarification "according to the 1994 US CDC CFS criteria"	Thank you for your comment. This section sets the scene for the guideline and references are not usually included.
The ME Association	2	8-12	The use of multiple diagnostic criteria, which vary from narrow to broad in the way that they define ME, CFS and ME/CFS, in epidemiological	Thank you for your comment and information. We agree that the multiple diagnostic criteria have led to a

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			studies has also led to a confusing situation whereby widely varying prevalence rates are reported in both adults and children.	confusing situation. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.
Hope 4 ME Fibro Northern Ireland	2	19 - 22	**Children:** The issues in this section need to be more carefully described, so that a future guideline does not permit the problems that the previous CG53 guideline facilitated. **Schooling:** Without appropriate doctors' letters, schools are obliged to report long term pupil absences to social services, and if the doctor still does not properly explain the severity of ME, the parents get blamed for the children's absences. This can lead to child protection issues and the parents being effectively forced to send their children to school or risk facing court orders to remove their children. The dilemma is serious for parents: send the severely ill child to school thus worsening their condition, or risk losing custody of the child. No parent should have to face this on top of the issue of having a severely ill child. No child should be taken from his/her family at a time when they are most vulnerable. Yet it happens. This issue is one that the new guideline must specifically address in order to protect children from inappropriate removal from their family situations. The scope must allow for this.	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.

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			Treatments: When parents opt to refuse a NICE recommended treatment for their child, an issue can again arise with the medical establishment feeling that they know better. Parents should not have to accept NICE guidelines on marginally effective treatments. Medical professionals should not be allowed to over-rule parental discretion regarding treatments that are not in any way guaranteed to be effective. Again, this issue is one that the scope needs to specifically address in order to protect children from inappropriate and forced treatments.	
Invest in ME Research	2	4-7	Ongoing research into the causes and pathological processes underlying the symptoms of ME/CFS includes examination of immune function, autonomic function, neuroendocrine disorders and gene expression. This sentence needs to be altered to add – neuroimaging, gut microbiome and metabolomics It should read – Ongoing research into the cause(s) and pathological processes underlying the symptoms of ME/CFS includes examination of immune function, autonomic function, neuroendocrine disorders, neuroimaging, gut microbiome, metabolomics and gene expression.	Thank you for your comment. We have added other examples to the text. This list is not intended to be definitive and are examples of areas of ongoing research.

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The ME Association	2	4-7	This should also include reference to the current research involving neuropathology, mitochondrial dysfunction and muscle energy metabolism, and metabolomics.	Thank you for your comment. We have added other examples to the text. This list is not intended to be definitive and are examples of areas of ongoing research.
Hope 4 ME Fibro Northern Ireland	2	11 - 13	**GPs:** The scope states that "many GPs lack the confidence and knowledge to diagnose and manage ME/CFS". Unfortunately, we find a number of local GPs think ME is a psychological condition undeserving of their time and effort. This is a major problem, which the CG53 guideline tends to encourage because of its huge emphasis on behavioural & rehabilitation type treatments. It is essential, in our view, that the new guideline should make a very strong statement to the effect that ME is an organic condition and that it has no underpinning psychological basis. We suggest that the scoping document include the following statement: "Many healthcare practitioners are operating under the false assumption that ME has no organic basis. This has led to an inappropriate attitude towards the care of ME patients". Considering the massive impact of the biopsychosocial paradigm on ME care, and its capacity to ensure that many healthcare practitioners	Thank you for your comment. In this section we do acknowledge that people with ME/CFS report a lack of belief and acknowledgment among health and social care professionals about their condition and related problems. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with up to date reviews of evidence will improve understanding and care of patients,

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			disregard the physical symptoms that their patients report, we feel it is important that the scope document should address these issues head on. **Suggestions for the Guideline Committee to consider:** a) Adding ME to curriculum in medical schools* & also for trainee allied health professionals b) Continuous Professional Development modules to be offered to all existing practitioners c) Creating new posts for specialising in ME (GP specialists, Consultant specialists etc.) d) Removing from ME services, all clinics that specialise in behavioural rehabilitation. However, it is vital that the individuals delivering educational services are aware of the full implications of the organic nature of ME, and of the extensive harms that can be caused by attempting to rehabilitate patients through psychological therapies or exercise regimes. **We surveyed 2nd year medical students in Queen's University Belfast after a screening of UNREST, and they clearly stated the need for more information on ME during training.*	
Invest in ME Research	2	8-10	The estimated minimum prevalence rate of ME/CFS in the UK was 0.2% for 8 people meeting either the Centers for Disease Control and Prevention (CDC) 9 or Canadian case definitions	Thank you for your comment.

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			It is an improvement to see NICE stating the prevalence rates based on estimates that use the CDC or Canadian Criteria instead of the rate of 1-2% that the CFS/ME Research Collaborative (cmrc) used in its inaugural press release.	
Invest in ME Research	2	11-13	People with ME/CFS report delays in diagnosis, and research has highlighted that many GPs lack the confidence and knowledge to diagnose and manage ME/CFS. This statement is an indictment of the current ineffectual NICE guidelines. This should therefore serve as a warning sign for this new NICE revision as it demonstrates that the current NICE guidelines have failed in giving doctors what they need regarding ME.	Thank you for your comment. We hope that a new guideline with up to date reviews of evidence about the diagnosis and management of ME/CFS will improve understanding and the care of patients, to support this the guideline will address information, education and support for health and social care professionals.
LocalME	2	20-22	There are repeated issues around schools and medical professionals starting child protection action due to children being ill (and not believed) or parents report child protection is used as a threat to impose a treatment regime. Such proceedings or 'treatments' can harm children. The guidelines should make it clear that this is not acceptable.	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with up to

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				date reviews of evidence will improve understanding and the care of all people with ME/CFS.
Royal United Hospitals Bath NHS Foundation Trust	2	26-28	No-one should be 'pressured' into receiving any treatment. Informed consent and the ability to say 'no' to any treatment that you don't want or you don't think is working for you is crucial in all healthcare. In our unit, we have had considerable success using the existing NICE approved treatments but – unsurprisingly – not for all patients. We urgently need strategies and treatments for people who do not respond to what we have already, but we should not abandon existing treatments unless the review finds them not to be effective.	Thank you for your comment. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. The guideline will address treatments for ME/CFS. We hope that a new guideline with up to date reviews of evidence will improve understanding and the care of all people with ME/CFS.
The ME Association	2	2-4	As the scope infers, problems with late and misdiagnosis are being compounded by having over 20 different clinical and research definitions for ME, CFS and ME/CFS. Clinicians need a simple straightforward definition for use in the consulting room – one which incorporates and emphasises the main diagnostic features – activity induced muscle fatigue and post-exertional malaise/ symptom exacerbation, autonomic nervous system dysfunction, neurocognitive dysfunction and unrefreshing sleep – all of which commonly follow an acute infective episode or other form of immune system stressor.	Thank you for your comment. We agree there are many different clinical and research definitions and the use of the term ME/CFS in the scope does not pre-judge the terminology of the final guideline. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.

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			While the MEA does not endorse the proposal for a new name for ME/CFS – systemic exertion intolerance disease/SEID – that is contained in the Institute of Medicine report, there is merit in the way that these key symptoms are included in this definition. Serious consideration should be given to the way in which ME is defined in the London criteria.	
The ME Association	2	18-20	NICE should acknowledge that a small but significant proportion of health professionals still take a dismissive or even hostile attitude to ME/CFS. Such attitudes are both harmful and unprofessional. Others believe that ME/CFS is a self-perpetuating mental health condition. So there is clearly a desperate need to improve medical education on both diagnosis and management at undergraduate and postgraduate levels. We expect NICE to make reference to this in the new guideline and it would be reassuring to see this intention being included in the scope.	Thank you for your comment. We do acknowledge that people with ME/CFS report a lack of understanding among health and social care professionals about their condition and related problems. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with up to date reviews of evidence will improve understanding and care of patients,
The ME Association	2	18 - 20	Re management and care plans: The current guideline includes a clear recommendation regarding the need for management plans to form part of an on-going management programme. Patient evidence indicates that management and care plans are welcomed but are the exception rather than the rule. A comprehensively written management and (where appropriate) care plan that is prepared by all the health and care professionals who are involved is a very useful tool for patients to have - especially those with moderate to severe ME/CFS. A reference to management and care plans should therefore be included in the scope	Thank you for your suggestion. This section is a summary and sets the scene for the guideline and cannot include everything. The technical team will ensure the issue of management and care plans are brought to the attention of the committee when they are considering the final review questions and protocols**.**

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Forward ME	2	3-4	It is quite correct to say that, at present, patients are identified based on the clinical picture presented – and that this applies to both research and clinical care settings. However, this is rooted in the insistence on locating a single, unique biological identifier (not found to date and may not be findable, given the various stages through which this illness progresses) rather than in "lack of understanding" of aetiology. The fact that diagnosis is made clinically makes it even more important to ground the NHS in a recognition of the unique clinical profile that an ME patient presents. See the seminal work of A Melvin Ramsay, for example. More recently, the International Consensus Criteria, the Canadian Consensus Criteria the US IOM criteria are accepted by the ME community; these definitions are well grounded in empirical studies.	Thank you for your comment. We agree there are many different clinical and research definitions and profiles and this makes diagnosis a complex task. One of the tasks for guideline committee will be to consider diagnostic criteria and the issues you raise.
Forward ME	2	15-16	Delete from 'a primary' to end of sentence.	Thank you for your comment. Primary has been deleted.
Hope 4 ME Fibro Northern Ireland	2	1 - 2	**Triggers:** After stating that a virus is a commonly reported trigger, the scope says, "although the reasons for this being a trigger for ME/CFS are not understood." Adding this phrase, completely negates the importance of the previous statement. **We suggest the quoted words be deleted.** The fact that the scope does not explain any link is sufficient to indicate the process is not yet fully understood.	Thank you for your comment. We disagree that this negates the importance of the previous statement the reasons are not understood and we highlight that there is ongoing research into the causes.
Blue Ribbon for the	2	3 / 4	Unfortunately, historically a number of definitions have been used for research and clinical care – some of which such as the Oxford criteria,	Thank you for comment. We agree there are many different clinical and research definitions and profiles

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Awareness of ME (BRAME)			should not have been used, as it was never appropriate for ME, as it is just fatigue and one other symptom, and actually excludes neurological symptoms, when ME is classified by World Health Organisation (WHO) as a neurological condition (ICD10 G93.3). This was strongly highlighted with the last guideline over 10 years ago – and research using the Oxford criteria is far too broad to be true and reflective for people with ME. In more recent years the ME International Consensus Criteria (2011), and the Canadian Consensus Criteria (2003) are more accurate and truly reflective of the illness ME and accepted by the ME community. In the UK the ME ICC criteria, which was co-written by 3 eminent ME specialists from England, is the one which should be used both clinically and for research Will the NICE guideline group be discussing and deciding whether to make recommendations into research and what criteria should be used clinically and for research? Last time recommendations never amounted to anything.	and this makes diagnosis a complex task. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing statements such as the Canadian International Consensus Primer will be used to inform the committee. If the committee consider it to be appropriate during the development process they will be able to make research recommendations.
Blue Ribbon for the Awareness of ME (BRAME)	2	23/28	Glad to see this time that with GET and CBT, the management treatment for people with ME recommended in the last guideline - 'leading to a worsening of symptoms' has been added -acknowledging the enormous impact these had on people, who were often pressured into them. NICE was warned, and advised, of the unhelpfulness and potential detrimental harm of CBT, and especially GET, during the last Guideline	**Thank you for your comment.** We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision

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			Group, and surveys of thousands of people with ME were presented, showing the high percentage who reported being harmed, or made worse, by these treatments. Despite the reality of the patient evidence of harm, NICE still went ahead and recommended both CBT and GET. In the recent update to the CDC website (13.7.18) "Any activity plan for people with ME/CFS needs to be carefully designed based on individual presentation with input from each patient. If possible, evaluation by a rehabilitation specialist may be beneficial. For some patients, even daily chores and activities such as cleaning, preparing a meal, or taking a shower can be difficult and may need to be broken down into shorter, less strenuous pieces. While vigorous aerobic exercise can be beneficial for many chronic illnesses, **patients with ME/CFS do not tolerate such exercise routines.** Standard exercise recommendations for healthy people can be harmful for patients with ME/CFS" (Their bold). CBT has followed, and has, in some cases, continued to follow, the erroneous belief that ME is not a physical condition, but is 'all in the mind', and it is all about 'illness beliefs'. Needless to say, the treatment of CBT they have to endure, is not only unhelpful, but found to be harmful, for many who have gone through CBT, and who have often been pressured into it. As with any chronic long-term condition, for which there is no cure, CBT, used as a coping mechanism, can be a helpful part of the toolbox to offer patients, to help enable them to cope with life living with a chronic	on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

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			debilitating condition – it is not a first choice/line treatment – or to the detriment of biomedical care and management.	
Science for ME	2	23/28	We agree that the evidence for GET and CBT needs urgent review. The case for CBT and GET with ME/CFS is very weak. Trials producing positive results are not blinded but use subjective outcomes which makes them unreliable. This situation is made worse due to the way the CBT/GET interventions aim to change how patients think about symptoms and how much activity they can do – which is likely to have an effect on the subjective outcomes. More objective measures such as walking tests when provided as secondary outcomes do not support the effects claimed with the subjective primary outcomes. As such these trials are not properly controlled for reporting bias and the results are meaningless. These issues are discussed in peer reviewed papers (in the context of the PACE trial). Wilshire, C., Kindlon, T., & McGrath, S. (2017). PACE trial claims of recovery are not justified by the data: a rejoinder to Sharpe, Chalder, Johnson, Goldsmith and White (2017). *Fatigue: Biomedicine, Health & Behavior, 5(1)*, 62-67.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of

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			Wilshire, C., Kindlon, T., Matthees, A., & McGrath, S. (2017). Can patients with chronic fatigue syndrome really recover after graded exercise or cognitive behavioural therapy? A critical commentary and preliminary re-analysis of the PACE trial. *Fatigue: Biomedicine, Health & Behavior*, *5(1)*, 1-14. Special Issue: The PACE Trial Journal of Health Psychology Volume 22 Issue 9, August 2017 http://journals.sagepub.com/toc/hpqa/22/9 In addition to questionable benefits for CBT/GET there are also issues of harm and deterioration. Many patients report suffering relapses after GET. This is demonstrated by patient surveys carried out by the ME Association and Action for ME; for example, http://www.meassociation.org.uk/wp-content/uploads/2015-ME-Association-Illness-Management-Report-No-decisions-about-me-without-me-30.05.15.pdf. The evidence for harm has also been assessed in peer reviewed literature, http://iacfsme.org/PDFS/Reporting-of-Harms-Associated-with-GET-and-CBT-in.aspx Unfortunately, treatments such as CBT/GET/LP do not seem to be covered by the yellow card system used for reporting harms of drugs and equipment. This means that there is a lack of coherent evidence being collected. Few trials have assessed harm and the few that do fail to measure adherence to treatments making conclusions hard to form.	assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.

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			Hence, given the lack of evidence of a beneficial effect and patient reports of harm we believe that CBT/GET should not be recommended.	
Science for ME	2	23/28	When reviewing guidelines around CBT it is important to look at the specific model of CBT that has been used in trials for CFS, rather than assuming that CBT is about helping patients cope with chronic illness. Instead it is aimed at changing the interpretation of symptoms. For example, quoting the PACE CBT manual *"The essence of CBT is helping the participant to change their interpretation of symptoms and associated fear, symptom focussing and avoidance. Participants are encouraged to see symptoms as temporary and reversible and not as signs of harm or evidence of fixed disease pathology. In this way it is anticipated that they will gain more control of their lives, as they, and not their symptoms, dictate what they do."* …. *CBT also actively addresses the participant's understanding of their illness which may involve challenging unhelpful beliefs, e.g., about symptoms or activity that may be preventing recovery.* It is important to consider all of the problems which can occur when CBT is intended to get patients to view symptoms differently, of get rid of the	**Thank you for your suggestion.** Thank you for your comment. We agree that it is important to review the clinical and cost effectiveness of CBT and other treatments to identify the specific populations that treatments may benefit and or harm. This will enable the committee to make clear positive or negative recommendations on treatments. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of

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			'patient label', rather than supporting them in coping with their illness. A qualitative study examining problems encountered within the FINE trial noted of therapists that*: "Their frustration has reached the point where they sort of boiled over,"* said the supervisor*. "There is sort of feeling that the patient should be grateful and follow your advice, and in actual fact, what happens is the patient is quite resistant and there is this thing like you know, 'The bastards don't want to get better.'"* https://www.ncbi.nlm.nih.gov/pubmed/22192566 Encouraging people to believe that patients have greater control over their symptoms can lead to a range of side-effects, and cause social harms which risk being overlooked by those working within medicine. All of these issues need to be considered carefully in any examination of the costs and benefits of recommending CBT as a treatment for CFS. This also means statements such as 'CBT is offered with other chronic illnesses' which are often used in support of CBT for ME/CFS is not comparing like with like'.	outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.
Science for ME	2	23/28	The current guidelines recommend that treatments such as CBT/GET should be optional, but patients report they have been expected to complete GET/CBT by insurance companies and government welfare agencies, also children have been pressured through threats of child protection. Patients who were offered CBT/GET were not informed about the doubt as to the effectiveness of these treatments or the potential for harm; in	Thank you for your comment. We are aware of the concerns that people with ME/CFS have and agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments.

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			fact, many were assured of the safety of such interventions. Thus, patients were not giving informed consent when undertaking treatment. We believe that given these problems any guidelines should be stronger than using the word optional and make a strong statement against forced treatments and the need for informed consent.	
Blue Ribbon for the Awareness of ME (BRAME)	2	11/13	This paragraph highlights how much NICE needs to ensure that the correct information and advice is in the new guideline so that it may be of true assistance to Health Professionals (HPs), especially in primary care such as GPs, to help them have the correct information to enable them to make a provisional diagnosis, and offer good management advice, especially in the early stages, but also in the on-going care and support patients with ME need.	Thank you for the comment. We agree that information and support for healthcare professionals is important and have included this in the guideline. Monitoring and review has been included in the guideline to ensure the on-going care and support of patients with ME/CFS need is addressed.
Science for ME	2	20/22	"There are added issues for children, young people and their carers when illness makes school attendance difficult and families come to the attention of educational and social care services." There are repeated issues around schools and medical professionals starting child protection action due to children being ill (and not believed) or parents report child protection is used as a threat to impose a treatment regime. Such proceedings or 'treatments' can harm children. The guidelines should make it clear that this is not acceptable.	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline. NICE guidelines have remit for NHS and social care services only. We can however include recommendations about appropriate advice and support for access to education and work.

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Science for ME	2	18/19	"People with ME/CFS have reported a lack of understanding among health and social care professionals about their illness and related problems" Many patients have experienced medical professionals who dismiss their symptoms and refuse to take them seriously and dismiss and fail to investigate other problems. The guidelines should make clear that this is not acceptable.	Thank you for your comment. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for people with ME/CFS. The guideline will address information, education and support for health and social care professionals.
Support for ME	2	18/19	Our son's GP does not believe in ME, it is ***not*** a lack of understanding. He has said this to our face and is adamant that he will not learn. The result has been that it has caused our son increased stress and he is now unwilling to visit the doctor..	Thank you for your comment. We have reworded section 1 to include a lack of belief and acknowledgment rather than understanding. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for people with ME/CFS and reduce any stigma experienced.
#MEAction UK	2	2	Here is a link to an up-to-date 'ME/CFS Research Summary' produced by #MEAction. It is crucial NICE and the committee have an accurate understanding of what ME is -- at least what we know (and don't know) so far. For the current guidelines, which NICE has acknowledged are inadequate, the full range of evidence was not properly understood and evaluated. This cannot be allowed to happen again.	Thank you for the comment and the information.This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow

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				different levels of evidence but the level of evidence influences the strength of any recommendations made.
LocalME	2	2	ME/CFS are not understood"-suggest not fully understood. New emerging understanding of the many complex pathways impacted in ME and CFS are being unravelled. This in turn is changing our perception of chronic illnesses of which ME is perhaps, the most complex.	Thank you for your comment. This section has been reworded in light of stakeholder comments.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	2	- not understood "yet".	Thank you for your comment. This section has been reworded in light of stakeholder comments.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	4	Again, it must be made clear which of the different symptom-based definitions the guideline recommendations apply to, and which they do not. What may be safe for those just experiencing chronic fatigue may well harm those with post exertional malaise.	Thank you for your comment. We are aware there are different symptom based definitions and the scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use for different subgroups of people with ME/CFS.

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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
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	4	It will be important that those reviewing the research evidence are non-biased and aware of the controversy surrounding some of the published work on Cognitive Behaviour Therapy and Graded Exercise Therapy. They should make themselves aware of the research criteria used to recruit patients to studies and the implications of this for those fulfilling the more stringent ME criteria, especially where post exertional malaise has not been a required symptom for research participants.	Thank you for your comment. We are aware of the controversy about the current recommendations for GET and CBT and of the concerns that people with ME/CFS have. The clinical and cost effectiveness of GET/CBT will be reviewed in the guideline. We will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available.
Hope 4 ME Fibro Northern Ireland	2	2 – 4	**Aetiology:** Whilst we agree that the aetiology of ME is not yet fully understood, it is not true that there is a complete "lack of understanding of the aetiology of the condition", therefore this phrase is misleading. There are many aetiological factors currently described, to give just two examples: A clearly deficient 2nd day result on two-day cardiopulmonary exercise testing and Elevated levels of certain cytokines and other metabolites after exertion. It is of course true that current definitions of ME are mostly symptom based, and that these descriptive definitions are being used in both research and clinical care. We suggest the scope should note that the two definitions, most widely accepted for biomedical research, include the Canadian Consensus Criteria (CCC) and the International Consensus Criteria (ICC). We think	Thank you for your comment. This section has been reworded in the light of stakeholder comments. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing statements such as the Canadian International Consensus Primer will be used to inform the committee.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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			it should also be noted that fatigue-orientated definitions such, as the Oxford criteria, are no longer regarded as appropriate for ME research. **We suggest that this scoping document should mention the above 3 definitions by name,** and perhaps also clarify that certain definitions, such as Oxford, have now fallen out of favour with medical scientists investigating ME aetiology because of their over inclusive and fatigue orientated nature.	
ME Letterforce	2	6	This must include the research into exercise intolerance (as post exertional worsening is the hallmark of ME)	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We are aware there are other areas of ongoing research. This list is not intended to be definitive and are examples of possible areas.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	6	Include mitochondrial function and cellular metabolism.	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We are aware there are other areas of ongoing research. This list is not intended to be definitive and are examples of possible areas.
Hope 4 ME Fibro	2	7	**Ongoing Research:** Suggested additions: Gut biome, ATP synthesis, & muscle function.	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We are aware there are other areas of ongoing research. This

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Northern Ireland				list is not intended to be definitive and are examples of possible areas.
ME Research UK	2	7	Other areas of past and ongoing research, funded by ME Research UK, include cardiovascular, metabolic and neuromuscular function.	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We are aware there are other areas of ongoing research. This list is not intended to be definitive and are examples of possible areas.
The Ehlers-Danlos Support UK	2	7	Add 'collagen disorders'.	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We are aware there are other areas of ongoing research. This list is not intended to be definitive and are examples of possible areas.
Welsh Association of ME & CFS Support	2	8	WAMES believes it is a mistake only to mention the minimum estimated prevalence rate for ME/CFS in the UK of 0.2% and not also the upper rate of 0.4%. This could mislead people into underestimating the possible extent of the patient population and therefore the challenge to service providers.	Thank you for your comment. We are aware of the lack of clarity about accurate prevalence rates for ME/CFS and have stated that 0.2% is the minimum rate. Part of the NICE guideline development process includes cost effectiveness and investigations into resource impact. Part of this work will be to accurately identify prevalence rates to support the commissioning of services.
Stonebird	2	10	**P 2 line 10 Why is there no mention of the prevalance 25% of people who have a Severe ME diagnosis?** Why has any detail of Severe ME	Thank you for your comment. We are aware of the lack of clarity about accurate prevalence rates for

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			as a distinct group been ignored in this Scope, even to the extent of renaming Severe ME to 'people with Severe symptoms' which is absolutely not the same thing. Without this clarification people will be open to misdiagnosis as MUS.	ME/CFS and have chosen only to state the overall minimum prevalence. Part of this work will be to accurately identify prevalence rates to support the committee's decision making. Section 1 has been rewritten and more accurately reflects people with severe ME. In section 3.1 we have clarified that special consideration will be given to people with severe ME/CFS.
#MEAction UK	2	11	People with ME can remain undiagnosed for many years. GPs lack confidence and knowledge of how to diagnose and manage ME. However, problems are much more serious than this: medical professionals are often dismissive (Raine, 2004), not believing ME to be 'real', which is an unacceptable hindrance to proper care (Blease, 2018). This disbelief means patients lack care not just for their ME but also for any comorbid conditions, which are often also dismissed. This is despite the fact that autoimmunity rates are higher in people with ME than the general public (Morris et al., 2013). We suggest: "ME is both underdiagnosed and misdiagnosed, with research highlighting that many GPs lack the confidence and knowledge to diagnose and manage ME, as a result patients receive inadequate and sometimes hostile health care."	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. The guideline will specifically address information, education and support for health and social care professionals.

Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management (Oct 2020)

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Respect for ME	2	11	Raine 2004 and Blease 2018 suggest patients are dismissed and disbelieved, resulting in 'epistemic injustice'.	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. The guideline will specifically address information, education and support for health and social care professionals.
Healthwatch Bolton	2	12	Remove "diagnose" and insert "recognise" and treat symptoms, eg., sleep disturbance, pain, digestive problems	Thank you for your comment. We have reworded this sentence to include recognise.
ME Research UK	2	13	Please clarify that this review was carried out at a regional chronic fatigue referral centre.	Thank you for your comment. We have added in the reference.
Parents of children with ME/CFS Support Group	2	13	The draft scope here focusses on fatigue as the defining characteristic and uses an unnamed review, for which no source is cited. We suggest that lines 13 – 17 on page 2 be either removed completely or replaced with more robust data which focusses on Post-Exertional Malaise as the defining characteristic.	Thank you for your comment. We have altered this section following stakeholder consultation to clarify that fatigue is not necessarily the appropriate term and that other symptoms occur and included reference to post exertional malaise.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	13	There have been two reviews rather than one: Newcastle and another at Barts with similar findings.	Thank you for your comment and the information.

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Stonebird	2	13	**P2 line 13 why is there no mention of the need for those with a Severe ME diagnosis needing a home visiting service and special understanding by GP's of how to approach and safely care for this specific group of people? This needs to be in conjunction with full symptom recognition and better GP training.** If GP's do not visit the most severely at home, no wonder they do not know how to diagnose and manage ME. Attendance at a centre is quoted but why is there no mention that people with Severe ME, who are mainly bed/home bound cannot travel, cannot attend centres ? The Scope needs to recognise the urgent need for a home service for the most severely affected. The Scope should also raise the issue making sure that GP's are provided with the correct information that ME is a physical disease not a mental health condition . There needs to be a specific question that challenges the influence of the inappropriate psychosocial pathway for ME, upon GP's and other medical professionals, which leads them to not understand, appropriately manage or interact with people with Severe ME who are house and bed bound, leaving them at great danger of misinterpretation as MUS. NICE must protect this highly vulnerable patient group and acknowledge the full symptom experience.	Thank you for your comment. Section 1 has been rewritten and more accurately reflects people with severe ME. In section 3.1 we have clarified that special consideration will be given to people with severe ME/CFS. The guideline will address information, education and support for health and social care professionals.

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The 25% ME Group	2	13	The study cited bears out that lack of confidence among GPs in making a diagnosis is well grounded. Therefore suggest delete 'However' and replace with "This is borne out by".	Thank you for your comment. 'However' has been deleted from the sentence.
Blue Ribbon for the Awareness of ME (BRAME)	2	15	Several conditions so probably best just to stop at 'chronic disease'	Thank you for your comment. This list is not intended to be definitive and are examples of possible conditions that ME/CFS are associated with.
ME Research UK	2	16	This last sentence does not seem significant. Please consider replacing it with: '*This indicates that the referring doctors had possibly overly relied on one symptom of "fatigue" to make their diagnosis and subsequent referrals.*'	Thank you for your comment. This section is to provide context to the guideline and it is important to highlight the difficulties in diagnosing and treating people with fatigue.
Hope 4 ME Fibro Northern Ireland	2	17	Suggest replacing word "fatigue" on line 17 with "ill health".	Thank you for your comment. The study referenced here refers to fatigue and it would be inaccurate to replace it with ill health.
ME Letterforce	2	17	Fatigue needs to be removed and replaced with symptoms. ME/CFS is not fatigue	Thank you for your comment. We have altered the wording earlier in section 1 in light of stakeholder comments to clarify that fatigue is not necessarily the appropriate term and that other symptoms occur. The study referenced here refers to fatigue and it would be inaccurate to replace it with symptoms.
#MEAction UK	2	18	NICE must recognise the specific scientific-cultural context of ME and the decades of stigma, disablism, disbelief and discrimination. These	Thank you for your comment. We hope that a new guideline with more up to date reviews of evidence will

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			issues must be positively counteracted to improve care of people with ME and reduce the risk of iatrogenic harms and neglect. Attitudes towards people with ME by medical professionals has a significant impact on care.	improve understanding and care for patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.
#MEAction UK	2	18	It is not merely a 'lack of understanding'. Health and social care professionals have both received and further propagated incorrect information about ME. The result is that many healthcare professionals believe people with ME to be malingerers and unreliable witnesses to their own bodies (Raine, 2004), or even go so far as to stereotype people with ME as militant, a claim that has no compelling evidence but leads to the marginalisation and exclusion of patient voices (Blease, 2018). There is a widespread belief that people with ME can push through symptoms and that there is nothing seriously wrong with them; that they are deconditioned or fearful of exercise. This model is being proactively taught to Improving Access to Psychotherapy Practitioners (IAPT Education & Training Group, 2017), even though it has been emphatically criticised (Institute of Medicine, 2015). Many people with ME choose to avoid the clinic rather than risk further harm: in one survey, a third of those with ME/CFS had not even seen a GP in the past year (Action for ME, 2014). We propose changing this sentence to: "At	Thank you for your comment. We are aware of the concerns that people with ME/CFS have and agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. Section 1 has been reworded in the light of stakeholder comments to include a lack of belief and acknowledgment rather than understanding. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.

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			present, people with ME/CFS often experience hostility, ignorance and stigmatisation from health and social care practitioners."	
Healthwatch Bolton	2	18	Remove "understanding" and insert "belief and acknowledgement"	Thank you for your comment. We have reworded this sentence in light of your comment.
ME Research UK	2	19	Please consider adding the following: '*It is also not well understood that patients may experience a range of symptoms and comorbidities, some but not necessarily all of which are related to their ME/CFS. Some patients may be identified and/or treated in specialist centres, and others may not be in touch with healthcare professionals at all if their illness results in them being housebound.*'	Thank you for your comment. Section 1 has been reworded in the light of stakeholder comments and have highlighted the difficulties experienced by people with severe ME/CFS.
#MEAction UK	2	20	School attendance is often impossible or dangerous, not merely 'difficult.' These 'issues' can be traumatising for children and the whole family. Legal obligations on schools to make 'reasonable adjustments' should be stressed -- including, but not limited to supporting families to obtain home or virtual tuition, and support for families that may be under pressure from local authorities. Health may need to take precedence over education for a period of time. Getting a child to school does not mean they are well enough to learn, and that time might be more effectively used for rest.	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline.
Blue Ribbon for the Awareness of ME (BRAME)	2	20	After 'added' need to insert 'safeguarding'	Thank you for your comment. We don't think safeguarding is necessary in this sentence it is clear that as a result of poor school attendance these issues are raised by social care services.

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Forward ME	2	20	After 'added' insert 'safeguarding'.	Thank you for your comment. We don't think safeguarding is necessary in this sentence it is clear that as a result of poor school attendance these issues are raised by social care services.
Respect for ME	2	20	Schools have a legal obligation to make 'reasonable adjustments' for disabled patients (Equalities Act 2010). School attendance may not be the best outcome for children. Home or virtual/distance learning may be better options and should be considered by the GDG.	Thank you for this information.
The ME Association	2	20	There are additional safeguarding issues…..(add safeguarding)	Thank you for your comment. We don't think safeguarding is necessary in this sentence it is clear that as a result of poor school attendance these issues are raised by social care services.
Blue Ribbon for the Awareness of ME (BRAME)	2	22	The new guideline needs to give focus on the issues surrounding children and young people to help protect them, and their families, from the trauma of being put through safeguarding procedures, often simply because the child/young person has ME and when the families are trying their very best to care for their very ill child – and as the last guideline stated 'any patient has the right to refuse a treatment without detriment to their future care'. A patient should not be forced into a treatment against their will and the child forcibly removed from their family home – also against the advice of eminent ME specialists who are offering the child, and their family, their professional advice and care.	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Special consideration will be given to children and young people throughout the guideline. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all people with ME/CFS and reduce any stigma. The guideline will address information, education and support for health and social care professionals

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Forward ME	2	22	These can create an unnecessary burden on those involved in safeguarding procedures and the unwarranted stress can exacerbate the illness of the child or young person.	Thank you for your comment.
ME Research UK	2	22	Please consider adding: '*and are threatened with care proceedings because their children "are not getting better"* '.	Thank you for your comment. We think it is clear in this sentence that there are difficulties faced by children and their families as a result of children not getting better and these issues being raised by social care services.
Christians with ME, CFS, Fibro and their Carers	2	23	CBT & GET One of the most significant issues for people with ME/CFS is the use of CBT and GET to treat the condition. Many people have experienced a worsening of symptoms as a result, we feel that it is important that the review considers the evidence to support this treatment regime and makes a definitive statement regarding the use of CBT and GET. If the evidence that has challenged the use of these treatments is validated then it is important that the new guidelines state clearly that these treatments should not be used to ensure a change in practice occurs, by simply not identifying these as potential treatments may well lead to the continued use of them.	Thank you for your comment. We agree that it is important to review the clinical and cost effectiveness of GET/CBT and other treatments to identify the specific populations that treatments may benefit and or harm. This will enable the committee to make clear positive or negative recommendations on treatments. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made, This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the

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				previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. Any guideline development is however limited by the evidence available.
VIRAS	2	23	"The previous NICE guideline (CG53) made recommendations on the use of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The evidence supporting these interventions has been challenged" It is inaccurate to state: "The evidence supporting these interventions has been challenged", because there are serious doubts that there is or ever has been any 'evidence supporting' the use of these interventions. The theories underlying the use of GET and CBT claim to know the cause(s) of patient's illness but these theories have been proved wrong. Please replace the section with: "The previous NICE guideline (CG53) made recommendations on the use of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). Claims that these interventions help M.E. or CFS patients have been robustly challenged in peer reviewed literature. Serious flaws in research which claimed to support their use have been established."	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

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Invest in ME Research	2	24	As we also wrote in our comments regarding the current guidelines in 2007 – "Human Rights The recommendation from NICE to use psychological therapies for treating ME/CFS contravenes the human rights of patients with ME/CFS. It has been stated that by ignoring the serious issues with regard to CBT and GET the NICE guidelines would violate the right of clinicians and patients to the highest, safest standards of medical practice and care, amounting to a violation of their Human Rights, apart from major concerns about the efficacy of use of CBT or about the danger in the use of GET. There is no regulatory framework governing the development and use of CBT and GET thus leaving ME/CFS patients vulnerable to exploitation and abuse at the hands of the vagaries of power, politics and prejudice. IiME would state that this is already the case, as frequent letters to our information mailbox attest to this fact. In respect of informed consent for using these therapies the issue does not arise. There simply cannot be informed consent since there are important ethical, safety and regulatory questions arising from these treatments, to be addressed.	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made.

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			Ethical and safety questions such as those raised in the MRC Neuroethics Report 2005 should be paramount. It is hard to envisage any Independent authority clearing a drug for Human testing or use without ethical and safety issues, like those surrounding Psychological Therapy, being resolved. By ignoring these serious issues with regard to Psychological Therapy the NICE guidelines violate the right of clinicians and patients to the highest, safest standards of Medical practice and care, amounting to a violation of their Human Rights. This is a Human Rights issue. Without an answer to whether this type of therapy is 'acceptable to Society' and if it is, without an effective Regulatory framework governing its development and use, there is the serious risk that sick and vulnerable people everywhere will be vulnerable to exploitation and abuse at the hands of the vagaries of power, politics and prejudice. NICE (its chairman and CEO and the chair of these guidelines) should be accountable in a court of law for any harm done to patients given these treatments/therapies." This was stated at the time of the previous guidelines when they were drawn up. NICE did not listen then.	
Healthwatch Bolton	2	25	Remove "some" and insert "many"	Thank you for your comment. This sentence has been reworded to avoid quantifying the amount of people

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				who have been pressured into exercise programmes but to acknowledge this has been reported by people with ME/CFS.
#MEAction UK	2	26	GET and CBT were recommended based on the theory of deconditioning and 'unhelpful illness beliefs' (Bavinton J et al, 2004), which has no evidence base. There is no objective evidence that GET/CBT works for anyone under any ME or CFS criteria (Davenport, 2018). Yet some adults and children are coerced into undergoing GET/CBT. For example, they may be told they must complete a course in order to get benefits or insurance payouts, in which case it is no longer possible to ethically obtain consent. The lasting impact of GET/CBT on medical practice for ME is the result of intransigence from a small group of researchers who refuse to use objective or advanced physiological measurement in their research or to accept evidence which counters their favoured paradigm. It is only possible to continue to prescribe these treatments by ignoring the testimony of people with ME, considering them unreliable narrators of their own experience (Faulkner, 2016), as well as a body of science which contraindicates their use.	Thank you for your comment and information. It is important to review the clinical and cost effectiveness of GET/CBT and other treatments to identify the specific populations that treatments may benefit and or harm. This will enable the committee to make clear positive or negative recommendations on treatments. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. Any guideline development is however limited by the evidence available. The NICE

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				guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	26	There is an issue with any approach that encourages graded increases in activity, not just with "exercise programmes". Harms can occur when patients are encouraged/pressurised to gradually increase their activity and ignore increases in symptoms. Harm and permanent deterioration can result. These harms can also occur when patients are encouraged to maintain levels of activity when symptoms are increasing. These issues do occur under the care and guidance of the specialist CFS/ME services where experts are providing the management advice.	Thank you for your comment and information. We are aware of the concerns that people with ME/CFS have and agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. Patients' experiences of interventions will also be taken into account when the committee make decisions about the treatments.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	26	A reference to the letter to the Lancet re the PACE trial from international academics should be numbered and included in the reference. (It is not just 'some people' as is currently written)	Thank you for your comment. This section is an overview and sets the scene for the guideline and does not include specific references. The clinical and cost effectiveness of GET/CBT will be reviewed in the guideline. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. This sentence has been reworded to avoid quantifying the amount of people who have been pressured into exercise programmes but to acknowledge this has been reported by people with ME/CFS.

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Royal College of Psychiatrists	2	26	No patient should be pressured to participate in treatment programmes. Evidence-based treatments should be offered and patients should have access to high quality, evidence based advice and information to help guide their decisions.	Thank you for your comment. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. The guideline will address treatments for ME/CFS. We hope that a new guideline with up to date reviews of evidence will improve understanding and the care of all people with ME/CFS.
South London & Maudsley NHS Foundation Trust	2	26	No patient should be pressured to participate in treatment programmes. Evidence-based treatments should be offered and patients should have access to high quality, evidence based advice and information to help guide their decisions.	Thank you for your comment. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. The guideline will address treatments for ME/CFS. We hope that a new guideline with up to date reviews of evidence will improve understanding and the care of all people with ME/CFS.
Healthwatch Bolton	2	27	New sentence after "...symptoms." Severely affected and children are being coerced under the Mental Health Act or care orders.	Thank you for your comment. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. We think it is clear in this sentence that there are difficulties faced by children and their families as a result of children not getting better and these issues being raised by social care services.
ME Letterforce	2	13, 14	It would be useful in this section to make it clear that patients who present with chronic fatigue (but not post exertional worsening and other	Thank you for your comment. The clinical and cost effectiveness of methods used for the identification

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			hallmark ME symptoms) should not be referred to ME/CFS clinics. Cost implications and funding need to be examined. If a clinic is set up to treat people with ME and it has patients referred to the service who do not met the criteria for the disease, how are patients who do have ME being disadvantaged? A clinic may be able to offer extra services to (as an example) housebound patients if funding allows it but not if monies are spent evaluating patients with other conditions in such large numbers. New patients may have their appointments delayed as they wait (unfairly) in longer list of patients.	and assessment before diagnosis and diagnosis of with ME/CFS has been included in the guideline. Depending on the evidence identified the committee will be able to make recommendations on who should and should not be referred to ME/CFS clinics.
Parents of children with ME/CFS Support Group	2	27	The draft scope mentions that exercise programmes have led to 'a worsening of symptoms'. We argue that this needs amending to include 'a worsening of symptoms, in some cases causing permanent and serious harm that has led to sufferers being housebound or bedbound'.	Thank you for your comment. We think it is clear in this section that exercise programmes can lead to harm in some people with ME/CFS.
Parents of children with ME/CFS Support Group	2	28	The draft scope identifies the need to review evidence for various interventions. We argue that this evidence should be broad and wide-ranging and include trial reanalyses in order to provide a balanced, objective view.	Thank you for your comment. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of

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				evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	28	There is no independent mechanism to report harms of the treatment and management techniques experienced at specialist CFS/ME clinics. Clinics can be keen to discharge patients who do not find the treatment approaches helpful and do not improve. When patients do not improve they can be blamed for remaining ill. Patients can be reluctant to complain to clinics as they need their support with the DWP, accessing education support etc. Even when patients do mention issues with treatment they are not always listened to and it is not clear whether the points they raise are ever formally reported. There may well be limited official evidence of harms but that is likely the result of there being no clear independent pathway for patients to report harms. Given this situation, harms reported in patient surveys carried out by charities should be given serious consideration.	Thank you for your comment. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. Patients' experiences of interventions will also be taken into account when the committee make decisions about the treatments and we intend to include a call for evidence in the guideline to address the issues you raise.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	2	28	There is an issue of definition with regard to treatment and management approaches. Pacing and activity management are poorly defined and are used to mean different things by different people. Any approach that encourages graded increases in activity whilst disregarding increasing symptoms is potentially harmful. It is important that any treatments or management approaches are clearly defined whilst the guideline review takes place and clearly defined in the final guideline. Patients often favour an approach where they rest as necessary and try to keep within an energy envelope that prevents them from experiencing post exertional malaise. This is often known as pacing, although some	Thank you for your comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. One of the tasks of the committee will be to consider the categorisation and definition of treatments.

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			consider pacing to also include a gradual increase in activity. Clarity of definition is vital.	
Stonebird	2	28	**P2 line 28 it is essential that the guidance for Activity Management, drawing on elements of CBT and GET for people with Severe ME , as recommended in the previous guidelines, is specifically questioned, not just CBT and GET, for ME.** Activity Management is totally inappropriate and given the poor FINE Trail results and should be withdrawn. The FINE trial, for people with Severe ME, was a resounding failure . There is no mention of this. Also, there is no explicit recognition that the psychosocial attitude underlying these therapies is profoundly damaging across the board.	Thank you for your comment. We understand the concern by patients about the current recommendations for GET and CBT. We agree it is important to review the clinical and cost effectiveness of GET/CBT and other treatments to identify the specific populations that treatments may benefit and or harm. This will enable the committee to make clear positive or negative recommendations on treatments. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. Special consideration will be given to people with severe ME/CFS throughout the guideline and addressed in every review question.
#MEAction UK	2	29	All workers for the DWP, including non-medical staff and outsourced staff, should be included. Access to appropriate benefits is a right.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators,

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				occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate. :
Hope 4 ME Fibro Northern Ireland	2	29	**Who is this Guideline for:** Add: Benefit Agencies, e.g. Department of Work and Pensions	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
LocalME	2	29	**Who is the guideline for? I**F the guideline this time is acceptable to the affected public patient/carer population, Add DWP as agreed in January engagement meeting.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a

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				remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Respect for ME	2	29	DWP staff should be included.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
LocalME	2	18,19	"People with ME/CFS have reported a lack of understanding among health and social care professionals about their illness and related problems".	Thank you for your comment. We are aware of the concerns that people with ME/CFS and agree that no one should be pressured into undertaking treatment. Section 1 has been reworded in the light of

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			Suggest adding, "People with ME/CFS have reported a lack of understanding among health and social care professionals about their illness and related problems. Children and young people and their parents can be bullied and intimidated by local authority education officers and school staff who threaten over what is considered to be "non authorised attendance. Many families are put at risk of false *allegations* of Fabricating and Inducing Illness (FII) and these cases are not reported nor is the data on numbers collated by the relevant authorities. This presents a distorted picture, and one that discriminates against mothers trying to cope under very difficult circumstances. Most patients have experienced medical professionals who dismiss their symptoms and refuse to take them seriously and dismiss and fail to investigate other problems. The guidelines should make clear that this is not acceptable.	stakeholder comments to include a lack of belief and acknowledgment rather than understanding. Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.
Welsh Association of ME & CFS Support	2	18 & 19	WAMES would like to clarify that people with ME/CFS have not just reported a lack of understanding among health and social care professionals about their illness and related problems, but also often a lack of respect and desire to listen and believe them. People with ME/CFS then often cannot access basic general care, let alone specialist care, and can suffer psychological stress, adding to their symptoms	Thank you for your comment. We are aware of the concerns that people with ME/CFS and agree that no one should be pressured into undertaking treatment. Section 1 has been reworded in the light of stakeholder comments to include a lack of belief and acknowledgment rather than understanding. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all patients and reduce any stigma. The

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				guideline will address information, education and support for health and social care professionals.
Welsh Association of ME & CFS Support	2	20 & 21	WAMES would like to add that illness does not just make school attendance difficult, but impossible, and undesirable, due to the potential for triggering a relapse, for some young people.	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.
ME Letterforce	2	26, 27	The latest research and analysis of data from these trials would suggest that CBT and GET are at best ineffective and claims of their efficiency exaggerated. It is therefore vital that NICE ensures that an immediate caveat about GET and its associated CBT to change 'false illness beliefs' is issued to all medics, including nurses, physios, Occupational therapists etc, rather	Thank you for your comment. We recognise the concern about the current recommendations for GET and CBT. This new guideline will replace CG53. We will address the clinical and cost effectiveness of treatments including GET and CBT as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to identify any specific

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			than wait till 2020, to prevent further harm. The question was raised in the Parliamentary debate of who would be responsible for future harms now that NICE is aware of the risks of serious harm but still continues to recommend them. Patients are being offered CBT and GET at NHS clinics and by private practitioners as often the only treatments, and told they will improve, but are not told of the risks including possible lifelong severe deterioration. Some patients do experience severe deterioration of their condition after these treatments, but this adverse reaction is not reported to a central agency as it would be it were a drug therapy. Some are simply discharged and not followed up by the clinics. This has led to a situation where patients cannot make an informed choice on their treatment as the information given does not include the adverse reaction rate and also because claims of their efficiency are exaggerated. Some patients who refuse CBT and GET have been discharged back to their GP and labelled as difficult or non-treatment compliant, which can	populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments.

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			also adversely affect family's opinion of the patient and family relationships. This has created This has created an atmosphere of coercion and blackmail of patients. Either they do CBT and GET or lose any chance of medical care and benefit reports and mobility aid help from NHS clinics. It is disingenuous to suggest that patients can make a decision to turn down a treatment given these circumstances. Additionally, patients who have an insurance policy to cover their ill health are sometimes told that they must do CBT and GET in order to be classed as “fully treated”. This causes delays in payment of insurance benefits or a straight refusal to pay out on a policy. Patients are not advised by the insurance company or the practitioners carrying out CBT and GET that there are risks associated with them. This has led to some patients undertaking these treatments and their health deteriorating further, therefore also increasing the cost burden to the nation.	
The Young Sufferers of ME Trust	2	26 & 27	This includes children and young people where school attendance is used to create a graded exercise/activity programme. Pressure to increase school attendance has, as reported to us, been the cause of severe and long term relapses- resulting in many years of interrupted education.	Thank you for your comment.
Royal College of	3		Please consider BAME groups – CFS/ME under-diagnosed and under-treated.	Thank you for your comment. BAME groups are included in the equality assessment.

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General Practitioners			Ediriweera De Silva RE, Bayliss K, Riste L, Chew Graham CA. Diagnosing Chronic Fatigue Syndrome in South Asia: Lessons from a secondary analysis of a UK qualitative study. Indian Journal of Family Medicine and Primary Care. 2013. Vol 2; 3: 277-282. Hannon K, Riste L, Fisher L, Wearden A, Peters S, Lovell K, Chew-Graham CA. Diagnosis and management of Chronic Fatigue Syndrome/Myalgic Encephalitis (CFS/ME) in Black and Ethnic Minority people. A qualitative study. Primary Care Research and Development. 2013;:doi:10.1017/S1463423613000145	
The ME Association	3	1-5	The guideline is also for health professionals who carry out medical assessments for DWP benefit claims	Thank you for your comment. Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Action for ME	3	6-9	Under 'Who the guideline is for', the majority of patients (52%) felt that this section was appropriate. However, a significant minority (31%) felt	Thank you for your comment and information. NICE guidelines are relevant for all settings where NHS or

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			that more groups needed to be included. Their comments consistently highlighted that a wider pool of professionals could make use of this guideline, namely those involved with benefit provision, employers and educators. Additionally, many children with M.E. who are unable to attend school have then been referred to social services. Action for M.E.'s 2017 survey found that 20% of respondents had a safeguarding referral had been made against them, commonly for fabricated/induced illness. 70% of cases were dropped within a year, and Action for M.E. is not aware of any of these referrals being upheld [Action for M.E. (2017), Families facing false accusations]. This further underlines the need for professionals outside of the health and care sector to make use of this guideline, to understand the condition and the impact it has on capability, to prevent such referrals. Therefore, this guideline would also be relevant for professionals working in social services. Action for M.E. recommends the addition of the below professionals, who are frequently involved with patients with M.E., to the list of those who this guideline may be relevant for: - Department for Work and Pensions benefits assessors and providers (including Capita, Maximus and Independent Assessment Services employees who are commissioned on behalf of the DWP) - Employers - Department of Education and individual schools	social care is provided or commissioned, including health services related to education and occupational health. This includes professionals working in social services. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate. .

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			- Social services A lack of understanding of the nature of M.E., and how it can be best managed, among these groups has caused additional hardship for those with the condition. The information in this guideline could improve their understanding of the condition and the support they offer. Naming them in this scope shows that it contains information that would enable them to better support people with M.E. in their professional capacities.	
Invest in ME Research	3	6-9	It may also be relevant for: • education services 7 • occupational health services 8 • voluntary sector organisations Also add • Chief Medical Officers especially as the current CMOs of the UK seem to know very little about ME as well	Thank you for your comment. Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate. CMOs are already included as healthcare professionals.

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Blue Ribbon for the Awareness of ME (BRAME)	3	10/12	Hope the guideline will be accurate, truly reflective and informative to enable it to be adopted universally across the UK, to enable good quality, appropriate, biomedical care, for all those living with ME	Thank you for your comment.
The Young Sufferers of ME Trust	3	2	Need to include all local authority teams that deal with education, absence and alternative provision. Clear information on the fact that this is a chronic illness with no known timescales for recovery will help families access appropriate long term support allowing their children to receive a suitable education. Fluctuating attendance is common in children with ME and education professionals/education welfare officers/children missing from education teams/children and families teams need to be made aware that this is a common issue, made worse by inappropriate education demands.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Blue Ribbon for the Awareness of ME (BRAME)	3	3	Need good guidance for all in this section - but need it for commissioners as patients have great problems in trying to get an appropriate service for ME in their area – despite following all appropriate actions and pathways to achieve it – can give examples of enormous problems with commissioners – there is a national inequality of care for people with ME	Thank you for your comment. Commissioners are included in this list.
LocalME	3	3	"Commissioners - add- Governing bodies and Senior Officers of CCGs. **Public Health England, NHS England and NHS Improvements,** care agencies and private care providers, Faculty of Occupational Medicine,	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care

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			NHS Choices, (Bazian the company who coordinate), **NHS Health and Work, The Council for Work and Health**, Insurance occupational health medical advisors and the DWP and their third party companies, ATOS, CAPITA and MAXIMUS; All Royal Colleges, RC GPs, RC Psychiatrists and RC Surgeons, Nurses, Anaesthetist, Continuing Health Care assessors., Alternative Educational Needs providers who oversee Education and Health Care plans- required under the 2014 Children and Families Act, Local Authority Safeguarding staff – the media and Science Media centre likewise.	organisations and professionals. Commissioners, governing bodies and senior officers of CCGs are included here. . In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Stonebird	3	3	**P3 line 3 it is important that Commissioners are made aware that ME is not MUS, as specifically and wrongly stated in a Joint Commissioning Panel for Mental Health Report, disseminated to Health Commissioners in 2017. Commissioners need to have the correct information that ME is not MUS and this new Guidance needs to ensure that this is so.** Much of the current literature on "CFS/ME" incorrectly suggests that ME is a functional somatic syndrome. That has caused untold damage and distress to countless people with ME over the years, who have been abandoned by the Health Service, left to cope, on their own, often for	Thank you for your comment and this information. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. The use of the term 'ME/CFS' in the scope does not imply acceptance of any particular definition or meaning and does not pre-judge the terminology of the completed guideline this will be the task of the committee.

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			decades on end, with no tests, treatment or hope, this must surely be acknowledged by NICE.	
Royal College of Paediatrics & Child Health	3	4	People with suspected disease can be excluded as it may not be relevant to involve them until sure about the diagnosis.	Thank you for your comment. We have used this term to ensure we can include people who are waiting for a diagnosis. Diagnostic criteria can mean people are not given a diagnosis until they have problems for six months or much longer.
Blue Ribbon for the Awareness of ME (BRAME)	3	6	Change 'may' to 'will'	Thank you for your comment. NICE guidelines are for health and social care and do not have a specific remit outside this.
Buckinghamshire Healthcare NHS Trust	3	6	Change to: **It is also relevant for:**	Thank you for your comment. NICE guidelines are for health and social care and do not have a specific remit outside this.
Forward ME	3	6	Delete 'may', insert 'will'	Thank you for your comment. NICE guidelines are for health and social care and do not have a specific remit outside this.
Healthwatch Bolton	3	6	Remove "may also be relevant" and insert "will also be vital"	Thank you for your comment. NICE guidelines are for health and social care and do not have a specific remit outside this.
LocalME	3	~~6~~	Suggest- It is **essential that the following have due regard for the revised guidance.**	Thank you for your comment. NICE guidelines are for health and social care and do not have a specific remit outside this.

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ME Letterforce	3	6	Care agencies could also be included	Thank you for your comment. NICE guidelines are developed for the NHS and make recommendations for health and social care organisations and professionals. Social care agencies are included.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	3	6	Might the guideline also be relevant for DWP and health insurance assessors?	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Royal College of General Practitioners	3	6	Guidance may also be relevant to the Department of Work and Pension DWP and insurance companies	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector

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				organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Royal College of Occupational Therapists	3	6	Should it also be relevant for the Department of Work and Pensions in relation to assessments of health related benefits, such as ESA and PIP. Patients often comment that assessors have no knowledge or understanding of this condition and its fluctuating nature so the Guideline could help support better understanding and accuracy of assessments through recognising the functional implications.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
The ME Association	3	6	The guideline will also be relevant for (not may also be)	Thank you for this suggested wording. This is standard wording in this section of NICE scopes.
Welsh Association of ME & CFS Support	3	6	WAMES suggests that the guideline may also be relevant for Benefits assessors.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a

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				remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Buckinghamshire Healthcare NHS Trust	3	7	Education services; improving access to home schooling, home tuition and distance learning	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Parents of children with ME/CFS	3	7	The new guideline will be relevant for education services. This group should be added to the list of people for whom the guideline is relevant, not the the list for whom the guideline may be relevant.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a

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Support Group				remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
The Young Sufferers of ME Trust	3	7	As inappropriate education demands are frequently a key cause of relapse for children and young people, examples of good practice in education should be covered, e.g. access to home-based education (whether elective home education or local authority tutors at home), online learning, school sending work home, part time timetables, reasonable adjustments or a mixture of these and more. Pupil Referral Units (PRUs) are often inappropriate environments for educating children with ME due to the sensory issues experienced by many children and young people with this condition – e.g. sensitivity to noise, light and sound. Specific consideration needs to be given to Education Health and Care Plans and how fluctuating conditions are catered for within these.	Thank you for your comment and information.
Parents of children with ME/CFS Support Group	3	8	The new guidelines will be relevant for occupational health services. This group should be added to the list of people for whom the guideline is relevant, not the the list for whom the guideline may be relevant.	Thank you for your comment. Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. We recognise that

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				occupational health services are important and include them in the section,' who the guideline may also be relevant for'. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
The 25% ME Group	3	2 and 8	Occupational health services appear twice (once on each list)	Thank you. The first point related to professionals working in services, the second to services themselves.
LocalME	3	13	**The equality statement** does not deal with issues and ``'barriers to access" for those with ME, such as light and noise sensitivity, or difficulties with sleep cycles and low, blood pressure brain fog on rising and difficulties early in the day in the mornings, For example, ensuring access to buildings, places to rest, having meetings and appointments at ME suitable and friendly times. Use of telemedicine is limited. Severe ME patients, who represent an estimated 30% of the ME population, are denied home visits even by GPs let alone consultants. Some Equipment in hospitals is not adapted to patients who cannot sit up even if well enough to get to hospital by stretcher. Few hospitals can accommodate very severe ME patients needs with e.g. light, noise, chemical sensitivities.	Thank you for your comment. We have added more detail to the equality impact assessment following stakeholder consultation.
Parents of children with ME/CFS	3	13	The draft scope currently excludes equality for children and young people aged 16 and under who face significant inequalities in accessing effective paediatric support and education services, and who were not identified in the equality impact assessment. We argue that equality of	Thank you for your comment. The scope does not exclude equality for children and young people. We have added more detail to the equality impact assessment following stakeholder consultation.

Stakeholder	**Page no.**	**Line no.**	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
Support Group			service based on age should be addressed in the new guideline, to support the special consideration listed in the draft scope on page 3, line 24.	
Parents of children with ME/CFS Support Group	3	13	We argue that the draft scope for the guideline should also look at inequalities relating to people with ME/CFS who have been harmed by medical treatments from Cognitive Behavioural Therapy and Graded Exercise Therapy in the previous NICE guideline, as there is the potential for them to receive ongoing discrimination once the new guideline is in place. Many of these people have a severity of symptoms such that they cannot travel for healthcare appointments and face discrimination due to the lack of understanding about home visits being required, and this will support the special consideration listed in the draft scope on page 3, line 25.	Thank you for your comment. We have added more detail to the equality impact assessment following stakeholder consultation.
Science for ME	3	13	The equality statement does not deal with issues of access for those with ME. For example, ensuring access to buildings, places to rest, having meetings at ME and travel friendly times. Or allowing members of the GDG to attend meetings on line.	Thank you for your comment. We have added more detail to the equality impact assessment following stakeholder consultation.
The 25% ME Group	3	13	We endorse the submission of the Forward-ME group in this regard. We would add that access to 'wait and return' stretcher service for out patient appointments can be vital for people with severe M.E. This is a further example of the type of practical issue that requires to be robustly addressed in the forthcoming guideline if equal access to health and social	Thank you for your comment. We have added more detail to the equality impact assessment following stakeholder consultation.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			care is to be achieved for people with M.E., particularly those who are most severely affected. Lack of reasonable adjustments to facilitate access to services can result in patients not attending hospital and other healthcare appointments, not seeking investigation for red flags, not participating in screening programmes with all the potential adverse consequences this entails. The current vogue for 'reablement' as a first line/default response to expressed need for care, including as a means of 'assessment' is of huge concern. Despite raising such concerns with NICE when developing relevant guidance the resulting guideline - NG74 Intermediate care including reablement - signally fails to provide any protection for people with ME. The consequences of the above can be dire. As submitted to the consultation on NG74: "Viewing 'reablement' calls as part of an assessment creates a paradox whereby people are having workers in to 'assess' whether or not they require care support, with a starting point being that this requires to be demonstrated in this way, and only in this way. This is both flawed in principle and can be highly dangerous in practice. Case example from M.E. support: 'We were called for by a woman with ME and other conditions. She was sound and light sensitive and had lost several stones in weight and was not coping with eating. Had fridge and freezer stocked but too weak to eat.	

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			We asked for an assessment of her condition and she was allocated two Carers to see her for 6 weeks reablement. The only way to get her any kind of help. They encouraged her to engage with them in the kitchen to prepare food despite her extreme weakness and grossly swollen legs. The reablement had to run for 6 weeks before future help would be decided so Social Services would not discuss her needs further. She regularly called out the ambulance for severe breathing condition CPOD but would not go into hospital with them because of previous experience of A&E's noise and bright lights. We prepared her for admission to hospital. Only way was through A&E, so called GP. GP would not have her admitted even though we could see she was dying (weighed less than 5 stones). Finally Carers visited and found her unconscious, admitted straight to Ward and medical staff asked where she had been and why she was not admitted earlier. Fought to save her for a week and she then died."	
The ME Association	3	13	Equality considerations: Should also refer to access to dentists, opticians etc	Thank you for your comment. We have added more detail about access to services to the equality impact assessment following stakeholder consultation.
#MEAction UK	3	14	The Equality Impact Assessment is worryingly inadequate. While considering inequality relating to ethnic origin is welcome, this guideline must also legally consider inequality relating to disability (including of course ME itself), gender, LGBTQI+ status, and age. ME affects more women than men, in an approximate ratio of 4:1. It is shocking that these	Thank you for your comment. We have added more detail to the equality impact assessment following stakeholder consultation.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			considerations have been ignored given the history of ME and the intersecting oppressions of people with ME.	
ME Research UK	3	14	In addition to addressing people living in rural areas, there is no mention in the equality impact assessment of the 'severely affected ME/CFS sufferers' who cannot access medical services, including dentistry and ophthalmic services. There is also a lack of access to mental health services for ME/CFS sufferers with anxiety as a result of extensive periods of social isolation or absence from large parts of developmental life due to suffering severe ME/CFS, and who may have been fearful of requesting assistance due to the (mistaken) belief that all psychologists view ME purely as a psychological problem.	Thank you for highlighting this issue. We have added more detail about access to services to the equality impact assessment following stakeholder consultation.
Respect for ME	3	14	The equalities section is insufficient. At least one study showed higher-than-average rates of ME in Nigeria (https://www.ncbi.nlm.nih.gov/pubmed/17439996) and another showed increased rates among UK Pakistani patients in particular and all BAME patients in general (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3072345/) compared to their white peers. These studies, and other factors such as language barriers and prejudice, may mean BAME communities need particular consideration. We are also concerned that issues of gender identity and sexuality may create barriers to accessing treatment (or may confound hormone therapies) for LGBT people. ME patients often report being refused tests and referrals because they are considered to be	Thank you for your comment. NICE recognises the duty to consider all protected characteristics and the equality assessment form outlines how those characteristics are considered at all stages of guideline development. BAME groups were raised at stakeholder workshop as a group requiring specific consideration and are included in the equalities assessment.

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			malingerers or hypochondriacs, which is ableism. NICE has a legal duty to consider all protected characteristics in its scope.	
VIRAS	3	14	"NICE has carried out an equality impact assessment during scoping. The assessment: lists equality issues identified, and how they have been addressed" The assessment omits the single most significant cause of inequality encountered by patients and its omission is of concern. Patients with M.E. and CFS have been subjected to 30 years of discrimination in every area of their lives. They encounter micro and macro discrimination in medical care, social care, the benefits system, in the media and in society. They have been denigrated, marginalised and bullied. NICE contributed to this discrimination by recommending treatments which do not help patients and which have harmed some. By recommending Graded Exercise Therapy (GET) and Cognitive Behaviour Therapy (CBT), NICE confirmed to medical professionals, the media and the public that patients are only suffering from 'deconditioning' (laziness) and irrational 'illness beliefs' (hysteria, hypochondria), in other words, they have a trivial, subjective illness which they would not have if they 'pulled themselves together'. **E.g.: Three and a half years after the 2007 NICE guideline was published and when it had long been in effect, the PACE Trial (2011) report was published in the Lancet. National newspapers**	Thank you for your comment. The equality assessment specifically addresses characteristics protected under the equality law and people affected by health inequalities and inequities in access to health, public health and care services associated with socioeconomic factors and with other forms of disadvantage. The guideline update is being undertaken to ensure the most up to date evidence is used to inform care. The guideline will address the management of ME/CFS and will include GET and CBT. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The [NICE guidelines manual] does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We hope that a new guideline with more up to date reviews of evidence will improve understanding

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			reported it with these headlines: The Daily Mail: "Got ME? Fatigued patients who go out and exercise have best hope of recovery, finds study" The Independent: "Got ME? Just get out and exercise, say scientists" The Guardian: "Study finds therapy and exercise best for ME" The Telegraph: "Exercise and therapy can help ME sufferers, study claims" The Daily Express: "TRIAL OFFERS HOPE FOR ME SUFFERERS" The Daily Record: "Exercise and therapy can reverse effects of ME" These false claims have compounded and perpetuated discrimination against patients and it should be noted: the PACE Trial report was NOT in contradiction of the 2007 NICE guideline. NICE may not want to address this elephant in the room – but it must, because their task is not simply to educate the medical professions and the public, it is their duty to reeducate them. Judging from the draft scope, this will not happen unless NICE themselves are reeducated and can ensure that the guideline development committee avoids repeating this historic prejudice and discrimination. NICE have not yet "carried out an equality impact assessment", because if they had, then this horrible discrimination and inequality would have been identified.	and care for patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals. We have updated the equality impact statement following scope consultation.

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Welsh Association of ME & CFS Support	3	14	WAMES wishes to see the Equality Impact statement acknowledge the wide range of challenges facing people in rural settings, including variable access to broadband and mobile phone coverage. *Children* should be included for the same reasons given for men and older people. Children younger than 15/16 rarely visit the GP alone, so they rely on the support and understanding of their parent/carers/guardians to get a diagnosis and access appropriate health, education and social care, which is not always available to them. There is also the question of functional disability and lack of mobility making it difficult for moderately and severely affected people with ME/CFS to access care. Also, the high proportion of females experiencing ME/CFS can result in the illness being disregarded by some professionals as 'merely a women's issue'. Many women have experienced gender bias when seeking care and support.	Thank you for your comment. We have updated the equality impact statement following scope consultation.
Blue Ribbon for the Awareness of ME (BRAME)	3	16	How much has the equality issues addressed those who are severely affected, who are basically invisible because they are house/bed bound for most of the time, and have often dropped through the cracks in the system, and taken into account the impact on their daily lives without access to medical services, home visits, dentists, opticians etc. It is important to ensure the severely affected voice and evidence is truly heard and reflected during the guideline process and in the final	Thank you for your comment. We have updated the equality impact statement following scope consultation.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			guideline, especially as there is very little research done into the severely affected. It is also vital that the voices and evidence of children and young people with ME are heard and reflected in the guideline, as this is again another group for whom there is very little research done. General equality issues should be addressed and an all-inclusive policy adopted and followed	
Forward ME	3	16	The Equality Impact Assessment is perfunctory, being confined to identification of certain groups in respect of whom "there are challenges for these groups to be identified and diagnosed with ME/CFS" followed by a glib assurance that "these groups are not excluded from the scope". If equality is truly to be achieved, the guideline will require to think through a suitable NHS approach to people with ME in these groups *with regard to other health issues*. For example, the need for pregnant women with ME to have due cognisance taken of their ME in terms of pre- and neo- natal health care, as well as at the time of delivery, similarly, for transgender ME patients, presence of ME has to be factored in – the person cannot tolerate hormone treatment as a person without ME would. There are Equality Issues which apply to all: the core issue of having ME *is in itself a potential barrier* to the achievement of Equality. Most fundamentally, there are the challenges for *any* ME patient to be diagnosed with ME.	Thank you for your comment. We have updated the equality impact statement following scope consultation.

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			There are also 'challenges' for the health and social care needs of any person with ME to be factored in when providing for the other health needs, and the home care needs. People with ME lack access to suitably delivered healthcare, and many live in dread of requiring hospital treatment, for example, due to the impact of the hospital environment (light, noise and other stimuli) on their ME. Similarly, some very sick people do without home care and suffer neglect of most basic care needs in consequence of failure of home care providers to deliver care in a manner that does not exacerbate ME. The current vogue for 'reablement' as a first line/default response to expressed need for care, including as a means of 'assessment' is of huge concern. Despite raising such concerns with NICE when developing 'reablement' guidance (NG74 Intermediate care including reablement) the resulting advice signally fails to provide any protection for people with ME. The equality issues failed to identify the fact that the severely affected, wherever they are located, do have difficulty with access to paramedical services such as dentists, opticians and podiatrists, for example. Such services are required on a domiciliary basis for all but the least severely affected or those in remission. In respect of hospital outpatient appointments, social care has a role in assisting. This is a significant unmet need for people with ME who lack family or other informal support. In this, as in other respects we would wish to see joined-up thinking on NHS and social care roles when the guideline id developed.	

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	3	16	Patients significantly disabled by their illness suffer inequality accessing care. They may be too unwell to travel to appointments without serious harm, or to travel at all. There needs to be provision made for them to access specialist care, including for the initial assessment, for example via phone calls, email, skype, home visits.	Thank you for this information. We have updated the equality impact statement following scope consultation.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	3	16	Many with moderate, severe and very severe ME/CFS will be too unwell to contribute to this guideline review through the usual processes. Steps should be taken to find out what adaptations would be necessary to enable them to do contribute, and they should then be implemented.	Thank you for your comment. We recognise that people with ME/CFS need adaptations to allow them to contribute and are working with the public involvement programme to ensure appropriate adaptations are made.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	3	16	Ethnic minorities may suffer the same disadvantages, but also have to contend with the added problem they might have (which was a problem gleaned in a conversation as a patient advisor with highly experienced researcher who had read a variety of studies that suggests) "ME/CFS is common in ethnic groups but very few are being diagnosed in specialist clinics." When further clarification was sought, regarding why this happens the answer elicited	Thank you for your comment. BAME groups were raised at stakeholder workshop as a group requiring specific consideration and are included in the equality impact assessment.

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			was that perhaps they describe their symptoms differently to GPs, OR the GPs do not listen to these patients, OR they (GPs) make mistaken assumptions about what is going on. This therefore means they get even less access to help, support or intervention or could possibly be even airbrushed from subsequent research studies. This needs to be addressed; if it is not, it could lead to a skewing of data by the non-representation of the ethnic minorities. Which could subsequently mean there is no evidence of what happens to them and when researchers use clinics where there are no such patients assessed, clearly the data they collect is non-representative of the ME Community as a whole. The question is what is the view of NICE on this topic. Do they feel this needs to be addressed? If so how? Could the answer be the need for more clinics in the areas where there are more ethnic minorities or could charities help to provide access to more of this group of people?	
Welsh Association of ME & CFS Support	1 & 2	26 - 7	WAMES finds the summary of the research situation for ME to be expressed too negatively. While full answers have not been revealed yet, many clues have been uncovered and this is ongoing, if underfunded. The biomedical direction that research is taking should shape the attitudes of health professionals and the approach to diagnosis and management, thus removing the stigma and disbelief currently hampering doctor/patient relationships. We propose:	Thank you for your comment. This section has been reworded in the light of stakeholder comments. We are aware there are other areas of ongoing research and have added other examples. This list is not intended to be definitive and are examples of possible areas.

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			The search for the aetiology of the condition is progressing worldwide, with major research groups finding clues in areas such as immune function, autonomic function, neuroendocrine disorders, gene expression, neurobiology and the microbiome for biomarkers, pathogenesis and possible treatments. Sports scientists have extended their exploration of exercise intolerance to include the ME experience and a number of groups are investigating the ongoing dysfunction in the body, following physical and mental activity. This, and the likelihood of subgroups of patients with variations in pathology, has significant implications for management and treatment – one size will not fit all. *An incomplete understanding of the nature of ME/CFS and the wide range of patient experience has led to a number of different symptom-based definitions being used in research and in clinical care, which, when applied and compared to each other produce different, but overlapping patient groups.*	
Hope 4 ME Fibro	3	20	**"Who is the Focus?"**	Thank you for bringing the needs of these patients to our attention and for suggesting how these needs should be met. Section 1 has been reworded to clarify

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Northern Ireland			When considering ME as a whole, we suggest it is best to start with a consideration of Severe ME. It seems appropriate that ME guidelines should be written in with the aim of preventing those who have either Mild or Moderate ME from having their illness progress to Severe ME. This approach should be similar to how people presenting with minor symptoms of early cancer, are given appropriate treatment, and due respect, whilst their ongoing care is aimed at either curing the cancer or preventing the cancer from progressing. The potential for any ME patient to have their ME presentation progress to the severest form of ME should now be forefront in any discussion on ME care. Please can the draft scope include a statement such as the following: "**The severest presentations of ME can result in patients existing in an almost comatose state for extended periods of time (sometimes years). These patients can: experience intermittent paralysis; unremitting pain; require tube-feeding; need 24-hour nursing care; be intolerant of light and sound; and generally, exist in a state described by many such patients as a "living death". It is therefore essential that all ME patients are treated with the due respect, concern and care offered to patients with other similarly devastating diagnoses."**	the care needed for people with severe ME. Special consideration will be given to people with severe symptoms throughout the guideline.

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Royal College of Psychiatrists	3	21	Black and ethnic minority groups should also be considered as they are underdiagnosed and undertreated. Carolyn Chew-Graham has published on this. See also: Chronic fatigue syndrome: comparing outcomes in White British and Black and minority ethnic patients after cognitive-behavioural therapy. Ingman T, Ali S, Bhui K, Chalder T. Br J Psychiatry. 2016 Sep;209(3):251-6.	Thank you for your comment. BAME groups were identified by stakeholders during stakeholder workshop and are included in the equality impact assessment.
Royal United Hospitals Bath NHS Foundation Trust	3	21	Groups to be covered should also include those who suffer with chronic fatigue even though this maybe secondary to other acute /chronic conditions. The chronic fatigue maybe the most debilitating factor and they should not be excluded from specialist support.	Thank you for this suggestion. The guideline intends to provide recommendations for people with ME/CFS. . It will be beyond the resources of this guideline to develop recommendations for people with chronic fatigue associated with other disorders e.g. multiple sclerosis and heart failure. Recommendations on management of fatigue associated with MS are already included in the MS guideline.
South London & Maudsley NHS Foundation Trust	3	21	Black and ethnic minority groups should also be considered as they are underdiagnosed and undertreated. Carolyn Chew-Graham has published on this. See also: Chronic fatigue syndrome: comparing outcomes in White British and Black and minority ethnic patients after cognitive-behavioural therapy. Ingman T, Ali S, Bhui K, Chalder T. Br J Psychiatry. 2016 Sep;209(3):251-6.	Thank you for your comment. BAME groups were identified by stakeholders during stakeholder workshop and are included in the equality impact assessment.

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LocalME	3	22	What is the focus?- those that meet the Canadian International Consensus diagnostic criteria. Important at delay in diagnosis causes harm. • **International Consensus Criteria (ICC) for ME-** Immediate diagnosis **Institute of Medicine (IOM) Report** Beyond ME aka Systemic Exertion Intolerance Disease (SEID) IOM is now National Academy of Medicine- Six months wait period	Thank you for this suggestion.
Royal College of Occupational Therapists	3	22	Should the guideline also not cover or at least refer to 'post viral fatigue syndrome' as some people who are in a subgroup of CFS/ME may be excluded from gaining appropriate help under the guideline by its exclusion.	Thank you for this suggestion. One of the tasks for guideline development is to consider diagnostic criteria. There is not an intention to specifically exclude post viral fatigue.
The 25% ME Group	3	22	We would prefer to see a guideline that delineates M.E., facilitating specificity of diagnosis and congruent care recommendations - guidance on both being urgently required. This implies that the guideline should not set the bar at relating to "people with suspected ME/CFS". It should strive to permit, through it's application, the relevant diagnosis to be confidently confirmed, or not.	Thank you for this suggestion. One of the tasks for guideline development will be to consider diagnostic criteria and the use of the term 'ME/CFS' in the scope does not imply acceptance of any particular definition or meaning and does not pre-judge the terminology of the completed guideline.
The ME Association	3	22	Re People with suspected or diagnosed ME/CFS: I raised the issue of post-viral fatigue syndrome (PVFS) during the scope stakeholders meeting. The name PVFS is often used to describe people who are taking longer than usual to recover from an acute infection and who may (or may not) progress to developing ME/CFS. The new guideline needs	Thank you for your comment. The issues you outline are recognised and there is not an intention to specifically exclude post viral fatigue.

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			to address the diagnosis and management of people with a PVFS (as did the Chief Medical Officer's Working Group report on ME/CFS) and how to decide when and how an often short but self-limiting PVFS is/may be developing into ME/CFS.	
The Pernicious Anaemia Society	3	22	The symptoms of ME/CFS are almost identical to those of Pernicious Anaemia which should be suspected especially if there is a family history of the disease in the past when diagnosis was much better.	Thank you for your comment and this information.
Action for ME	3	24	As well as specifically considering children and young people in the guideline, the scope also ought to give the NICE guideline committee the remit to consider the transition from paediatric services to adult services. Action for M.E. often hears from children who either do not receive care when they reach adult age, or who find themselves routed to inappropriate support for their life stage. For example, one young person in an adult service kept on receiving advice on how to manage employment, despite continuing to point out that they were still attending school. Therefore, they missed out on the support that could have targeted their specific educational needs.	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults' services for young people using health or social care services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
British Dietetic Association	3	24	Children and young people can often present with changed and restricted eating behaviours due to nausea and other reasons (many reasons not understood), the resulting inadequate nutritional intake can impact on growth. Due to this impact, the consideration and inclusion of nutrition and eating for children and young people is important for the scope of these guidelines	Thank you for your comment. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.

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Hope 4 ME Fibro Northern Ireland	3	24	**Children and Young People:** Please also see our comment #10	Thank you for your comment. The study referenced here refers to fatigue and it would be inaccurate to replace it with ill health.
Royal College of Psychiatrists	3	24	Children and young people can face particular challenges at transitions of care to adult services.	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults' services for young people using health or social care services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
South London & Maudsley NHS Foundation Trust	3	24	Children and young people can face particular challenges at transitions of care to adult services.	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults' services for young people using health or social care services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
Action for ME	3	25	54% of survey respondents felt the section on groups and settings was appropriate, while 28% felt that changes were needed (18% did not have a strong opinion). While patients welcome the need to address severe M.E., the NICE committee developing this guideline need to be aware that the different groups of severity are not discrete. As one patient explains: "*All those who have the illness should be treated with the same degree of*	Thank you for this information. The reason to specifically mention people with severe ME is because it was suggested they had specific needs. This does not imply a view that groups are discrete.

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			care. Without that those in the moderate to severe range could become or are becoming worse through lack of care. The distinction between moderate and severe was not an accurate representation of what the illness is like. Some of us go between moderate and severe verging more to the severe end depending on the time of year of other health issues on top". Severe patients do need particular consideration, given the extra burden the disease places on them and the acute lack of research and understanding of severe and very severe M.E. The scope ought to additionally recognise that the severity of a person's condition is on a spectrum and that the guideline's recommendations for each level of severity cannot be treated as completely distinct.	
British Dietetic Association	3	25	Those with severe symptoms often are at very high risk of poor or inadequate nutrition for many reasons. Dietetic input as part of the pathway is very important to reduce the impact of an often compromised and very poor nutritional intake. Nutritional monitoring in this group is an integral part of their treatment.	Thank you for your comment. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.
Hope 4 ME Fibro Northern Ireland	3	25	**People with Severe Symptoms:** Please also see our comment #13	Thank you for your comment. Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a

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				wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	3	25	Including severe patients is very important. Severe illness is not just an exaggerated version of moderate illness but can have an entirely different set of symptoms. It is important that assumptions are not made about the experiences of these patients. Engagement with these patients directly as well as through charities is vital. Consideration must be given to how to do this effectively given the severe physical and cognitive difficulties experienced. The details of how this will be done need to be documented in the draft scope (in itself derived from dialogue with severely affected).	Thank you for your comment. We are exploring ways of involving people with severe ME and enabling them to share their experiences with the committee.
Stonebird	3	25	**P3 line 25 'people with severe symptoms' is not a satisfactory term that will acknowledge or keep people with a Severe ME diagnosis safe.** They do not just have severe symptoms, they have a Severe ME diagnosis, the prognosis of which is unlikely to significantly improve after 5 years. To just refer to " people with Severe symptoms" is to shut out people with Severe ME from recognition and the possibility of appropriate health care. It will not enable the Guideline to recognise their specific needs.	Thank you for your comment. We have reworded this to 'people with severe ME/CFS'.

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			The Severe ME illness experience including all the range of severe symptoms possible, needs to be fully specified, so that people are safe. There needs to be a statement of realistic prognosis and the need for long term care, not a continuing pretense that people will improve, given there is no universal treatment or cure. If guidance is to be produced for this profoundly disabled and ill group of people, it must be safe and respect their disease experience. The experience in hospital as inpatient and outpatient must be improved through accurately portraying Severe ME and the real level of illness. This must be enabled by the Scope asking the right questions and providing the right information.	
The 25% ME Group	3	25	A specific focus on severely affected M.E. patients will be welcome. However, please reword this proposal. All people with M.E. experience "severe symptoms". The requirement is to produce a guideline that adequately covers the care needs of the most severely affected patients, whose suffering is extreme. We would argue that the primary focus should be on the most severely affected patients, on the basis that if the guideline gets it right for the most severe then the needs of less severely affected patients will de facto be covered.	Thank you for your comment and suggestion. We have reworded this to people with severe ME/CFS. People with severe ME/CFS will be considered in every review in the guideline and separate recommendations will be made where this is appropriate. This will ensure that all people with ME/CFS have their care needs covered.
The 25% ME Group	3	25	The emphasis on "symptoms" here - as in other parts of the draft scope - tends to the 'reification' of symptomatic manifestation. In other words,	Thank you for your comment and suggestion. We have reworded this to people with severe ME/CFS.

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			viewing symptoms as entities in themselves, rather than rooted in underlying disease. We suggest that "people who are most severely affected by this illness" would be appropriate	
The 25% ME Group	3	25	It is essential that guidance on appropriate care for severely affected patients has a high profile, including when presented on the NICE website. At present, when health professionals consult the 'NICE' website for guidance on this condition the on line presentation omits crucial awareness raising guidance on severely affected patients. For example, in the full version of CG53 the chapter specifically titled 'People with Severe CFS/ME' contains this guidance "People with severe CFS/ME may face many difficulties in achieving adequate and balanced dietary intake including … *[list follows].* The healthcare professional should work with the patient and carers to address these problems. In some extreme cases, this may include the use of tube feeding, if appropriate." However this Chapter begins over 300 pages into the document, which is now construed as 'evidence' (https://www.nice.org.uk/guidance/cg53/evidence) It is very difficult to find, unless you first know what you are looking for (and even then not too easy). Few if any professionals are aware of it, in our experience.	Thank you for your comment and suggestion. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
The ME Association	3	25	Re severe ME/CFS: We believe it is essential that, as with the new guidance from the CDC on ME/CFS, there is a separate section covering issues that are specific to people with severe ME/CFS. These include	Thank you for your comment and suggestion. People with severe ME/CFS will be considered in every review in the guideline and separate recommendations will be

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			on the need to some form of on-going monitoring by a health professional. This monitoring must include nutritional status, provision of adequate support in relation to all types of care needs; provision of home visits from the primary care team; advice and help relating to appropriate disability aids and appliances; suitable out-patient and in-patient facilities for those who require hospital care.	made where this is appropriate. This will ensure that all people with ME/CFS have their care needs covered.
Healthwatch Bolton	3	24 & 25	Please see general statement at end	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. Thank you also for outlining potential practical areas that help children and their families. Special consideration will be given to children and young people throughout the guideline and addressed in every review question. The guideline will address diagnosis and management in children and the recommendations should allow for review of existing practices.
LocalME	3	21,22, 23	***How*** will these groups, **Children and people with severe symptoms** be "covered"; be delivered, without some means of sanctions against CCGs and providers,; many who are private limited companies	Thank you for your comment and information. The commissioning and audit of services is not part of

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			operating as Community Interest Companies and say are not subject to normal public scrutiny or accountability? A proper audit of commissioning of services, commissioning and outcomes data should be provided by partners, NHS England and NHS Improvements to assist NICE with their task. NHS Public Health input data and Needs Assessments could help NICE's task. This is what happened in Norfolk and Suffolk where there exists a clear audit trail and available data to feed into NICE. Full NHS Public Health Needs Assessment and New Service Specification https://docs.google.com/file/d/0B1KcCpwxF0UHNkpLejk4NlZSTDg/edit If some sort of audit or surveillance is not done, NICE guidance will evaporate into the ether with no one accountable for the consequences to patients with ME and their carers. Http://nandsme.blogspot.com/search?updated-max=2017-08-17T13:09:00%2B01:00&max-results=7 http://nandsme.blogspot.com/p/the-story-so-far.html	NICE's remit although the resource impact team do provide tools to support clinical commissioning groups.
Parents of children with ME/CFS Support Group	4	general	Many comorbid conditions need to be considered alongside ME/CFS. For example, Postural Tachycardia Syndrome (PoTS) comorbidity is high with ME/CFS and has a higher prevalence in children and young people. Other common comorbid conditions include Ehlers-Danlos syndrome, Hypermobile Ehlers-Danlos Syndrome, migraines and restless legs syndrome. It is important that comorbid conditions are identified and managed holistically, as having ME/CFS affects the treatment of many comorbid conditions.	Thank you for your comment and suggestion. The guideline will not consider the specific treatment of comorbid conditions but the committee will take these into account when appropriate.

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Invest in ME Research	4	6-16	We will look at evidence in the areas below when developing the guideline, There should be a point 7 7 Information, education and support for schools and educational institutions	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
The ME Association	4	6-16	As was raised during the scope stakeholders meeting, management of ME/CFS is not just about providing information and guidance on activity management and symptom control. It is also about improving the general well-being of people with this illness So, an equally important part of any management plan, which some health professionals are reluctant to be actively involved with, includes provision of DWP benefits (Employment and Support Allowance and Personal Independence Payment in particular), provision of disability aids and appliances where appropriate, support for those who are still able to continue with some form of education or employment, social and respite care for those who are severely affected. These are very important	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations

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			aspects of management aimed at improving quality of life and need to be included in the new guideline.	outside of the remit of the guideline would use the recommendations where appropriate. The guideline includes a question on the self-management of people with ME/CFS which may address some of the areas you have highlighted.
LocalME	4	6- and 12	**Key area "Monitoring and Review"-** NICE needs to specify a minimum standard for monitoring and review. At our local clinic there is a re referral rate of 30%. this is because the clinic does not offer ongoing care and GPS do not have the expertise to care for these patients	Thank you for your comment and suggestion. The guideline has draft questions that address the most clinically and cost effective method of monitoring and reviewing people with ME/CFS.
Healthwatch Bolton	4	17-21	Particular attention needs to be paid to sensitivity to medication, using caution in initial dosage, close monitoring for reactions. Off-licence prescribing can be useful, if carefully considered and discussed with the patient. Individual symptoms should be treated.	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
The 25% ME Group	4	17-21	Because of the absence of much research evidence of the use of drugs for symptom relief in M.E., a pragmatic approach using drugs that may not be licensed for this condition is justifiable, based on pharmacological principles and the judicious use of therapeutic trials. To do otherwise is to condemn patients to what may be quite unecessary suffering. Medications may have a logic as to why they may help certain symptoms, on the basis of the pharmacology of the drug and with an understanding of what underlying pathophysiology may be contributing/causing the symptoms that the physician is attempting to treat. Clearly this would imply that medication introduced on a 'trial' basis	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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			for a period in respect of the patient concerned, so that the patient is not left on the medication if it proves ineffective.	
Welsh Association of ME & CFS Support	4	17-21	WAMES understands the need for a strong policy governing which drugs should be prescribed, to avoid harm, however, as no drugs have been licensed in the UK for ME/CFS we are concerned that experienced medical specialists should be able to exercise their clinical judgement, particularly with regard to antiviral medication and future drugs which are licensed in overseas countries ahead of the UK..	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols..
Action for ME	4	22-25	When asked about the section 'Activities, services or aspects of care', 40% of patients surveyed felt that changes were needed. In their comments, people raised two common concerns. We have addressed the first concern here, with the second concern addressed in comment 11. Firstly, patients highlighted that the information included in the related guidelines may not be appropriate for a person with M.E. For example, one person said "*when prescribing medication, [health professionals] need to think about the fact that people with M.E. are often highly sensitive to drugs and will need to be prescribed a lower dose*". Another said "*pain may need to be managed differently with M.E. than other illnesses*". While the related guidelines do address some of the symptoms of M.E., there is a need for some information in the M.E. guideline to highlight the ways in which patients may require adjustments to the general care and support on offer. This ought to be included clearly so that practitioners	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. The recommendations in NICE guidelines are arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. The guideline does not override the responsibility to make decisions appropriate to the

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			know that they cannot use the related NICE guidance wholesale and must consider the individual needs of their patient.	circumstances of the individual, in consultation with them and their families and carers or guardian.
Welsh Association of ME & CFS Support	4	22-25	WAMES supports the indication that the management/ treatment advice contained in the guidelines of comorbid conditions may not always be appropriate for people with ME/CFS. It may be unclear at this date whether symptoms reflect a comorbid condition or a variation that is part of the ME/CFS symptomology. Some treatments may also be unsuitable for people with ME/CFS due to over-sensitivity or exercise/activity intolerance.	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Forward ME	4	17 - 19	This may be the 'normal scenario but such strictures are highly problematic in the present context. Because of the absence of much research evidence of the use of drugs for symptom relief in ME, a pragmatic approach using drugs that may not be licensed for this condition is justifiable, based on pharmacological principles and the judicious use of therapeutic trials. We ask that this context is reflected in the process of guideline development. It is important to note that, because people with ME may not respond to prescribed medications in the same way as people who do not have the illness, it may be advisable for prescriptions for medications for people	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			with ME to start at a very low dose and, if no adverse reaction occurs, to build up the dose gradually.	
The ME Association	4	17-19	Re the use of licensed and unlicensed medications: The information here is presumably standard wording at this stage of a NICE guideline preparation. It does, however, fail to appreciate that several of the drugs used for symptom control in ME/CFS (eg amitriptyline for pain and sleep disturbance; melatonin for sleep disturbance in children) are not licensed for this use in ME/CFS. The same situation applies in many other chronic disabling conditions. The provision of a patient information sheet can be useful here.	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
London School of Hygiene & Tropical Medicine	4	24-25	I suggest it should read: "and management is not expected in most cases to be different in ME/CFS. However, specific differences in managing these in people with ME/CFS will be addressed".	Thank you for your comment. We think it is clear that if differences in management are identified they will be addressed.
The ME Association	4	23-24	As raised during the stakeholders meeting, there is obviously no effective treatment for the underlying disease process. So while it can be helpful to refer to existing NICE guidelines on the management of symptoms such as neuropathic pain and irritable bowel syndrome, control of key symptoms such as orthostatic intolerance and PoTS, bowel symptoms and nausea, pain (which may be musculo-skeletal, arthralgia or neuropathic in character) and sleep disturbance must be properly addressed in relation to the extent and characteristic manner in which these symptoms affect people with ME/CFS.	Thank you for your comment. The outline for the guideline is for ME/CFS and this guideline will address specifically the diagnosis and management of ME/CFS and not co-morbid conditions. Where they are identified we will address differences in the management of co morbid conditions in people with ME/CFS.

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			Equally, the diagnosis and management of co-morbid conditions which may co-exist with ME/CFS (eg fibromyalgia, hypermobility syndromes, migraine type headaches, mast cell disease) needs to be included and not just linked to existing NICE guidelines on these conditions.	
Blue Ribbon for the Awareness of ME (BRAME)	4	17/21	Whilst this statement may be appropriate for many conditions, this is not entirely so for people with ME due to their hypersensitivity to medication. People with ME usually require medication to be given at a much lower level than the normal dose to prevent adverse reactions, and be monitored to see if they can tolerate it, and what positive, or adverse, effect it has. Unless required to begin two medications at the same time, usually one medication is started, and a level found that can be effective and tolerated, and then another medication may be tried	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Blue Ribbon for the Awareness of ME (BRAME)	4	22/25	The statement immediately above is also relevant here, as people with ME have a hypersensitivity to medication. Therefore, people with ME who have, or develop a co-morbid condition, will quite probably not respond in the same way as patients who solely have those conditions, for which NICE guidance already exists, due to the unique way people with ME respond to medications – and of course other therapies/management that may be recommended if it included eg physio/exercise, for reasons already stated earlier at point 3 and point 12.	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. . The outline for the guideline is for ME/CFS and this guideline will address specifically the diagnosis and management of ME/CFS and not co-morbid conditions. Where they are identified we will address differences in the management of co morbid conditions in people with ME/CFS.

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			Co-morbid conditions for people with ME need to be addressed in the new guideline, and advice and recommendations given to help prevent harm and an alert to possible adverse reactions.	
Science for ME	4	22/25	Other guidelines may be useful for treating particular symptoms or comorbidities; however, particular caution should apply with people with ME due to reported harms from common treatments such as drug intolerances, difficulties with exertion, increasing exercise and physical therapies. In addition, medical staff should be aware of the problems that an ME/CFS patient may have when being treated for other diseases. For example, getting access to hospitals can be hard necessitating home visits or hospital transport. Waiting areas can also be an issue where they are crowded and noisy or where patients need to lie down.	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. .
The 25% ME Group	4	26 / 27	Include on the list of related NICE Guidance, published: • Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition NICE clinical guideline 32 (2006). • Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005) Please be aware that both are listed as 'related NICE guidance' on webpage for CG53 www.nice.org.uk/guidance/cg53/chapter/6-Related-NICE-guidance	Thank you for your comment. We have added these guidelines.

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#MEAction UK	4	3	Will this cover DWP assessments (and any training programmes for work-related activity groups)? Assumptions from DWP staff about ME can have serious financial implications for those who are too ill to work full time, which is 87% of us (Kingdon, 2018). The current benefit assessment system is not structured to accommodate our impairment, with the assessment process inadequately designed to deal with post-exertional malaise, the fluctuating nature of symptoms and stamina impairment more generally.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
LocalME	4	4	**Settings** Add- Hospital schools and Alternative provision like Pupil Referral units, home tutor services and Special schools for sick children.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations

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				outside of the remit of the guideline would use the recommendations where appropriate.
ME Research UK	4	4	Please consider adding: '*This will also need to consider the situation where patients cannot access services (e.g. because they are housebound).*'	Thank you for your comment. People who are housebound are included under ' all settings where NHS or social care is provided or commissioned, including health services related to education and occupational health'.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	4	4	Might the guideline also be relevant for DWP and health insurance assessors?	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
The Young Sufferers of ME Trust	4	4	Physiotherapy teams are often part of the multi-disciplinary team working with families and should be included.	Thank you for your comment. Physiotherapists are included.

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ME Letterforce	4	6	Another key area for inclusion should be Relapse and exacerbation We need a section that covers how rest is the best way for many patients to recover from a relapse or downturn in their health	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final questions in the monitoring and review section.
Royal College of Psychiatrists	4	6	Predictors or moderators of treatment effect for ME/CFS should also be considered.	Thank you for your suggestion.
Royal United Hospitals Bath NHS Foundation Trust	4	6	A support pathway; and how that would look; for those who are not progressing or need longer intervals before they are in a position to progress. (also see point 10)	Thank you for your suggestion.
South London & Maudsley NHS Foundation Trust	4	6	Predictors or moderators of treatment effect for ME/CFS should also be considered.	Thank you for your suggestion.
VIRAS	4	6	"Key areas that will be covered"	Thank you for your comment. The guideline will address the identification and referral of people with ME/CFS and the information, education and support for health and social care professionals. Correctly and

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			NICE have overlooked misdiagnosed patients and patients who develop additional diseases. These must be specifically addressed in the scope and guideline because they represent serious risks to patients. 30 years of biased 'research' and media reporting, was been compounded by the 2007 NICE guideline recommendations and false reporting of the PACE Trial. These have been effective in branding patients as phobic, neurotic, hypochondriac, lazy and unmotivated, and as a result, these illnesses are widely perceived to be trivial, psychological diagnoses with no medical basis. This perception means that patients do not have equal access to healthcare. Patients with these diagnoses who go to a doctor with a new or worsening symptom are sometimes investigated properly, but are sometimes dismissed. This creates two significant risks for patients: 1/ Missed diagnoses. Patients could have a disease which has never been diagnosed but which is the actual cause of their illness. Delay, or failure to ever identify the cause of a patient's illness, especially if it is chronic and progressive, would obviously be a serious medical error. E.g., Lyme disease is a common missed diagnosis. 2/ Delay in diagnosing and treating additional diseases. The aforementioned perceptions mean that patients' accounts of their symptoms are viewed by some, as unreliable and exaggerated. Therefore there is a risk that new symptoms and diseases which occur in	quickly identifying people with ME/CFS and providing more information and support for healthcare professionals should help to address the issues you have raised.

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			patients will not be promptly or properly investigated. This could have serious consequences for those who develop, e.g., cancer or heart disease – which are two major causes of death amongst M.E. and CFS patients.	
Royal United Hospitals Bath NHS Foundation Trust	4	7	At a stakeholder consultation there has already been a suggestion that all 'evidence' should be qualified with a level to reflect what is considered 'gold standard' to 'anecdotal'. Recognising that there are many areas of debate because of lack of knowledge in relation to this condition there should be an acknowledgement with all evidence that it reflects the current knowledge rather than being regarded as absolute fact. Having this built into guidelines may allow agreement between disparate views that evidence may be lacking even while strong views on help or treatment approaches may be valid.	Thank you for your comment. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. As you note any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We intend to include a call for evidence in the guideline to address the issues you raise.
Healthwatch Bolton	4	13-4	Much more robust statement than in previous guideline about cooperation and collaboration between professionals and patients. Patients have the right to refuse or withdraw from treatment. DWP, insurance companies and some employers are insisting that patients complete inappropriate, even harmful "treatments".	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Healthwatch Bolton	4	15-6	As lines 13-4	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	4	9	Recommendations regarding management before diagnosis are required. Poor management in the early stages of the illness can lead to long term or permanent harm.	Thank you for this comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
#MEAction UK	4	10	It could be useful to add a question to the scope to determine which issues are core to ME and which issues are common, but indicate separate comorbidities. For example, there is reasonable evidence to suggest gut issues are core to the disease process of ME, rather than a separate IBS comorbidity. The open trial by Wallis et al. (2018) found improvements in 'several clinical outcomes including total symptoms, some sleep (less awakenings, greater efficiency and quality) and cognitive symptoms (attention, processing speed, cognitive flexibility, story memory and verbal fluency)' from treating with erythromycin and probiotics in relevant patients. Studies such as Giloteaux et al. (2016) indicate that the gut microbiome is dysregulated enough in ME to serve as a potential biomarker.	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols on diagnosis. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. .

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			Gut dysfunction can be very serious, as noted in Merryn Crofts' inquest: her death was due to gastrointestinal failure caused by ME. Doctors told Merryn that they didn't believe in ME and dismissed her as hysterical. Eventually she was tube-fed and still not able to absorb sufficient nutrients. This type of misunderstanding can also lead people with ME to be misdiagnosed with anorexia nervosa, and be detained under the Mental Health Act.	
Healthwatch Bolton	4	10	Diagnosis confirmed by specialist. Criteria used will be key. Needs to be International Consensus Criteria (ICC) or Canadian Criteria, which are robust. Also take into account findings of common comorbidities, including fibromyalgia, etc.	Thank you for your comment. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing statements such as the Canadian International Consensus Primer will be used to inform the committee.
Patient Advisory Group to the CMRC (CFS/ME Research	4	10	Chronic fatigue is often confused with ME/CFS. The difference needs to be made clear.	Thank you for your comment and this information. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. The use of the term 'ME/CFS' in the scope does not imply acceptance of any particular definition or meaning and does not pre-judge the terminology of the

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Collaborative)				completed guideline this will be the task of the committee.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	4	10	Sometimes doctors confuse ME/CFS with depression. The difference needs to be made clear.	Thank you for your comment and this information. This difference will be made clear.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	4	10	What are the exclusion criteria? Need to determine this.	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
Respect for ME	4	10	Some symptoms may be considered separate but overlapping conditions, while others may be integral to ME. For instance, there is some argument that gut problems are not a separate entity (e.g., IBS) in ME but a core and potentially unique part of the disease (Giloteaux 2016). Orthostatic intolerance may be distinct from POTS and result from, for instance, the repeated finding of reduce blood flow in the brainstem of patients with ME (https://www.ncbi.nlm.nih.gov/pubmed/8542261).	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.

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Royal College of General Practitioners	4	10	This should include the differential diagnosis of chronic fatiguing illness other than CFS/ME, including appropriate lines of questioning, examinations and investigations	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
Royal College of Psychiatrists	4	10	The diagnosis heading should also cover important differential diagnoses to consider, such as depression, which can present with or exacerbate fatigue. There may also be specific considerations regarding the management of depression or anxiety in chronic fatigue syndrome.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
South London & Maudsley NHS Foundation Trust	4	10	The diagnosis heading should also cover important differential diagnoses to consider, such as depression, which can present with or exacerbate fatigue. There may also be specific considerations regarding the management of depression or anxiety in chronic fatigue syndrome.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
The 25% ME Group	4	10	Poor medical education on this topic has been a barrier to diagnosis and appropriate care. The dearth of suitable medical education makes the provision of robust guidance on M.E. diagnosis in the guideline all the more important. A confident and early diagnosis based on medical history and clinical presentation would facilitate the identification, diagnosis and care of M.E. patients. Major costs are implicated in multiple 'second opinions', delayed diagnosis and/or irrelevant investigations - while relevant investigations may be overlooked.	Medical education covered under information education and support for health and social care professional

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			The process of guideline development could coherently go hand in hand with a focus on addressing and responding to shortcomings on medical education, with expertise enlisted on the Guideline Development Committee to identify areas of shortfall in education on M.E. and to champion new guidelines and communicate them as part of continued professional development for practitioners and to introduce this topic to the medical school curriculum. cost saving recommendation would be to appoint a professional committee member with	
The Ehlers-Danlos Support UK	4	10	Recommend the inclusion of a section on trying to identify causes of illnesses where chronic fatigue can be a predominant symptom (e.g. connective tissue disorders) in addition to information on diagnosing CFS/ME. People with the Ehlers-Danlos syndrome often get a diagnosis of CFS/ME incorrectly before they are diagnosed with EDS.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
The Pernicious Anaemia Society	4	10	It is important that Pernicious Anaemia (or at least Vitamin B_{12} Deficiency be ruled out as the possible cause of the patient's symptoms. Although there are serious problems with the Serum B_{12} test (measures only total B_{12} and not the 'active' B_{12} and that there is no consensus of what constitutes a 'deficiency' the B_{12} status of the patient should be investigated.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
The Pernicious Anaemia Society	4	10	It should be noted that Vitamin B_{12} Deficiency can occur without the patient having any enlarged red blood cells. The current Guideline states that no investigation into the B_{12} status of the patient should take place 'unless there is macrocytosis'. Only around 50-60% of patients with low B_{12} will have enlarged red blood cells.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.

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#MEAction UK	4	11	Does inpatient care come under management? Does 'management' include how to care for those severely ill - e.g. feeding, creating and maintaining a safe environment and pain management? The MS guideline includes referrals for 'end of life care', which is also appropriate for the ME guideline.	Thank you for your comment and information. Treatments and interventions come under management and alongside this is where they are delivered. Special consideration will be given to people with severe ME/CFS throughout the guideline and specifically addressed in each review questions.
Forward ME	4	11	Whilst recognising that most of the management for patients with ME will be in the Primary Care sector, there is a need for all patients to have access to consultant-led, multi-disciplinary services with early referral, accurate diagnosis and expert care and advice	Thank you for your comment. This issue of multidisciplinary care, including team composition will be addressed by the guideline.
Healthwatch Bolton	4	11	Management: referral to and treatment of individual individual symptoms by other relevant specialists, including investigations for common co-morbidities, eg., endocrine conditions, PoTS, EDS, etc.Must take into account patient preferences and informed decisions, including information about possible harms. Listen to patients and their experiences. Do not ignore their experience of PEM and PENE, for example.Accept need for telephone/email/ domiciliary consultations to support patients. Allow further testing for new or worsening symptoms. GET has been proven to be harmful for many and should not be included. Pacing can be helpful in encouraging a patient not to do too much, so as not to exacerbate symptoms. CBT can be helpful to some patients, but it needs to be the model used in other long-term conditions such as MS, or in life-changing conditions such as cancer, to aid	Thank you for your comments and suggestions. These are concerns that have been commonly raised at the stakeholder workshop and in consultation. These will be addressed in the management section of the guideline. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.

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			acceptance of having a life-altering condition and adapting to it, and helping people to give themselves permission to pace effectively and do less without feeling guilty. Definitely NOT the model used in some clinics, to correct "exercise avoidance or perceived "false or unhelpful illness beliefs. Similarly, conventional sleep management techniques, such as discouraging daytime napping, are ineffective, inappropriate, even harmful, for some patients. There is particular concern in the enforced use of this technique in children and adolescents.	
Respect for ME	4	11	In-patient care, domiciliary care, and palliative and end-of-life care (as mentioned in the MS scope) should be included.	Thank you for your suggestions. Care of the dying adult in the last days of life NG31 has been added to the related NICE guidance. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
Royal United Hospitals Bath NHS Foundation Trust	4	11	This sentence implies that only evidence for managing the condition will be considered. There have been several research studies into the clinical and cost effectiveness of different treatments/interventions for this illness too, which should be included in the scope of the evidence review.	Thank you for your comment. The management of ME/CFS will include treatment and interventions as indicated in the draft questions.
Science for ME	4	11	"Management of ME/CFS" The NICE MS guidelines have recommendations for assessing bone health, need for mobility aids, risk of pressure ulcers and referral to end of life palliative care. This seems appropriate for severe ME given similar or greater levels of disability.	Thank you for your suggestions.. Care of the dying adult in the last days of life NG31 has been added to the related NICE guidance. The technical team will ensure the areas you raise are brought to the attention

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				of the committee when they are considering the final review questions and protocols.
The 25% ME Group	4	11	Avoiding the conflation of M.E. with disorders with quite different care needs is of paramount importance if harm is to be avoided.	Thank you for your comment.
The 25% ME Group	4	11	Addressing M.E. patient need implies: • ameliorating symptom impact (given that there are few established treatments aimed at addressing underlying cause); in other words, a form of palliative care; • appropriate management advice for those patients who haven't already figured out how best to manage activity within the strictures of their illness; • an end to the tendency to fail to treat co-morbid conditions. Suggest tap into existing expertise in the field of palliative care, as M.E. patients may benefit from expertise developed in this field. Rebut the present tendency of professionals mindset to shy away from the relevance of palliative care simply on the basis that the patient is not in an end of life situation, even though such expertise may hold key to best quality of life. Aim to provide robust guidance as to how people with M.E. are treated across the spectrum of provision, including: within 'specialist' clinics; hospital outpatients; hospital inpatients; community services (e.g. tube feeding specialist nurse); GPs.	Thank you for your suggestions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.

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The 25% ME Group	4	11	In keeping with the 2015 supreme court judgement on patient consent, the guideline must equip staff to explain to patients the prospective benefits and potential harms of any intervention(s) they are suggesting / advising: https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf http://www.medicalprotection.org/uk/for-members/news/news/2015/03/20/new-judgment-on-patient-consent	Thank you for your comment. The guideline will address information, education and support for health and social care professionals.
#MEAction UK	4	12	'Monitoring and review.' Some doctors believe people with ME should not have symptoms thoroughly investigated, especially new ones. Doctors can be reluctant to order required tests. For example, papers from the 1990s advised: "Whatever the label, all agree that physical investigations [of fatigue] are rarely helpful, except in certain groups such as the elderly" (Wessely, 1998). People with ME can go on to develop cancer, heart disease, and new autoimmune diseases. They should be able to access the same range of tests as anyone else, and doctors should be alert to changes in symptoms and the possibility of new comorbid conditions.	Thank you for your comment. The guideline will address information, education and support for health and social care professionals.
Healthwatch Bolton	4	12	There needs to be annual monitoring of patients, which could be done by a practice nurse. Should include blood tests (including vitamin D, white and red blood count snd erythrocyte sedimentation rates, etc), heart checks, disability and quality of life scales. Too many patients are left for years without any care or oversight at all. New conditions can develop,	Thank you for your suggestions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are finalising the draft review and protocols for monitoring.

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			which if caught early are straightforward to treat, both clinically and cost effectively.	
Respect for ME	4	12	Perhaps since Wessely 1998, clinicians have been reluctant to offer people with ME the same investigations as other patients would receive. This is clearly a form of ableism.	Thank you for your comment.
Stonebird	4	13	**P4 line 13 and 14 ' Information, education and support for people with suspected and diagnosed ME/CFS, and their families and carers' should ensure it includes the long term ill and the support of people who are homebound, not just those newly ill.** The key issue here is whether NICE abandons the unwanted psychosocial approach which misinterprets the illness and misinforms about the nature of the illness. Any education, advice and support must be based on specific criteria, honest prognosis, a recognition of the full symptom experience, the dangers of long term harm from wrong or poor interventions and acknowledge the need for a highly skilled individual, flexible person-centred approach to caring. The literature is full of advice on Pacing etc, but techniques like Pacing are inappropriate for someone with Severe ME, who will not have the necessary energy required to identify a baseline and pace. Here you need to know how to create and maintain a physical environment, based on equality, respect and partnerssship, where there is the maximum possibility for a supportive and helpful interaction, to engage with and make a difference in the person's life, and see and	Thank you for your suggestions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are finalising the draft review and protocols for information and support.

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			meet their need and importantly get it right, not cause harm. This is called the MOMENT Approach.	
Parents of children with ME/CFS Support Group	4	15	The draft scope should also include information, education and support for education professionals.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	4	15	Information, education and support for DWP and insurance assessors is required.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations

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				outside of the remit of the guideline would use the recommendations where appropriate.
The Young Sufferers of ME Trust	4	15	Special attention should be paid to social care professionals. We have supported 200+ families who have been subjected to erroneous child protection investigations (see False Allegations of Child Abuse in Case of Childhood Myalgic Encephalomyelitis by Jane Colby https://www.tymestrust.org/pdfs/falseallegations.pdf). The majority of these cases were initiated by education professionals – either school/college based or local authority based – and in the majority of cases their reasons for referring were: - a disbelief that ME is a chronic illness - a belief that there is a cure for ME and families just need to commit to this (i.e. GET/CBT) The acceptance that there is no cure for this condition, and that there are contradicting viewpoints on its treatment, does not seem to be accepted by many social workers involved with families. <u>Information needs to reach existing and trainee social workers on:</u> • how this condition presents • crucially, that there is no cure • interrupted school attendance is a key symptom • enforcing school attendance, in a bid to reduce isolation, will exacerbate symptoms	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals. This includes social workers and there is a question on information and support for health and social care professionals. We agree that people should not be pressured into receiving any treatment and that the principles of shared decision making should be followed for all decisions about treatments. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate

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			• ME clusters in families, schools and communities (see https://www.tymestrust.org/pdfs/dowsettcolby.pdf) • Parents must be listened to- they are the experts in their child's health	
Parents of children with ME/CFS Support Group	4	16	In line with our comment number 15, we argue that the draft scope should also include a point 7 on this list, namely 'Management of comorbid conditions not covered in other guidelines'.	Thank you for your suggestion. The outline for the guideline is for ME/CFS and we will provide recommendations for the management of ME/CFS. It will be beyond the resources of this guideline to develop recommendations for the management of comorbid conditions not covered in other NICE guidelines.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	4	17	The lack of research into ME/CFS means that there will be a lack of evidence for the use of medications outside of licensed indications. An effort should be made to identify medications being used for ME/CFS patients in this way and identify the benefits experienced by patients. Personal note: the medication most helpful to me is not licenced for ME/CFS, I feel very lucky to have been prescribed it. The same drug has been refused to another patient on the grounds that it is unlicensed for this use.	Thank you for your comment. The guideline will address the clinical and cost effectiveness of pharmacological treatments used in the management ME/CFS. We are aware of the limited evidence in this area. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations. People's' experiences of interventions will also be taken into account when the committee make decisions about

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				the treatments and we intend to include a call for evidence in the guideline. The areas raised by stakeholders will be used inform the committee's decision making as they develop the review questions and protocols.
Healthwatch Bolton	4	23-5	Needs to take into account specific issues with, for example, extreme sensitivity to medication.	Thank you for your comment.. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols. .
Support for ME	4	18	"exceptionally, and only" should be deleted. In my experience combining conventional and unconventional treatments have been effective in controlling our son's illness. Therefore, provided there is good evidence that alternative/unlicensed treatments are successful and also safe, there should be no need for "exceptional circumstances"	Thank you for your comment. The guideline will address the clinical and cost effectiveness of pharmacological and non-pharmacological treatments used in the management ME/CFS. We are aware of the limited evidence in this area. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations. People's' experiences of interventions will also be taken into account when the committee make decisions about the treatments and we intend to include a call for evidence in the guideline. The areas raised by stakeholders will be

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				used to inform the committee's decision making as they develop the review questions and protocols**.**
Blue Ribbon for the Awareness of ME (BRAME)	4	15 point 6	Glad to see health and social care professionals have now been added as this is very important	Thank you for your comment.
#MEAction UK	4	22	*"Areas that will not be covered: The management of comorbid conditions"* has been removed, but *"Areas that will not be covered: The specific management of symptoms where NICE guidance already exists"* remains [p4, 24] with nothing added to say management of comorbid conditions could be impacted by this guideline -- specifically that usual management of other conditions may be contraindicated in ME or that doses of drugs may need to be reduced initially. Potential clashes with other guidelines include "Intermediate care including reablement NG74" and "Irritable bowel syndrome in adults: diagnosis and management CG61" guidelines (which recommend 'positive risk taking' and increased physical activity, respectively). However, these are just two examples and this issue should be further explored by the committee. Comorbidity as well as non-exclusionary overlapping conditions are common in people with ME (Friedberg, 2014). See table below:	Thank you for your comment and information. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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			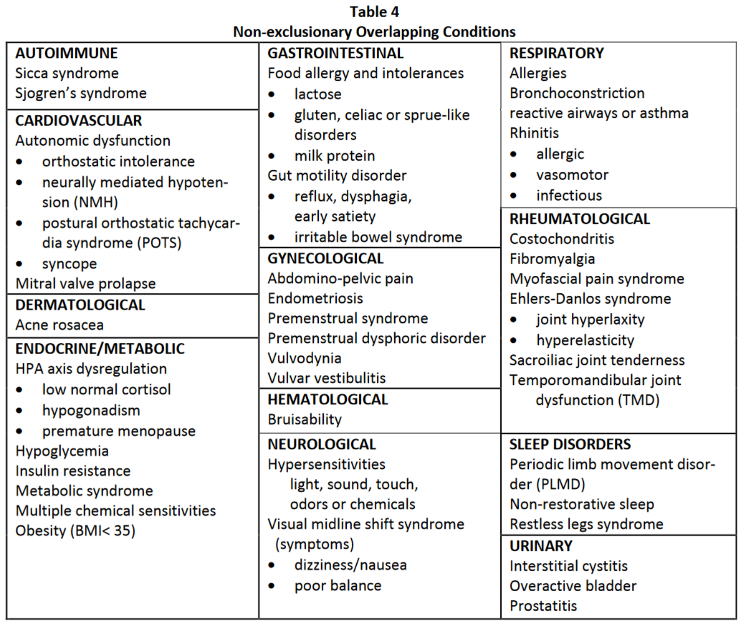 **Table 4** **Non-exclusionary Overlapping Conditions** **AUTOIMMUNE** Sicca syndrome Sjogren's syndrome **CARDIOVASCULAR** Autonomic dysfunction • orthostatic intolerance • neurally mediated hypotension (NMH) • postural orthostatic tachycardia syndrome (POTS) • syncope Mitral valve prolapse **DERMATOLOGICAL** Acne rosacea **ENDOCRINE/METABOLIC** HPA axis dysregulation • low normal cortisol • hypogonadism • premature menopause Hypoglycemia Insulin resistance Metabolic syndrome Multiple chemical sensitivities Obesity (BMI< 35) **GASTROINTESTINAL** Food allergy and intolerances • lactose • gluten, celiac or sprue-like disorders • milk protein Gut motility disorder • reflux, dysphagia, early satiety • irritable bowel syndrome **GYNECOLOGICAL** Abdomino-pelvic pain Endometriosis Premenstrual syndrome Premenstrual dysphoric disorder Vulvodynia Vulvar vestibulitis **HEMATOLOGICAL** Bruisability **NEUROLOGICAL** Hypersensitivities light, sound, touch, odors or chemicals Visual midline shift syndrome (symptoms) • dizziness/nausea • poor balance **RESPIRATORY** Allergies Bronchoconstriction reactive airways or asthma Rhinitis • allergic • vasomotor • infectious **RHEUMATOLOGICAL** Costochondritis Fibromyalgia Myofascial pain syndrome Ehlers-Danlos syndrome • joint hyperlaxity • hyperelasticity Sacroiliac joint tenderness Temporomandibular joint dysfunction (TMD) **SLEEP DISORDERS** Periodic limb movement disorder (PLMD) Non-restorative sleep Restless legs syndrome **URINARY** Interstitial cystitis Overactive bladder Prostatitis	
Forward ME	4	22	People with ME may have co-morbid conditions that will not respond to recommendations for in the same way as patients who have those conditions for which NICE guidance is already available because of the unique way in which their bodies respond to medications. Co-morbid	Thank you for your comment and information. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people

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			conditions in these patients need to be dealt with within this guideline if the intention is to reduce harm.	with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols**.**
LocalME	4	22	**Areas NICE propose not to cover : Comorbidity-** We challenge this approach suggested by NICE- People with ME may have **co-morbid conditions** that will not respond to recommendations in the same way as patients who have those conditions and for which NICE guidance is *already* available. ME is a condition for which highly personalised and individualised medical approaches are necessary; this is in part because of the unique way in which their bodies respond, with intolerances, sensitivities and commonly serious adverse reactions to medications. Co-morbid conditions in these ME and CFS patients, also may not tolerate the NICE Guidance management approach in these condition guidelines due to PEM. These "co morbid" conditions need to be dealt with within this guideline if the intention is to reduce harm. The same risks apply to ME patients who are also facing medical challenges such as pregnancy and additional serious life threatening conditions like cancer; personalised and individualised medical approaches are necessary.	Thank you for your comment and information. The outline for the guideline is for ME/CFS and this guideline will address specifically the diagnosis and management of ME/CFS and not the management of co-morbid conditions. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The technical team will ensure the areas you raise are brought to the attention of the committee
ME Letterforce	4	22	NICE guidelines that recommend exertion need to be re-assessed to see how suitable they are for people with ME. This may be a level of exertion that is considered trivial. Caution is needed. Management of people with ME/CFS is going to be difficult or impossible if	**Thank you for your comment and information. The management of ME/CFS is included in the guideline. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a**

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

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			1. It is only available in an outpatient hospital setting as many patients are unable to get to a hospital and there are few wards to admit them to 2. If exertion is required as part of the treatment such as physiotherapy that involves exercises or cancer after care that involves exercise even gentle. People with ME may not be able to do weight bearing exercise for Osteoporosis treatment or exercise within a swimming pool. We need to be mindful that for some patients post exertional symptoms may be triggered after what would normally be considered trivial exertion and this may outweigh any benefits gained. 3. If a treatment is given over consecutive days in an outpatient or hospital setting as this would trigger post exertional symptoms 4. If the treatment is only available at a particular time of day that corresponds with the time a patient experiences severe symptoms If a hospital clinic cannot accommodate patients on a stretcher or complete investigations on patients who are unable to sit up	**more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The** NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. Patients' experiences of interventions will also be taken into account when the committee make decisions about the treatments. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols**.**
Respect for ME	4	22	Consider adding a note that treatments for co-morbidities may need to be prescribed at a reduced dose (for drugs) or may be contraindicated (for exercise regimes) altogether.	Thank you for your comment and suggestion. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be

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				used to inform the committee's decision making as they develop the review questions and protocols.
The 25% ME Group	4	22	We welcome the qualification of the exclusion of *"Specific management of symptoms where NICE guidance already exists"* with "*and management is not expected to be different in ME/CFS*". However this matter needs careful attention when developing the guideline. Notably, co-morbid conditions in people with M.E. may not respond to recommendations for these conditions in the same way as other patients - this may be because of the unique way in which their bodies respond to medications, another reason why this may occur is the M.E. patient's adverse response to exercise / activity. Some consideration must be given to such issues when addressing co-morbid conditions in these patients within this guideline, if the intention is to reduce harm.	Thank you for your comment and information. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
VIRAS	4	22	"Areas that will not be covered" "The specific management of symptoms" "Lyme disease (2018). NICE guideline NG95" We recommend that the short-version of NG95 should be required reading for the guideline development committee and suggest the British Medical Journal summary (https://www.bmj.com/content/361/bmj.k1261) and Rapid Responses by VIRAS and others (https://www.bmj.com/content/361/bmj.k1261/rapid-responses) should be taken into account.	Thank you for your comment and information. Lyme disease is included in the related guidance in the scope. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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			It will be necessary to include a specific sections on Lyme disease in the NICE guideline when covering both the diagnosis and the review of patients. We recommend that the committee view this short presentation by a doctor experienced in diagnosing and treating both 'CFS' and Lyme disease: https://www.contagionlive.com/videos/is-there-a-link-between-lyme-disease-and-chronic-fatigue-syndrome	
ME Research UK	4	23	How will the review group ensure they are clear which of the existing guidelines apply directly to patients with ME/CFS? The disease is heterogeneous and in some cases usual care would be of benefit to patients while in others such care may be harmful.	Thank you for your comment and information. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Differences will be identified with the support of the committee and in the evidence. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols**.**
Stonebird	4	23	**P4 lines 23,24,25' The specific management of symptoms where NICE guidance already exists (see below for related NICE**	Thank you for your comment and suggestion. We are aware that the usual management of other conditions

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			guidelines) and management is not expected to be different in ME/CFS' We would suggest that this statement shows a lack of understanding of the unique nature of ME, which is not like other illnesses. People with ME are at enormous risk of deterioration and harm from unaware recommendations, from a lack of appropriate understanding of the disease process, particularly PENE and from a general lack of knowledge of how to safely interact with and treat patients especially the most ill. Across the board there is a need to better understand ME especially the full symptom experience, particularly when dealing with co-morbid illness and symptoms. Despite existing NICE guidance then, specific ME and Severe ME guidance is always likely to be needed for this group of patients.	may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Coeliac UK	4	26	NG20 Coeliac disease: recognition, assessment and management is not listed under related guidance. As there are common symptoms between ME and coeliac disease and the current NICE guideline for CFS/ME (CG53) recommends that screening blood tests for gluten sensitivity are carried out, cross referencing between the NICE CG NG20 and the CFS/ME updated guideline seems logical.	Thank you for your suggestion. We have added NG20 Coeliac disease: recognition, assessment and management is not listed under related guidance to the related guidance in the scope.
Buckinghamshire	5	1-13	Lyme disease is a relevant link. p. 5 links to management of primary presentation: pain/headaches/mental health/irritable bowel/thyroid	Thank you for your suggestion. We have included related guidance that has been identified by

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Healthcare NHS Trust			disease. These links should be removed. Primary guidelines can be found separately if judged by a professional to be clinically relevant. For patients with ME/CFS these symptoms could be secondary complications. The evidence used for these 'related' conditions is not based on ME/CFS patients, dosing may not be appropriate, outcome data is not known, a potential risk of harm. Guidelines, particularly for pain/headaches in ME/CFS patients, should be included in the ME/CFS guidelines (see comment 10 below).	stakeholders as being important. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Action for ME	5	5-6, and 23-24	The second common concern expressed by patients was the inclusion of two guidelines relating to mental health, under 'Related NICE guidance' (*Common mental health problems: identification and pathways to care* and *Service user experience in adult mental health*). M.E. is a neurological condition, with the evidence base continuing to find ways in which the condition has a physiological impact on patients. While patients can experience co-morbid mental health problems, this is frequently due to the isolation and lack of understanding they face from peers and professionals. The scope states that the list of related guidelines are for the "*specific management of symptoms where NICE guidance already exists*". Mental health issues are not a symptom of M.E. If these guidelines are to be included in this list, the scope should explicitly state that the related guidance applies to co-morbid conditions (rather than exclusively symptoms of M.E.) One patient explained:	Thank you for your suggestion. These are included as related guidance, this does not indicate that mental health issues are a symptom of ME/CFS but may be a comorbid condition. These guidelines are routinely included in the scope for guidelines for people with chronic conditions.

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			"As no mention of mental health was made in the symptoms section, the rationale for [the inclusion of mental health guidelines] could be made clearer. This is particularly important as the focus of previous guidelines on GET and CBT have treated M.E. as a primarily psychological condition. If the purpose of this guidelines is to rethink this approach then reference to mental health needs to be justified".	
Hope 4 ME Fibro Northern Ireland	5	5-6	**Related NICE guidance: Mental Health Problems** We would like to query the addition of the NICE guideline CG123 for "Common Mental Health Problems: Identification and Pathways to care" in this list. Whilst we understand that people with ME may also present with mental health problems, we do not believe that this issue is specifically linked to ME, and thus this guideline is no more relevant to this scope than a guideline relating to cancer or heart disease.	Thank you for your suggestion. These are included as related guidance, this does not indicate that mental health issues are a symptom of ME/CFS but may be a comorbid condition. These guidelines are routinely included in the scope for guidelines for people with chronic conditions.
Invest in ME Research	5	23-24	Service user experience in adult mental health (2011) NICE guideline 23 CG136 Why is this required?	Thank you for your suggestion. This guideline is routinely included in the section,' NICE guidance about the experience of people using NHS services 'in all guideline scopes. This does not indicate that mental health issues are a symptom of ME/CFS but may be a comorbid condition.
The 25% ME Group	5	5-6	The guideline on: 'Common mental health problems: identification and pathways to care' (2011; NICE guideline CG123) is not related to the care of people with M.E. and should not be listed as such.	Thank you for your suggestion. This guideline is routinely included in the section,' NICE guidance about the experience of people using NHS services 'in all

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				guideline scopes. This does not indicate that mental health issues are a symptom of ME/CFS but may be a comorbid condition.
Blue Ribbon for the Awareness of ME (BRAME)	5	17/25	Regarding points 17-25 we believe there will be a necessity to include additional recommendations on the topics of:- medicine optimisation; patient experience in adult NHS services; experience in adult mental health and medicines adherence - as there are specific issues related to ME	**Thank you for your comment. These guidance is included in the scope section,'NICE guidance about the experience of people using NHS services'. We are aware that the usual management of other conditions may be cont**raindicated in people with ME/CFS. Where differences are identified we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
British Dietetic Association	5	2	We feel the guideline review should consider including nutrition assessment in the primary care or diagnostic pathway to review whether an inadequate diet could be a contributing factor.	Thank you for your comment. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.
Invest in ME Research	5	5	Common mental health problems: identification and pathways to care (2011). NICE guideline CG123	Thank you for your suggestion. These are included as related guidance, this does not indicate that mental health issues are a symptom of ME/CFS but may be a

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			Why is this required?	comorbid condition. These guidelines are routinely included in the scope for guidelines for people with chronic conditions.
Royal College of General Practitioners	5	7	The NICE guideline on irritable bowel syndrome in adults was published in 2008 and is potentially in need of an update with the increased understanding of the complexities of the gut microbiome as well as other bowel disorders such as gastroparesis	Thank you for your comment. The guideline was last updated in February 2017 and will be considered again for update according to NICE's standard surveillance review schedule.
The Ehlers-Danlos Support UK	5	7	The IBS guidance is likely to be out of date. For example, potentially debilitating gut-related symptoms of Ehlers-Danlos syndromes are now recognised (Fikree et al, 2017. Am J Med Gen 175C:181–187) and this is an active area of research.	Thank you for your comment. The guideline was last updated in February 2017 and will be considered again for update according to NICE's standard surveillance review schedule.
British Dietetic Association	5	9	Specialist dietary advice in the treatment pathway to ensure that malnutrition is not an exacerbating factor and that the diet is nutritionally sound could eliminate the need for supplementation.	Thank you for your comment. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.

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The 25% ME Group	5	9	The guideline in development on 'Suspected Neurological Conditions' (GID-CGWAVE0800 https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0800) should be included.	Thank you for your comment. This guideline has been added.
Royal College of Paediatrics & Child Health	5	12	The NICE guideline on 'Chronic Pain' is also currently under review, and there might be scope in combining with the CFS/ME. This must overlap with the CFS/ME guideline and should possibly be considered together.	Thank you for your comment. This guideline has been added.
Blue Ribbon for the Awareness of ME (BRAME)	5	14	Glad to see 'updated' and has been changed to 'replaced'	Thank you for your comment
The 25% ME Group	5	17	The Guideline on: Service user experience in adult mental health (2011; NICE Guideline CG136) is not related to the care of people with M.E. and should not be listed as such.	Thank you for your suggestion. This guideline is routinely included in the section,' NICE guidance about the experience of people using NHS services 'in all guideline scopes. This does not indicate that mental health issues are a symptom of ME/CFS but may be a comorbid condition.
ME Letterforce	5	26	We need to be mindful of the additional economic burden to families and society, after severe relapse through GET and other activity treatments, compared with negligible benefits.	Thank you for your comment and information.
Optimum Health Clinic Foundation	5	26	We have commissioned and completed an extensive pharmacoeconomic study into the overall cost to the economy of CFS/ME. The total cost to the UK economy of CFS/ME in 2014/15 was at least £3.3 billion, assuming	Thank you for your comment and information. The guideline will address the clinical and cost

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			a cautious estimate of 0.4% prevalence within the UK population.[2] In our unweighted analysis, we found an average cost per person with CFS/ME of £16,966. These figures account for health care costs, the majority of disability-related welfare payments, productivity losses and unpaid informal care.	effectiveness of the pharmacological management of people with ME/CFS.
Parents of children with ME/CFS Support Group	5	26	We are aware that there are currently no accurate figures for the number of people in England with ME/CFS, nor the number of children under the age of 16 who have the illness. We argue that this should be evidenced as part of the draft scope in order to ensure that economic models and analyses are based on scientifically rigorous data.	Thank you for your comment. We are aware of the lack of clarity about accurate prevalence rates for ME/CFS and have stated that 0.2% is the minimum rate. Part of the NICE guideline development process includes cost effectiveness and investigations into resource impact. Part of this work will be to accurately identify prevalence rates to support the commissioning of services.
Science for ME	5	26	"Economic aspects" When assessing economic aspects of treatment, it is important to fully understand and assess the methodologies behind any economic analysis. Where open label trials are run (especially where they include treatments such as CBT/GET designed to change how patients think of symptoms) then self-reported outcomes should be considered unreliable	Thank you for your comment. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in

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			since they are subject to reporting biases. In general, this is covered in a later comment which refers to evidence from the special issue of the Journal of Health Psychology that covers PACE http://journals.sagepub.com/toc/hpqa/22/9). From the perspective of the economic analysis it is important to realise that the EQ5d scale is a subjective questionnaire and as such it is subject to reporting biases for open label trials, particularly with CBT/GET where interventions aim to change patient views on their symptoms.	assessment of outcomes which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made.
The Pernicious Anaemia Society	5	27	A great many members of the Pernicious Anaemia Society were originally diagnosed as having CFS/ME only to be correctly diagnosed as having Pernicious Anaemia (or unaccountable B_{12} Deficiency due to the inaccuracy of the Competitive Binding Luminescence Assay used to diagnose 'true' Pernicious Anaemia). This problem with non-diagnosis or misdiagnosis leads to 33% of members of the Pernicious Anaemia Society waiting five years or more to receive a diagnosis and treatment for their symptoms. This leads to repeated visits to GPs over many years which costs at least £4.8 million in wasted consultations every year. Therefore it is important that GPs: a. Investigate any family history of Pernicious Anaemia Orders a Serum B_{12} test and Intrinsic Factor Antibody Test. The results of these tests should be treated with extreme caution.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on diagnosis.
Patient Advisory Group to the	5	5,23	Is it usual for NICE guidance on mental health to be included as related guidance in the guideline scope for physical health conditions? It was a	Thank you for your suggestion. These are included as related guidance, this does not indicate that mental health issues are a symptom of ME/CFS but may be a

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CMRC (CFS/ME Research Collaborative)			surprise to see this here. If it is not common practice for it to be included when reviewing guidelines on physical ill health, it should not be here.	comorbid condition. These guidelines are routinely included in the scope for guidelines for people with chronic conditions.
ME Letterforce	5	18, 19, 20	These guidelines need to be assessed to see if they cover patients who are not able to attend a hospital or would be physically worse after a hospital visit due to exertion. They also need to be assessed to see if they cover a patient group who cannot exercise and are worse physically after exertion that would be deemed trivial in other patient groups	Thank you for your comment and information. We are aware that the usual management of other conditions may be contraindicated in people with ME/CFS. Where differences are identified in the evidence we will address differences in the management of co morbid conditions in people with ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Royal United Hospitals Bath NHS Foundation Trust	6	general	There is a need to consider what to offer for severely affected individuals, who may have a complex presentation with other co-morbidities (such as inadequate nutrition, inadequate pain management, extreme anxiety, somatisation disorders, pervasive avoidance/refusal, Autism Spectrum Disorders) In our experience (with children and young people), when they are rarely able to leave their bedroom and too unwell to interact with therapists, it is challenging or impossible for community teams to provide the level of care needed; there are few suitable inpatient facilities. We have had adolescents who have been on a	Thank you for outlining the difficulties experienced by people with severe ME/CFS both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help people with severe ME/CFS. Special consideration will be given to people with severe ME/CFS throughout the guideline.

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			waiting list and become adults and therefore no longer eligible for a place	
Action for ME	6	22-31	Action for M.E. recommends the addition of the question 'What is the clinical and cost-effectiveness of management within primary care for people with ME/CFS?' Patients with M.E. are commonly treated within the primary care system, given the lack of secondary specialist care for those with the condition [Action for M.E. (2017), Spotlight on specialist services]. It is vital that management within primary care is considered by the NICE guideline committee, to ensure that any recommendations they make take account of this aspect of care. It is particularly important that primary care is made accessible to those with severe M.E. The services that do exist commonly focus on patients with mild or moderate symptoms, and people who are severely affected must receive some care and support, with provision available for domiciliary visits.	Thank you for your comment. This question will be addressed as part of the other questions and where treatments are delivered. In addition draft question 3.4 specifically reviews the clinical and cost effectiveness of different models of multidisciplinary care, including team composition.
Royal College of General Practitioners	6	22-31	Management of ME/CFE It will be important to identify trials where harms are identified.	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.
Royal College of General Practitioners	6	7-15	Diagnosis of ME/CFE The differential diagnosis of ME/CFS needs to be considered to prevent misdiagnosis as well as under and over diagnosis.	Thank you for your comment. The guideline will address the diagnosis of ME/CFS and the information, education and support for health and social care professionals. Correctly and quickly diagnosing people with ME/CFS and providing more information and support for

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				healthcare professionals should help to address the issues you have raised. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
The Ehlers-Danlos Support UK	6	7-15	Recommend care is taken to consider symptoms which may be due to other conditions rather than or as well as CFS/ME, for example connective tissue disorders.	Thank you for your comment and suggestion. The guideline will address the diagnosis of ME/CFS. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols about diagnosis.
LocalME	6	4-9	1**.2 Key Issues** Use of the CIC approach- the Functional severity, Symptoms and Symptom hierarchy scoring chart	Thank you for your comment and information.
LocalME	6	29-31	**3.4 Multi disciplinary Teams?** This is currently a Clinical Governance and patient safety issue. The model which should be used for ME should be equal to and certainly no less than those offered to MS and other conditions which are classified as neurological patients. there is a need for all patients to have access to consultant-led, multi-disciplinary services with early referral, accurate diagnosis and expert care and advice. Acute, out patient, community and therapy services with well qualified nurses specialised in acute, intensive and palliative care for the most severely affected at risk patients, many who currently are in receipt of effectively no proper care at all.	Thank you for your comment. We agree that the model used for people with ME/CFS should be appropriate for the population's needs. The draft question proposed will aim to identify the mot clinically and cost effective model.

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LocalME	6	11-12	**1.3 Disability or assessment scales** tend to be based on subjective outcomes, especially commonly used and poor "fatigue" scales. ME is not just "fatigue. The fluctuating nature of the condition, complex symptomatology together with subjective bias in scales would be unlikely to give constructive accurate information.	Thank you for your comment. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made.
LocalME	6	16-17	**Diagnosis of ME/CFS**- test coeliac, Romberg's test, POTs OI, food-environmental intolerances and sensitivities leading to gut problems, hormonal and HPA axis deregulation and insufficiency not suited to usual NHS thyroid and adrenal test, (saliva and 24hours urine metabolites are effective indicators), hyper-mobility, EDS, sleep studies, heart variability and irregularity	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when considering the protocol for the questions on diagnosis.
LocalME	6	19-20	(Canadian Criteria) **International Consensus Criteria. (ICC)**	Thank you for your comment. The technical team will ensure this criteria is brought to the attention of the committee when considering the protocol for the questions on diagnosis.

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LocalME	6	23-24	**3.1 Management of ME/CFS** Clinically appropriate and cost effective interventions exist, for pain, sleep, gut problems, POTs and OI, but most services do not have prescribing rights.	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when considering the protocol for the questions on the management of ME/CFS.
LocalME	6	25-26	3.2 Activity management, use of heart monitors which NICE previously recommended, pacing	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when considering the protocol for the questions on the management of ME/CFS.
LocalME	6	27-28	3.3 Objective monitoring and recording data by the use of activity measurement devices- to limit over exertion and avoid risks from PEM using Heart monitoring devices.	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when considering the protocol for the questions on the management of ME/CFS.
Blue Ribbon for the Awareness of ME (BRAME)	6	1/3	Cost effectiveness has to include real consideration of patient evidence and the QALY outcome	Thank you for your comment.
Blue Ribbon for the Awareness of ME (BRAME)	6	22/31	Management section – as I highlighted at the last stakeholder meeting under each heading there should be the question about barriers and facilitators. So need to add here:- 3.5 – What are the barriers and facilitators to the management of ME?	Thank you for your suggestion. This will be addressed in the draft question 4.3, What are the barriers and facilitators to the care of people with ME/CFS?.

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Blue Ribbon for the Awareness of ME (BRAME)	6	22/31	Need to address the special needs of the severely affected:- 3.6 – What are the special needs and what is clinically effective for those who are severely affected?	Thank you for your comment. People with severe ME/CFS will be given special consideration in the guideline and will considered separately in every review question.
Blue Ribbon for the Awareness of ME (BRAME)	6	22/31	Need to address the special needs of children and young people:- 3.7 – What are the special needs and what is clinically effective for children and young people?	Thank you for your comment. Children and young people with ME/CFS will be given special consideration in the guideline and will be considered separately in every review question.
Blue Ribbon for the Awareness of ME (BRAME)	6	22/31	Management Section – need to include a further question under this heading; 3.8 - What adverse reactions are reported, and has patient evidence and QALYs been taken into consideration when looking at what is clinically, and cost, effective?	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.
Blue Ribbon for the Awareness of ME (BRAME)	6	19/20	The ME International Consensus Criteria (2011)	Thank you for your comment. The technical team will ensure this criteria is brought to the attention of the committee when considering the protocol for the questions on diagnosis.
Blue Ribbon for the Awareness of ME (BRAME)	6	25/26	Pleased to see GET and LP removed here	Thank you for your comment.
#MEAction UK	6	4	As children and young people are a specific focus of this guideline, it is vital to also include a draft question addressing transition to adult services. We suggest the following wording: *"How should transition from*	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults' services for young people using health or social care

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			paediatric services to adult services be managed for young people between the ages of 16 and 18?"	services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
Hope 4 ME Fibro Northern Ireland	6	4	**Key Issues and Draft Questions** Whilst we agree with all the questions listed in this section, we think that one crucial question must first be answered regarding ME. That question relates to the premise under which ME is to be treated. The CG53 guideline had a heavy emphasis on rehabilitative strategies. This approach to ME care strongly suggested to practitioners that an underlying psychological problem lay at the heart of ME aetiology. We think it is important that the scope adds a question that instructs the guideline committee to agree on the nature of the aetiology of ME before they proceed to making recommendations about ME care. It is not appropriate that the new guideline should have an approach that in any way confuses secondary or comorbid mental health issues, with the primary physiological issues faced by patients. Thus we suggest adding: **Key Issue: The Nature of ME** 1) Can it be agreed, that there is now sufficient evidence to declare ME an illness with an organic, physiologically based aetiology? 2) Can it also be agreed that ME should not be regarded as a psychosomatic disorder, treatable with therapies aimed at behavioural rehabilitation?	Thank you for your comment. NICE guidelines do not generally review aetiology, pathology and biological research.. These areas can be discussed when helpful for diagnosis and management.

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Invest in ME Research	6	4	*3.5 Key issues and draft questions* As mentioned earlier for Key issues and draft questions Point 7 should be added 7 Information, education and support for health and social care 11 professionals 7.1 6.1 What information, education and support do schools and educational institutes who provide education for people with ME/CFS need? This is important as pressures from schools or universities to force a patient to return, without having any knowledge of the disease or the effects on the patient from this ignorance, could cause relapses or deterioration in the health of the patient.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
ME Letterforce	6	4	The Finished Guideline needs a section on Aetiology of symptoms as GP's need education. It would be desirable to add a section of Aetiology of the disease symptoms at some point with a question on the physical findings which explain key symptoms of the disease so that GP's can understand them.	Thank you for your comment. NICE guidelines do not generally review aetiology, pathology and biological research. These areas can be discussed when helpful for diagnosis and management.

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			We need an evidence search that returns papers on (as an example post exertional symptoms) on exercise research such as the 2 day CPET test and immune system changes after exercise The question could read "What is the current knowledge / evidence that explain key symptoms of ME/CFS such as post exertional worsening"	
Respect for ME	6	4	Please include a question about transitioning from paediatric to adult services.	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults' services for young people using health or social care services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
Forward ME	6	8	Patients with post viral fatigue syndrome (PVS) should be considered as possible candidates for ME. Although most patients with PVFS recover spontaneously, there may be some for whom standard recovery procedures – e.g. – reducing rest time and increasing activity, may not be suitable. Proceed with caution!	Thank you for your comment. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the protocols for the identification of people with ME/CFS.
Healthwatch Bolton	6	8	Use robust criteria	Thank you for your comment. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of

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				outcomes which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients.
Parents of children with ME/CFS Support Group	6	8	This question would be better worded as 'What defining characteristics of ME/CFS [such as Post-Exertional Malaise] can be used to identify the possibility of the illness?"	Thank you for your suggestion. The technical team will ensure this is brought to the attention of the committee when they are considering the final review questions and protocols for the identification of people with ME/CFS.
The Pituitary Foundation	6	8	Those patients who have Adrenal Insufficiency should be included in diagnostic tests- this hormonal deficiency should be considered as potential for ME/CFS	Thank you for your comment and information. The technical team will ensure adrenal insufficiency is brought to the attention of the committee when they are considering the final review questions on diagnosis.
F.O.R.M.E	6	9	Our latest research published in BMJ Open in November 2017 demonstrated the presence of physical signs found in M.E. sufferers. These physical signs are present in the early stages of symptoms, a phase sometimes called 'Pre-M.E'. Examining a suspected sufferer using The Perrin Technique can detect these signs, potentially preventing significant worsening of symptoms. The quicker the diagnosis the better the outcome for the patient, the speedier and more cost effective their recovery.	Thank you for this information.

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Healthwatch Bolton	6	9	Emphasis needs to be on what is clinically effective, as that will become cost effective in the long term. There is new evidence of physical signs in the majority of people with ME/CFS using. Dr Raymond Perrin's technique: very cost-effective method of diagnosis. Blinded clinical trials have been carried out and published. Exclusionary blood tests need to be done, and any issues dealt with (eg., low vitamin D).	Thank you for your comment and information. The guideline will follow the methods set out in the NICE guidelines manual. Clinical and cost effectiveness will be explored for each review question.
Blue Ribbon for the Awareness of ME (BRAME)	6	11	Caution over what disability or assessment scales used – these can also be based on subjective outcomes – also have to account for those for whom ME is a fluctuating condition	Thank you for your comment. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients.
Forward ME	6	11	Disability or assessment scales tend to be based on subjective outcomes. The fluctuating nature of the condition would be unlikely to give accurate information.	Thank you for your comment. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded. Any guideline development is however

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				limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients.
Healthwatch Bolton	6	11	May be useful, alongside thorough history, and listening to patient carefully.	Thank you for your comment.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	11	In terms of criteria for severely affected the International Consensus Criteria (Carruthers – 2011) is very useful.	Thank you for your comment.
Royal College of General Practitioners	6	11	Management of ME/CFE It will be important to identify trials where harms are identified and recorded	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.
Royal United Hospitals Bath NHS Foundation Trust	6	11	Disability scales need to be age appropriate and sufficiently sensitive to monitor progress. Eg Chalder Fatigue scale compares everything to 'usual' and this can be difficult to quantify if the person has been ill for a long time. Visual scales as used in Pain evaluation may be a bit more	Thank you for your comment and information.

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			meaningful. However, it is important that any form of questionnaire is part of a clinical assessment and not used in isolation.	
Stonebird	6	12	**P6 line 12 we think it is not enough to ask, ' Can disability and Assessment scales aid the identification of people with ME/CFS?'** It should ask which one is suitable? Which are not appropriate?	Thank you for your comment. The most appropriate ones will be identified in this review question.
Blue Ribbon for the Awareness of ME (BRAME)	6	13	Main barriers continue to be the erroneous, and/or misinformation and pre-conceived ideas, amongst HPs and other professionals, about the most complex and debilitating neurological illness ME, and their lack of understanding of the enormous and overwhelming impact it has on the person, and how it can become a multi-system, multi-organ illness, - which is relevant for each section of 3.5 Main facilitators are of course to have well informed HPs/GPs who understand ME and are able to diagnose and appropriately manage the illness. But most important is listening to the patient, and their carer(s) and taking a full and accurate history, and the HP acknowledging that they have listened, and can see how ill they are feeling, and will do everything they can to try and find out what is wrong with them. Giving the patient and carer that understanding, belief and support, whilst offering well informed information and advice, in the early stages is vital. Once a diagnosis of ME is reached, then that continued belief in the patient and the illness, accurate information, understanding, support is needed, and of course that good quality management, monitoring and on-going care continues.	Thank you for your comment and information. We agree there are many barriers and facilitators to achieving optimal care and have included this area for review in all the sections of the scope.

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Forward ME	6	13	Preconceived views by professionals are potential barriers to identification. Listening to the patient and taking a full history are facilitators.	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.The guideline will address information, education and support for health and social care professionals.. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all people with ME/CFS and reduce any stigma.
Healthwatch Bolton	6	13	Barriers: lack of knowledge and understanding from GPs and others. Believing causation and/or perpetuation is psychological, not physical. Facilitators: open mindedness, listening to patients.	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols**..** The guideline will address information, education and support for health and social care professionals.. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all people with ME/CFS and reduce any stigma.
LocalME	6	13	1.4 The 30% most severely affected are too ill to go from home to appointments so the barriers are immense. SAs are rarely seen outside the home and rarely are they seen at home, even by GPs or community health staff. Therefore they don't exist. The true seriousness and severe presentation of ME is therefore beyond most health, social care, education and benefit's staff realm of experience. Therefore there is a	

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			preconception by professions as to the true presentation of ME. These preconceived views by professionals are potential barriers to identification. Listening to the patient and taking a full history at home with home visits, which minimise relapse, are essential facilitators and should be recommended by NICE. Another barrier is that ME services are largely placed in "planned care and community services. There are few services of the appropriate type in Acute medicine. Hospital settings are problematic; they challenge the moderately affected and are often unsuitable for the severity affected.	
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	13	Barriers to identification include confusion amongst healthcare workers. The model of the illness currently utilised is incorrect and is therefore not working in practice. The guideline needs a robust definition of post exertional malaise as a required symptom. NICE also needs to advise briefly on common co-morbidities such as Ehlers Danlos syndrome, Postural Tachycardia Syndrome and Orthostatic Intolerance.	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.. One of the tasks for guideline development will be to consider diagnostic criteria and the definitions to be used Use of the terms in the scope does not imply acceptance of any particular definition or meaning and does not pre-judge the terminology of the completed guideline. In addition the guideline will address information, education and support for health and social care professionals.. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all people with ME/CFS and reduce any stigma.

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The Pituitary Foundation	6	13	Routine blood test to check all pituitary hormones should be given to rule out hypopituitarism which if left untreated can cause severe fatigue.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Forward ME	6	14	Advise patients to listen to their bodies and to stop activities before they exceed their tolerance threshold. Involve family who will be better able to observe when limits are being reached.	Thank you for your suggestion. The technical team will ensure the area you raise is brought to the attention of the committee.
Healthwatch Bolton	6	14	First do no harm. Encourage rest.	Thank you for your suggestion. The technical team will ensure the area you raise is brought to the attention of the committee.
ME Letterforce	6	14	Before diagnosis doctors should stress the importance of rest and pacing	Thank you for your suggestion. The technical team will ensure the area you raise is brought to the attention of the committee.
The Pituitary Foundation	6	14	Patients with a diagnosed pituitary condition who have optimal hormone replacement yet still have significant fatigue should also be considered for ME/CFS diagnosis.	Thank you for your comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
ME Letterforce	6	16	It might be useful here to have a question to cover common misdiagnoses and explain what ME is not i.e. not deconditioning or a lifestyle disorder or a mental illness or a medically unexplained disease The question could read	Thank you for your comment and information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.

Stakeholder	**Page no.**	**Line no.**	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
			"what are the common misdiagnoses in ME / CFS patients and how are they different"	
ME Research UK	6	16	The following points need to be considered when reviewing the diagnosis of ME/CFS: the limitations and applicability of diagnostic criteria, the variation in symptoms over time, and the fact that 'non-engagement' with medical services may be due to illness severity rather than personal choice.	Thank you for your comment and information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Science for ME	6	16	"Diagnosis of ME/CFS" In looking at the diagnosis of ME/CFS it is important to ensure other causes of chronic fatigue symptoms are explored as appropriate. For example, testing for hypothyroidism, anaemia, sleep disorders, MS etc. Guidelines could help avoid mis-diagnosis by documenting common problems. The issue of the fatigue as a central symptom may also relate to the number of misdiagnoses. Other diseases also have patients with symptoms of chronic fatigue. As mentioned in our comment 2 many patients, scientists and doctors view PEM (Post exertional malaise) as a central symptom and this was identified as such by the IoM report into ME/CFS. http://www.nationalacademies.org/hmd/Reports/2015/ME-CFS.aspx PEM should be an important diagnostic feature.	Thank you for your comment and information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.

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University of Central Lancashire	6	16	Based on 29 years of clinical research in this field, there is strong evidence that CFS/ME is a disorder of retrograde lymphatic drainage leading to neurotoxic build up within the central nervous system. This produces physical signs that have been recently validated as an effective diagnostic aid in a blind controlled trial in the UK. The results were published in the BMJ Open November 2017. This was the first study that explored agreement on the presence of physical signs in the screening of patients with chronic fatigue syndrome/myalgic encephalomyelitis with two practitioners using only the physical signs to diagnose without any conversation with participant or case history taken. The results showed a high diagnostic accuracy (86%) (Hives L. et al. 2017) The latest scanning techniques have proven the long-held view that cerebrospinal fluid drains into the lymphatic system with studies showing 'glymphatic' system and lymphatic vessels in the human. The independent parliamentary Gibson Inquiry into CFS/ME of 2006 described The Perrin Technique as a useful and empirical method. Since the initial PhD thesis (Perrin R, 2005) many published studies have provided concrete scientific evidence of increased pro-inflammatory neurotoxins and the dysfunction of the hypothalamus and sympathetic pathways which ultimately will affect the lymphatic drainage of the brain, spine and musculature.	Thank you for this information and reference. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.

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			At present, it takes the NHS months of costly blood tests to exclude all other pathologies and that diagnosis of CFS/ME is unfortunately confirmed by exclusion. An early indicator and an aid to diagnosis is what most patients need. As mentioned above, the diagnostic signs that have been observed for almost 3 decades were tested in a recent NHS sponsored Blind Controlled Study. Therefore, we have an effective and a very cost effective tool that primary health care practitioners could use in early screening for the illness. It is hoped that all patients with CFS/ME will benefit from the research that could help provide a much earlier positive diagnosis within the NHS. We urge you to review the research and the evidence that gives a scientific explanation for the symptoms and signs of CFS/ME and potentially offers an early detection for the thousands of new CFS/ME patients that will be seen in this country alone in the next few years.	

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			I conclude by stating that I agree that my techniques are not stand alone diagnostics but together with other new tests for possible biomarkers should form a part of the diagnostic screening process of the new NICE guidelines for CFS/ME.	
F.O.R.M.E	6	17	Our latest research published in BMJ Open in November 2017, demonstrated the presence of physical signs found in M.E. sufferers and that The Perrin Technique is significantly more accurate at aiding diagnosis than current methods. Thus eliminating the need for costly blood tests, scans etc. leading to a quicker diagnosis for patients. Practitioners can be easily taught at day seminars how to examine patients for these physical signs, making prompt diagnosis accessible for all.	Thank you for your comment and information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Healthwatch Bolton	6	17	Need to use robust criteria to diagnose, in order to rule out primary depression, for instance. ICC and Canadian both use PEM/PENE as distinguishing feature, which differentiates from depression. Very cost-effective.	Thank you for your comment and information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Optimum Health Clinic Foundation	6	17	There is a need to update and harmonise the diagnostic criteria used to confirm a diagnosis. Fukuda and Oxford criteria are out of date and should no longer be used. We should aim to agree one set of diagnostic criteria to be included in the updated guideline.	Thank you for your comment. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. This will be one of the initial tasks for the committee. Existing

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				statements such as those from the Centre for Disease Control will be used to inform the committee.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	17	PoTS (Postural Tachycardia Syndrome) is a common and potentially treatable feature of ME/CFS. Tilt table testing should be considered for inclusion in these guidelines. If patients are effectively treated for this aspect of their illness their function will improve and the economic burden of their ill-health be reduced.	Thank you for this information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Royal United Hospitals Bath NHS Foundation Trust	6	17	At present the diagnosis is one of exclusion of other conditions. There are some tests which are not currently included, which should be considered for inclusion, particularly to reveal a treatable cause. Examples could be Vit D, Lyme serology, EBV markers of persistent infection, B12/folate, Magnesium. Autoimmune screening needs to be carefully considered as false positive tests often result (I would suggest only requested on clinical grounds. The evidence (or lack of it) regarding non-validated tests for factors such as mitochondrial function and ATP levels should be clearly stated.	Thank you for this information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Stonebird	6	17	**P6 line 17 'what tests are clinically and economically effective in making an ME diagnosis?** What does NICE mean by a "cost-effective pathway": is it a biomedical or a psychosocial one? Each approach will yield a very different result, both have conflicting information, support and methodology.	Thank you for your comment and. The guideline will follow the methods set out in the NICE guidelines manual. Clinical and cost effectiveness will be explored for each review question. The identification and referral and diagnosis of ME will be addressed in

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			We suggest that unless NICE better identifies the symptoms of ME, including the full symptoms of Severe ME, the GDG will not be able to safely and fully identify the tests required, not only to make the diagnoses, but also to rule out other diseases, particularly rare diseases in those people with Severe ME.	the guideline. This will include the identification of symptoms. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
The Pituitary Foundation	6	17	For adults with suspected ME/CFS, 9.00am Cortisol blood test should be undertaken. For children suspected, Cortisol and Growth Hormone levels should be tested,	Thank you for this information. The technical team will ensure the issues you raise are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Forward ME	6	19	CDC, IOM or International Consensus Criteria	Thank you for this information. The technical team will ensure the examples of criteria are brought to the attention of the committee when they are considering the final review questions on identification and referral and on diagnosis.
Healthwatch Bolton	6	25-6	Ineffective, even downright harmful, treatments such as GET or the Lightning Process (and the inappropriate model of CBT) are extremely costly in both short and long term. Very cost-effective to provide supportive letters for people to use for DWP, employers and insurance and pensions companies. Lack of good supportive letters can have a major detrimental effect on a patient's condition, which may require more intensive treatment as a result. There needs to be a method of reporting harms resulting from non-pharmacological therapies, similar to the yellow card system, which can be collated. Some researchers and clinics report no harm has been caused by their use of GET, for example, when	Thank you for your comment and suggestion. The guideline will follow the methods set out in the NICE guidelines manual. Clinical and cost effectiveness will be explored for each review question and outcomes on harms will be included in all the review protocols, adverse effects has been added to the list of outcomes. The technical team will ensure the issues you raise are brought to the attention of the committee when they

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			individual ex-patients assert otherwise. Not good enough just to complain to the treatment centre or local CCG: needs to be centrally collated in order to understand.	are considering the final review questions on management.
Healthwatch Bolton	6	27-8	Many patients, in the absence of NHS treatments, use such strategies as diet to improve symptoms. Strategies such as mindfulness can help to cope with the illness, but is not a cure. Some patients find specialist lymphatic drainage massage helpful. Vitamin supplementation, for example magnesium, had also helped some people to improve. Most of these have no cost to the NHS, but can have a heavy cost to the individual. Pacing is clinically and cost effective.	Thank you for your comment and suggestion. The guideline will follow the methods set out in the NICE guidelines manual. Clinical and cost effectiveness will be explored for each review question the technical team will ensure the examples you raise are brought to the attention of the committee when they are considering the final review questions on management.
Optimum Health Clinic Foundation	6	19	There are a number of patient sub- groups who exhibit symptoms which can be gut related, cognitive impairment, sleep disturbance, etc, which do not occur in all patients with CFs/ME. It is important to differentiate between these patient subgroups and tailor treatment and symptom management programmes to fit them, rather than a one size fits all approach.	Thank you for your comment. We are aware that not all the people with ME/CFS have the same symptoms and it is important to recommend the appropriate treatment for the right person. It will be the task of the committee to consider the terminology and diagnostic criteria to use for different subgroups of people with ME/CFS in order to identify the appropriate management.
Parents of children with ME/CFS Support Group	6	19	The draft scope needs to include provision in the guideline for a single, agreed set of diagnostic criteria which includes the use of objective biomedical markers. See, for example, the diagnostic criteria for Hypermobile Ehlers-Danlos Syndrome at https://www.ehlers-danlos.com/heds-diagnostic-checklist/ as an example of good practice.	Thank you for your comment and information. The scope is purposely worded to allow the committee to consider the terminology and diagnostic criteria to use. Existing statements will be used to inform the committee.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	19	In people with suspected ME/CFS how accurate are the criteria used to establish the diagnosis? Criteria include: 1994 Fukuda 2003 Canadian Consensus Criteria 2011 International consensus criteria 2015 Institute of medicine report The International Consensus Criteria is preferred by many patients with ME. It is vital that it is made clear in these guidelines which patients the guidelines do and do not apply to. Those only meeting the less stringent criteria may well be suffering from completely different illnesses to those meeting the more stringent criteria. The presence or absence of post exertional malaise (not just fatigue after exertion) is important. The approaches that may help those meeting only the less stringent criteria may do serious harm to those meeting the more stringent criteria.	Thank you for your comment and information. The scope is purposely worded to allow the committee to consider and review the terminology and diagnostic criteria to use. Existing criteria such as the ones you have listed will be used to inform the committee.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	19	Post exertional malaise is a cardinal feature of this illness. The recommendations made must distinguish between patients with post exertional malaise and those without. The symptom "chronic fatigue" is not the same as ME/CFS. It must be clear which patients any recommendations apply to. The criteria used for any research must be taken into consideration when evaluating the findings.	Thank you for your comment. We have altered section 1 following stakeholder consultation to clarify that fatigue is not necessarily the appropriate term and that other symptoms occur and included reference to post exertional malaise and deterioration of symptoms. It will be the task of the committee to consider the terminology and diagnostic criteria to use for different subgroups of people with ME/CFS in order to identify the appropriate management.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	19	The broader the criteria used the less accurate they are at diagnosing ME. Chronic fatigue as a symptom needs to be differentiated from ME/CFS as a disease of which Chronic fatigue is only one of many disabling symptoms.	Thank you for your comment. We have altered section 1 following stakeholder consultation to clarify that fatigue is not necessarily the appropriate term and that other symptoms occur and included reference to post exertional malaise and deterioration of symptoms. It will be the task of the committee to consider the terminology and diagnostic criteria to use for different subgroups of people with ME/CFS in order to identify the appropriate management.
The Pituitary Foundation	6	19	Basic Field Vision Test should be undertaken to assist with accurate diagnosis	Thank you for this information. The technical team will ensure the test you have raised is brought to the attention of the committee when they are considering the final review questions on diagnosis.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	20	1.PEM needs to be defined adequately. It is not sufficient to say it is a worsening of symptoms. Current NICE guidelines would allow worsening of a headache and fatigue as PEM. 2.Correctly defined PEM needs to be part of the outcome measures.	Thank you for your comment. We have altered section 1 following stakeholder consultation to clarify that fatigue is not necessarily the appropriate term and that other symptoms occur and included reference to post exertional malaise and deterioration of symptoms. It will be the task of the committee to consider the terminology and diagnostic criteria to use for different subgroups of people with ME/CFS in order to identify the appropriate management.
LocalME	6	21	**2.3 Barriers** are 2010 Health Service changes 1. Obstacles in Primary Care- Lack of GP training and 2. research indicates that a high percentage of GPs do not believe ME exists as a serious physical disabling and potentially life threaten	Thank you for this information. The technical team will ensure the issues you have raised are brought to the attention of the committee when they are considering the final review questions on barriers to diagnosis.

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			condition. As GPs, via CCGS and GP Federations, are now the principle gatekeepers to resources, there is a refusal to take ME/CFS seriously and enshrine it in their 5 year and 2 year planning. Therefore ME/CFS is below the radar at Governing Body level and outside public scrutiny and accountability. 3. Lack of serious acknowledgement of the need and prioritisation of investment at Government level since 2004. 4. Despite new legislation intended to help, it is not being applied and acknowledged in relation to ME/CFS. Statutory services are often in breach of the law, with respect to ME as a disabling condition, with both ignorance and abandon. 5. NICE should be granted some teeth to embarrass and sanction those who wilfully ignore any revised appropriate guideline. NCE can lead the CCGS and Social care agencies to the water, but it has little capacity to make them drink. 6. Lack of prescribing rights	NICE does not have a remit for commissioning services in CCGs.
Royal United Hospitals Bath NHS Foundation Trust	6	21	Comorbidity especially with mental health difficulties. Often those with comorbidity are prevented from accessing appropriate help because an attribution is made to one diagnosis as overarching i.e. mental or physical reflecting division in service provision rather than appropriate care.	Thank you for this information. The technical team will ensure comorbidity especially with mental health difficulties is brought to the attention of the committee when they are considering the final review questions on barriers to diagnosis.
#MEAction UK	6	22	None of these questions address the ongoing active care needs of severely ill people with ME. An additional question should be added such as: *"How should care be provided to the severely and very severely ill, both in the community and in an inpatient/residential setting (including: nutrition, tube feeding; pain management; sensory sensitivities; arising*	Thank you for your comment. All of the questions address the ongoing care needs of people with severe ME/CFS. Special consideration will be given to people with severe ME/CFS throughout the guideline and considered separately in every review.

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			comorbidities such as osteoporosis; and palliative or end of life care, as appropriate)?." We understand that NICE intends to repeat each section of the guideline specifically for children and the severely ill but this needs to be made explicit in the scoping document.	
Blue Ribbon for the Awareness of ME (BRAME)	6	8 and 14	Anyone who has PVFS – post viral fatigue syndrome – should be monitored and considered as possibly being at risk of developing ME – and so extra caution being taken in the early stages and taking time to rest, listen to their body, and not overdo things, so they stay within their energy threshold to try and hopefully aid recovery, or reduce the impact if ME develops.	Thank you for this information. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions.
ME Letterforce	6	22	It would be desirable to add a section of Aetiology of the disease symptoms at some point with a question on the physical findings which explain key symptoms of the disease so that GP's can understand them and treatments can be assessed within an evidence based framework. We need an evidence search that returns papers on (as an example post exertional symptoms) on exercise research such as the 2 day CPET test and immune system changes after exercise The question could read	NICE guidelines do not generally review aetiology, pathology and biological research. A guideline is not intended as a definitive account of all aspects of a condition. These areas can be discussed when helpful for diagnosis and management.

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			"What is the current knowledge/evidence that explain key symptoms of ME/CFS such as post exertional worsening"	
ME Letterforce	6	22	Another question should be "What is the clinical and cost effectiveness of offering treatment at home". This takes into account that many patients cannot access NHS treatments either for their ME but also for standard screening tests (breast cancer screening, cervical smears etc) and for treatment for secondary conditions such as cancer.	Thank you for your comment. This question will be addressed as part of the other questions and where treatments are delivered. In addition draft question 3.4 specifically reviews the clinical and cost effectiveness of different models of multidisciplinary care, including team composition.
ME Research UK	6	22	There is likely to be a lack of high quality published evidence on interventions for ME/CFS, partly because the condition is a syndrome with considerable patient heterogeneity. Given this fact, evidence from clinicians should be considered bearing in mind the spectrum of patients which any one clinician will come across, as well as the variations in diagnostic criteria and non-standard outcome measures used. Such evidence should be viewed and incorporated with care.	Thank you for your comment. The clinical and cost effectiveness of interventions will be reviewed in the guideline. The guideline will follow the methods set out in the NICE guidelines manual. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.

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Optimum Health Clinic Foundation	6	22	Recognition that the various stages of recovery from CFS/ME have different needs in terms of effective treatments. No one set of treatments is suitable for all the stages of recovery	Thank you for your comment. We are aware that not all the people with ME/CFS have the same recovery and it is important to recommend the appropriate treatment for the right person. It will be the task of the committee to consider the terminology and diagnostic criteria to use for different subgroups of people with ME/CFS in order to identify the appropriate management.
Parents of children with ME/CFS Support Group	6	22	In addition to clinical and cost effectiveness, interventions and strategies need to also be proven to do no harm to patients in points 3.1, 3.2 and 3.3 of the draft scope.	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. .
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	22	Neurological symptoms/outcomes should be included. They are definitely present in the moderately and severely affected.	Thank you for this information. The technical team will ensure the issues you have raised are brought to the attention of the committee when they are considering the final review protocols..
Respect for ME	6	22	Severe patients have been excluded from this list. Both in-patient and community care needs to be considered (such as tube-feeding, drips and managing comorbidities such as osteoporosis).	Thank you also for outlining potential practical areas that help people with severe ME/CFS. People with severe ME/CFS are not excluded. Special consideration will be given to people with severe

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				ME/CFS throughout the guideline and considered in every evidence review.
Royal College of General Practitioners	6	22	Management of ME/CFE A review by the Pacific Northwest Evidence-based Practice Center, Oregon Health & Science University, and Providence Cancer Center, Providence Health and Services Oregon, Portland, Oregon suggest that trials of rintatolimod, counselling therapies, and graded exercise therapy suggest benefit for some patients meeting case definitions for CFS, whereas evidence for other treatments and harms is insufficient. *Ann Intern Med.* 2015;162(12):841-850. DOI: 10.7326/M15-0114	Thank you for this reference.
Royal College of Occupational Therapists	6	22	We would recommend that the guideline also covers modes of treatment delivery, for example how in-patient care should be delivered as many patients do not have their particular needs recognised in this setting. Also the role of home based intervention or assistive technology, for people who are unable to travel.	Thank you for your comment. This question will be addressed as part of the other questions and where treatments are delivered. In addition draft question 3.4 specifically reviews the clinical and cost effectiveness of different models of multidisciplinary care, including team composition. .
Royal College of	6	22	The role of equipment and devices should also be covered as patients are often denied access to equipment such as wheelchairs for outdoor	Thank you for your comment. This question will be addressed as part of the questions on self-

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Occupational Therapists			use, or stair lifts, on the basis that they do not have a chronic disabling physical condition for which these would be appropriate. Specifically covering this within the guidance could prevent this exclusion.	management. The technical team will ensure the areas you have raised are brought to the attention of the committee.
ME Letterforce	6	11. 12	Scales to be used to monitor the progression of the disease should be added Heart rate monitoring should be added	Thank you for your suggestion. The technical team will ensure the areas you have raised are brought to the attention of the committee.
Stonebird	6	23	**P6 line 23 What is the clinical and cost effectiveness of pharmalogical interventions for people with ME/CFS?**'It should also ask what is the safety of these interventions? What risk assessments can be put in place to ensure no harm is done?	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.
Christians with ME, CFS, Fibro and their Carers	6	25	We welcome the review of non-pharmacological interventions as well as reviewing the, in our opinion, flawed use of CBT and GET, we assume that "other interventions" will include, amongst other things complimentary medicine and changes to diet, we feel that these two areas should be specifically mentioned in the scope of the review.	Thank you for your suggestion. The technical team will ensure the areas you have raised are brought to the attention of the committee. Diet has been included as an example.
F.O.R.M.E	6	25	The Perrin Technique is a non-pharmacological intervention that can be easily taught to existing primary care practitioners. This would be quick cost effective training benefiting huge numbers of sufferers.	Thank you for this information.

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Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	25	Patient reported harms of interventions must be taken into account. The lack of official channels for patients to report these harms must be considered; evidence from patient surveys should be taken into account. Harms should be considered in particular in relation to Cognitive Behavioural Therapy (this is of concern when used as a treatment for the physical illness, rather than as a supportive therapy for comorbid anxiety and depression), Graded Exercise Therapy, Activity Management if it includes a component of graded increase, any other treatment that encourages an increase in activity and ignoring of symptom increase (e.g. the Lightning Process). The value of rest and living within a sustainable energy envelop that prevents post exertional malaise should be considered (commonly known as pacing and often considered helpful by patients). Again, all interventions must be clearly defined. The impact of sleep restriction (clinics encourage the waking of patients when they feel they still need to sleep in order to encourage a more "normal" sleep pattern) should be considered as this has been found to be harmful by some patients.	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. The guideline will follow the methods set out in the NICE guidelines manual. . The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	25	2 What is the clinical and cost effectiveness of non-pharmacological interventions for people with ME/CFS (including dietary supplementation, graded exercise therapy, pacing, the lightening process and psychological interventions such as CBT)? * There is a small section in this video about dietary issues for patients: https://t.co/ceENSJFS It is called "Ketra's story after Unrest" and can be found at www.ketrawooding.com	Thank you for your comment and information. NICE has an existing guideline 'Nutrition support for adults' that includes recommendation s on how to assess for malnutrition and we will cross refer to this guideline. We do intend to examine diet and have added diet as an example of the areas included in section 3.5.

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			* We found this video really informative and believe medical practitioners in the UK could learn a lot from it to help patients. * Graded exercise has to come with a big warning because it can make patients worse for weeks, months or years. Any exercise programmes must be massively modified and loads drastically reduced, reducing the intensity. * A huge amount of research has to go into this area and any physiotherapists working with this must be educated about the disease. * Moderate and Severe patients may not manage this at all. * There are however a large amount of patients who have reported that exercise makes them worse. * Please refer to the video link provided as it suggests gentle floor exercises etc. I do not feel like we can give sufficient advice regards to this. * I have mild ME/CFS and I can walk 30 minutes per day with my dog but each evening I am experiencing symptoms of Post Exertional Malaise. I could be causing more damage? So although I can manage it, it could be making me worse. * The main challenge with this disease is actually restraining patients from doing too much. * ME/CFS is not psychological so any part that CBT may play would only be as a support to help a patient cope with the massive change that this disease plays. It is not a treatment or a cure. Again though the staff must be trained in the disease and how it affects the patient. * Lightening process in my opinion is a waste of time, money and resources. I would be interested to know if any patients have recovered	The guideline will follow the methods set out in the **NICE guidelines manual**. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline.

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			from this and if they have what diagnostic criteria was used to diagnose them. It might cure chronic fatigue but not ME/CFS.	
Royal College of Psychiatrists	6	25	A published case series suggests that rTMS (repetitive transcranial magnetic stimulation) may be effective in treating ME/CFS. As rTMS is available in some UK centres the committee should review the evidence for rTMS. If there is evidence for its use it may be helpful to comment on details such as area, duration and frequency of stimulation. **Reference:** Kakuda W, Momosaki R, Yamada N, Abo M. High-frequency rTMS for the Treatment of Chronic Fatigue Syndrome: A Case Series. Intern Med. 2016;55(23):3515-3519. Epub 2016 Dec 1.	Thank you for your comment and reference. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
South London & Maudsley NHS Foundation Trust	6	25	A published case series suggests that rTMS (repetitive transcranial magnetic stimulation) may be effective in treating ME/CFS. As rTMS is available in some UK centres the committee should review the evidence for rTMS. If there is evidence for its use it may be helpful to comment on details such as area, duration and frequency of stimulation. **Reference:** Kakuda W, Momosaki R, Yamada N, Abo M. High-frequency rTMS for the Treatment of Chronic Fatigue Syndrome: A Case Series. Intern Med. 2016;55(23):3515-3519.	Thank you for your comment and reference. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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			Epub 2016 Dec 1.	
Stonebird	6	25	**P6 line 25 and 26 'What is the clinical and cost effectiveness of non-pharmalogical interventions for people with ME/CFS?'I**t should also ask what is the safety of these interventions? What risk assessments can be put in place to ensure no harm is done? ME today costs the UK economy at least £3.3 billion per annum, the ME community have been stressing for years that CBT and GET are neither clinically effective nor cost-effective, this needs to be noted by NICE.	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	9,17	What tests are clinically and cost effective in supporting or excluding a diagnosis of ME/CFS? * Tests used to aid diagnosis. The Bateman Horne Centre in the USA have developed the NASA 10 minute Lean Test and this helps to check for orthostatic intolerance/postural orthostatic tachycardia syndrome (POTS) which many patients with ME/CFS suffer from. * Brochures for this NASA Lean Test can be downloaded from their website. * To check if a patient has this, stand the patient up against a wall and looking at their feet monitor their pulse and blood pressure every minute for up to 10 minutes. Many patients will not manage 10 minutes but results can become apparent sooner depending on severity. * Before the test feet will look relatively normal and after the test they will (may) have changed colour and appearance. This does not happen in healthy patients. * Note that there are skin colour, swelling and temperature changes.	Thank you for the comment and information. The technical team will ensure the areas you raise are brought to the attention of the committee.

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			* They see this appearance when a patients autonomic nervous system is not working properly. * Changes in heart rate are also obvious eg a resting heart rate could start at 62 and after 10 minutes it's up to 128 or more for doing nothing apart from standing. Again this is not normal. * Cardio pulmonary exercise testing in ME/CFS Management (CPET) * Test is done on treadmill or exercise bike and they measure a number of physiological variables. * The important thing they do in this test is to measure threshold points, (carbohydrates & fats). * In a healthy person these threshold points might occur at a high intensity of exercise eg running. * In an ME/CFS patient the aerobic metabolism sees a different output having a diminished ability to burn fat and carbohydrates. * New definitions of exercise is needed for ME/CFS patients as they may meet this threshold limit doing daily activities, household chores or daily hygiene. * You must also consider that these patients recover at a much slower rate from activity/exercise than healthy patients traditionally do.	
Patient Advisory Group to the CMRC (CFS/ME	6	27	What is the clinical and cost effectiveness of self-management strategies such as heart rate monitors for people with ME/CFS * Heart rate monitors and pacing can help ME/CFS patients.	Thank you for the comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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Research Collaborative)			* They are a useful tool for pacing because you can set an alarm and when the patient goes above a certain threshold this gives the patient a warning sign that they need to rest or schedule in rest and recovery. * Heart rate can also define for a person when they are actually resting and when they have recovered. * Looking at heart rate data retrospectively over time combined with activity logs and symptom logs can help a patient build up a framework of finding their personal activity limits and what they can do in a day and how much rest they are going to require. * Patients will need experienced experts to help with this.	
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	6	27	The value of seeking support from both local support groups and national charities should be considered; patients report benefits from doing so. Contact with and support from others living with the illness can be valuable.	Thank you for your comment. We do intend to include a call for evidence as part of the methods during the guideline development..
Stonebird	6	27	**P6 line What is the clinical and cost effectiveness of self-management strategies interventions for people with ME/CFS?** It should also ask what is the safety of these interventions? What difference in self-management might there be for someone with mild as opposed to someone with Severe ME? What risk assessments can be put in place to ensure no harm is done for any ME group, for example Pacing should not be recommended across the board for people with	Thank you for the comment and information. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.

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			Severe ME, without understanding that even this level of management can be too much - people are unlikely even to have the required energy to identify a baseline and then pace. ME today costs the UK economy at least £3.3 billion per annum, the ME community have been stressing for years that CBT and GET are neither clinically effective nor cost-effective, this needs to be noted by NICE. There must be an understanding recognised in the Scope of the difference between the experience of someone with mild ME and someone with long term Severe ME.	
The Pituitary Foundation	6	27	Education is essential for effective self-management. Patients need to understand the link between mental/emotional health and their physical state, in order to work effectively with HC professionals. Individuals should be responsible for their own health, but must understand the need to do so.	Thank you for your comment and suggestion. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
ME Letterforce	6	29	The multidisciplinary team should include a ME nurse who can do home visits for severely affected patients as MS patients receive	Thank you for your comment. This question will be addressed as part of the other questions and where treatments are delivered. In addition draft question 3.4 specifically reviews the clinical and cost effectiveness of different models of multidisciplinary care, including team composition.
Parents of children with	6	31	The draft scope currently excludes people who need aids and adaptations as part of the support for ME/CFS. We recommend point 3.5	Thank you for your comment. The scope doesn't exclude people who need aids and adaption. This

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ME/CFS Support Group			to be added: "What is the clinical and cost effectiveness of aids and adaptations for people with ME/CFS?"	question will be addressed as part of the questions on self-management. The technical team will ensure the areas you have raised are brought to the attention of the committee.
Parents of children with ME/CFS Support Group	6	31	The draft scope currently excludes children with ME/CFS who need educational support. We recommend point 3.6 to be added: "In children and young people suspected or diagnosed with ME/CFS, what is the effectiveness of different models of educational support?" We argue that educational support is a key factor in the management of ME/CFS in children and young people, and clear guidance needs to be provided to educational establishments about effective, creative and holistic solutions which are created by the parents/child working in partnership with education services. Because of the fluctuating nature of the illness, a complete break from education may be necessary if a child is not well enough. Schools and colleges often have very rigid policies about school attendance and therefore it is imperative that a joined-up approach is taken between health and education services so as to allow children time to rest and recover by reducing their hours as much as is needed and providing education outside of the school building.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Parents of children with	6	31	The draft scope currently excludes the transfer of children under paediatric care to adult services. We recommend point 3.7 to be added:	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults'

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ME/CFS Support Group			"For young people approaching 16, what is the effectiveness of different models of transfer to adult services?"	services for young people using health or social care services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
LocalME	6	32	**4. Monitoring and review** This is currently a Clinical Governance and patient safety issue. If appropriate accessible services do not exist, then the patient population effectively does not exist. Monitoring and reviewing are not conducted especially for the most vulnerable and at risk- children and the severely affected. It's a Human Rights issue and breach of the UNCRDP.	Thank you for your comment and information.
Science for ME	6	32	"Monitoring and review" It is important to point out that people with ME can get other illnesses and that new symptoms should be investigated as appropriate. And remind doctors that patients (particularly with severe ME) can have difficulties accessing health care.	Thank you for your comment and information.
ME Letterforce	6	25, 26	NICE should consider the cost burden of patients who deteriorate after GET compared with the minimal, if any, benefits.	Thank you for your comment and suggestion. We will the clinical and cost effectiveness in all the review questions.
Royal United Hospitals Bath NHS Foundation Trust	6	27,28	Patients who wish to self manage their condition are often disbelieved, required to produce written evidence of a diagnosis and may be unable to access support and services which are available to others with disabling conditions. Families of children who are not able to attend school experience a hugely variable degree of support. In some areas, the LA is able to	Thank you for outlining the difficulties experienced by children and their families both with their condition and with the treatments that may be offered. Thank you also for outlining potential practical areas that help children and their families. Special consideration will

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			provide an assessment for an Education Health and Care Plan, and can provide an appropriate, individually tailored level of Educational support. In others, the default position seems to be disbelieve the parents, threaten prosecution and/or safeguarding procedures. While this can be appropriate in some cases, it is often done because of a lack of understanding about the variable nature of the condition. Many children and young people with ME/CFS are unable to reach their academic potential because of the condition and may need lengthy periods of 1-1 tuition, online tuition and sometimes are too ill to access any meaningful education. I believe it would be helpful for children and young people who have not responded to current care, and who do not have any associated mental health conditions which are a barrier to engagement, to be considered on a care pathway more akin to those provided for other disabling conditions, ie more supportive. Some of these children and young people will improve over time, but if they do not, it will be important for them not to feel as though it is their fault. It will be important to decide what the pathway should look like and which are the most cost-effective teams to provide the support.	be given to children and young people throughout the guideline. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for all patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.
NHS Somerset CCG	6	31 (or indeed between 22 and 23)	An understanding of the pathology of ME/CFS is helped by an understanding of health and how to achieve and maintain this – ME/CFS is an illness with very much both a hardware body issue and a software being issue, and may involve electromagnetic fields in the body as well as physical, nutritional and pharmacological aspects A way of capturing this bigger perspective could be to ask	Thank you for your comment and suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.

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			3.5 What is the framework of understanding and overall strategy to help people with ME/CFS to regain health? Alternatively, should you wish to make this more prominent, this question could be posed at line 6/7 as a new 1, making the current 1 into 2 1.1 What is the framework of understanding and overall strategy to help people with ME/CFS to regain health? From this will flow an easier understanding of how to alleviate / remedy and maybe even reverse the illness state Please see my previous email submission to Joshua South on this	
Royal College of General Practitioners	7		Main outcomes – include anxiety and depression (as well as psychological well-being), employment and time spent inactive	Thank you for your comment. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
Action for ME	7	15-25	For the section 'Main outcomes', 36% of our survey respondents felt that changes were needed. Frequently, patients commented that there was a need to include objective measures in addition to the subjective questionnaires that have been listed in this draft scope.	Thank you for your comment. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee

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			For example, one person said "*where possible trying to restore some of the patient's previous goals*" whereas others suggested that a person's ability to participate in education or employment should be measured. Such measures would allow health professionals using the NICE guideline to consider the extent to which the condition was materially affecting a patient's ability to participate in normal, daily life. Another objective measurement would be a change in the benefit status of the patient, where it is linked to a change in their condition. Reliance on subjective questionnaires such as SF-36 means that patient ability may not be accurately measured. We wish to emphasise that employment or education must not be considered as the sole measure for a person's capability. Work or school attendance can be used as an outcome, but should not be an objective for a patient whose symptoms are preventing participation, as the exertion of attempting to attend could worsen their symptoms and the long-term severity of their condition. However, by including these as an outcome health professionals can capture one aspect of the patient's capability. Where a patient can sustain the levels of activity required to participate (even part-time), they are demonstrating a particular level of capability.	when they are considering the final review questions and protocols.
Hope 4 ME Fibro Northern Ireland	7	15 - 25	**Main Outcomes:**	Thank you for your comment. The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses

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			If this section relates to the search for evidence published in medical and scientific journals regarding ME aetiology, treatment and care, then it seems that this guidance is rather lean. Surely there needs to be guidance relating to the type of evidence that is acceptable (or at least where the committee might find descriptions of acceptable evidence), and the sources from which that evidence should be obtained? We would expect that the guideline development committee will read extensively. We hope that when recommended therapies are to be based on the conclusions of any particular trial publication, that the full paper, along with any criticisms of the trial, are read and considered. This essential recommendation should be written into the scope. Our concern stems from the undue influence generated when the PACE trial (and its predecessors) used non-blinded trials with subjective outcomes to make CBT and GET appear more effective than they really are. Also, that critiques of this trial were effectively ignored. **Regarding the various outcome measures listed**, it is our view that objective outcome measures are of greatest importance in determining the success or otherwise of any potential treatment. Every trial considered as evidence should be critically reviewed to elucidate whether the methodology used, and the outcome measures recorded,	on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded.. Any guideline development is however limited by the evidence available. The NICE guidelines manual does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.

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			might result in a bias that negates the stated conclusions. It is not sufficient to simply accept the authors' stated conclusions.	
Invest in ME Research	7	15-25	*3.6 Main outcomes* The topic is main outcomes when searching for evidence. We would ask NICE to be rigorous in its search for evidence and not accept poor evidence simply in order to be able to recommend something. We have always maintained that no treatment is better than a wrong treatment. NICE should not accept evidence from non-blinded studies that used subjective outcomes. This will lead for further calls for NICE to be held accountable for any damage suffered by patients due to biased recommendations made by NICE. The topics mentioned (pain, fatigue etc.) need to be carefully assessed based on cohorts selected, criteria used, methodologies and definition of recovery. As there are no FDA or EMA recommended outcome measures and hardly any trials have used objective measures and when objective measures such as actimeters have been used they have been dropped (PACE trial) or not reported (Dutch FITNET).	Thank you for your comment. The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded.. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee when they

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				are considering the final review questions and protocols.
The ME Association	7	15-25	Re Main outcomes: As raised during the stakeholders meeting, NICE needs to also look for (often non-existent) objective measures of outcome when assessing the results from clinical trials. As is already obvious, most clinical trials, especially those assessing the value of behavioural interventions, fail to make use of any form of objective outcome – eg the use of actometers to measure activity levels, changes to DWP benefit status, education and employment status. This is a serious defect in the way clinical trials are carried out and included in any evidence base review – as will be produced for the new NICE guideline. It is interesting to note that when an objective measure of outcome was used in the PACE trial (ie DWP benefit status) the overall amount of benefit being claimed actually increased. When looking at outcomes, NICE will also need to compare and query why there are seldom any reports of harm from GET in clinical trials whereas patient reports from a clinical setting frequently refer to adverse effects following GET.	Thank you for your comment. The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded.. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee when they

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				are considering the final review questions and protocols.
Healthwatch Bolton	7	16-25	Need to add: preventing/reducing PEM/PENE. Also rewrite DWP handbooks and educate assessors and decision makers.	Thank you for your comment and suggestion about PEM/PENE. NICE does not have a remit to write DWP handbooks.
ME Letterforce	7	18 - 25	We need to use measures that cannot be influenced by the tester and use objective measures Mobility measures such as actometers The patients entire mobility needs to be measured and not one test (which has the potential for the patient to perform well and then crash or to limit other areas of their lives) Ability to exercise without post exertional worsening of symptoms (i.e. 2 day heart function and oxygen tests, immune system parameters after exercise) Social inclusion – how often can ME patients see friends and family or continue hobbies Cognitive function tests Heart rate and blood pressure monitoring Flu like symptoms monitoring Infections and how frequently they occur (such as sinus infections which can be chronic in patients) Suicide rates in patients Early deaths through other diseases Muscle strength and stamina	Thank you for your comment. The guideline will follow the methods set out in the NICE guidelines manual. This guideline will not be using the content or analysis of the previous guideline but will conduct new analyses on any evidence available. The process of assessment of evidence has changed since the previous guideline with a more robust and transparent analysis of the evidence using GRADE system. This includes the use of blinding in assessment of outcomes which means more subjective outcomes are downgraded.. Any guideline development is however limited by the evidence available. The **NICE guidelines manual** does allow different levels of evidence but the level of evidence influences the strength of any recommendations made. We do intend to include a call for evidence in the guideline. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The

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			Ability to complete tasks repeatedly thorough a day and with no post exertional symptoms Ability to access NHS test such as smear tests, breast cancer and bowel screening Access to benefits at the correct level of remuneration (i.e. are patients able to physically fill in forms and go through the process) Adverse effects of treatment	technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
Royal United Hospitals Bath NHS Foundation Trust	7	7 -14	Specific guidelines for education regarding the management of those people who have a suspected Chronic Fatigue or CFS/ME diagnosis. To help prevent families being subjected to sanctions following reduced attendance in education.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
Patient Advisory	7	1-6	Travel is a significant barrier to patients with this illness. Many are bed bound or housebound and even those who are not may be unable to	Thank you for your comment and this information.

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Group to the CMRC (CFS/ME Research Collaborative)			travel far for appointments. Current arrangements do not support these patients. Consideration should be given to consultation by Skype, phone, email, home visits. The fluctuating nature of the condition (both physical and cognitive symptoms) makes attendance and engagement a challenge, even for those able to leave the house, should the appointment fall on a bad day. Attending appointments when this act pushes a patient beyond what they can safely manage can cause deterioration. It is ironic that attending an appointment intended to help can actually make a patient worse.	
Welsh Association of ME & CFS Support	7	3-6	WAMES proposes that Potential for, and Evidence of Harm, should be an additional outcome when searching for and assessing the evidence. It is also important that objective measures and evidence based on well-defined participant cohorts are used. Absence of relapse could be another outcome, indicating successful management of the post-exertional response.	Thank you for your comment. We will include outcomes on harms in the review protocols. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
London School of Hygiene & Tropical Medicine	7	27-29	I suggest pathways should be reviewed as soon as enough information is gathered to guide these, in the form of an interim pathway, and that the current pathways are dropped in the meantime along with the current guidance.	Thank you for your suggestion. We recognise the concern about the current recommendations. This new guideline will replace CG53 and the current pathways. We will address the clinical and cost effectiveness of treatments as soon as is feasible in the development of the guideline. To support the committee in making an informed decision on treatments we need to consider diagnostic criteria first. This is important to

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				identify any specific populations that different treatments may benefit or harm. To allow a robust analysis we also plan to review the published evidence on patient experience and conduct a call for evidence so that harms are identified and taken into account by the committee. Recommendations will reflect the evidence, and reviewing a specific intervention or area does not mean that a positive recommendation will be made. In line with this the current pathways will be reviewed.
Healthwatch Bolton	7	1-2	Please see comment on p.4 line 12.	Thank you for your suggestions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are finalising the draft review and protocols for monitoring
Healthwatch Bolton	7	5-6	Barriers: being referred for psychological treatments inappropriately. No central process for reporting harm, nor proper oversight of clinics. Some good clinics who try to help, but others push everyone into harmful interventions and ignore cautions in NICE guideline. Facilitators: health professionals accepting the serious nature of the illness, and accepting the WHO classification of the illness.Willingness to support patients with letters for benefit applications (many GPs and clinics will not).	Thank you for your suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
Healthwatch Bolton	7	9-10	Need belief and support, and signposting to relevant agencies, including social services, benefits advice or in work support if appropriate, and support groups.	Thank you for your suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.

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Healthwatch Bolton	7	21-22	Prevent unrealistic goal-setting by clinics, particularly for children, including inappropriate and harmful return to school or work.	Thank you for your suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
LocalME	7	1-2	4.1 Care plans, review of care plans, would be effective but with Specialist services failing to do more that diagnose and offer initial minimal management advice, there is no on going care which can be effectively monitored or review and no follow up once discharged, which increasingly occurs soon after diagnosis.	Thank you for your suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
LocalME	7	3-4	4.2 Use of the **International Consensus Criteria (**ICC) approach- the Functional severity, Symptoms and Symptom hierarchy scoring chart. Recording of objective scoring indicates progression of condition and most troubling symptoms, which will fluctuate and change over time.	Thank you for your suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.
The ME Association	7	13-14	Re NHS Services for people with ME/CFS: Whilst appreciating that recommendations relating to the actual delivery of NHS services, especially hospital-based referral services, is outside the remit of a normal NICE guideline, we believe it is vital that reference is made to the current highly unsatisfactory 'post code lottery' situation whereby many Clinical Commissioning Groups do not believe that ME/CFS is a priority for referral service funding or development. As a result, a significant number of the hospital-based services that were set up with the Department of Health funding that followed the 2002 Chief Medical Officer's report into ME/CFs are now being downgraded or closed. In addition, there are very few hospital-based referral services for children and adolescents.	Thank you for your suggestion. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.

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			Domiciliary and in-patient services for people with severe ME/CFS are non-existent in many parts of the UK and appropriate out-patient services are often impossible to reach for patients with this level of disability. There is no point in preparing management guidance if there are no hospital-based specialist services there to deliver this guidance. NICE cannot ignore this crucial issue.	
Blue Ribbon for the Awareness of ME (BRAME)	7	1/6	Monitoring and Review – two more questions need to be added here to ensure the needs of these specific groups are fully addressed and discussed:- 4.4 – What is needed to effectively and clinically monitor those who are severely affected? 4.5 – What is needed to effectively and clinically monitor children and young people?	Thank you for your suggestion. These two groups are already included in every review question as special groups for consideration; they do not need separate questions.
Blue Ribbon for the Awareness of ME (BRAME)	7	7/14	As I had already raised at point 29 need to add a further question here: 6.2 – What are the barriers and facilitators to information, education and support ?	Thank you for your suggestion. This draft question has been added.
Blue Ribbon for the Awareness of ME (BRAME)	7	15/25	Main Outcomes – need another vital point added here, as the first step of any health professional is to do no harm, therefore the guidelines must ensure that what is recommended:- 8 – Overall does no harm or causes adverse reaction	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.

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Parents of children with ME/CFS Support Group	7	1	The draft scope mentions monitoring, but does not explicitly reference tests as part of that monitoring. We argue that the new guideline should address any ongoing testing that needs to be done, for example cortisol, thyroid, vitamin B12, vitamin D, as these can highlight auto-immune deficiencies caused by the condition.	Thank you for your suggestion. The technical team will ensure ongoing testing is brought to the attention of the committee for consideration when finalising the monitoring review questions.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	7	1	Currently many long term and/or severely ill patients do not have any monitoring or review. Access to any medical care can be an issue for the housebound and/or bedbound. Difficulty finding supportive and knowledgeable doctors is also an issue for some – there does still seem to be an unacceptable level of misunderstanding and misconceptions about this illness among some in the medical profession. Specialist provision is not available country-wide. In Scotland, for example, the only ME specialist in the NHS is an ME nurse in Fife whose waiting list is over a year long.	Thank you for your comment and information. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients.
Royal United Hospitals Bath NHS Foundation Trust	7	1	There is a very variable level of knowledge and skill within the GP provision and often parents of our young people will bypass the GP service	Thank you for your comment. The guideline will address information, education and support for health and social care professionals. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients.
Christians with ME, CFS, Fibro and their Carers	7	3	Section 4.2 4.2 What is the most clinically and cost effective method of reviewing people with ME/CFS? We believe that the frequency of review is also important, not just the method of review. We believe that whilst some patients are reviewed at least annually, other patients do not have any review of their condition.	Thank you for your suggestion. The technical team will ensure the frequency of review is brought to the attention of the committee for consideration when finalising the review questions.

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			The scope of the review is also important, although it is acknowledged that this may be covered when the method of the review is established.	
LocalME	7	5	**4.3 Barriers to Care –** Failure of the agencies like NHS England, NHS Improvements and NHS Public Health, NHS Health and Work, Care Quality Commission to support NICE by commissioning and conducting proper audits, surveillance, inspection, data collection and Needs Assessments for people with ME/CFS. Increasingly Fewer Acute services, few consultant level multi disciplinary teams, fewer community based services, failure to provide home, domiciliary services, the dismantling of the NHS since 2010. Primary care lack of training, knowledge and expertise, GP disinterest and lack of resourcing of services, privatisation of the NHS, with many services now operating as private limited companies, lack of continuity in commissioning staff and arrangements with centralisation of large Commissioning entities who have limited knowledge or interest in local matters. Creation of "arms length bodies" leading to lack of Governmental and ministerial accountability on injustices such as the lack of equality for people with ME/CFS.	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols**.** NICE does not have a remit for commissioning of services. The guideline will address information, education and support for health and social care professionals.
Royal United Hospitals Bath NHS Foundation Trust	7	5	As above. Mental health services for people with ME/CFS struggle to accommodate the needs of this patient group and historically there is a wealth of anecdotal report that support has either not been forthcoming or unhelpful.	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Science for ME	7	5	"Information, education and support for people with suspected and diagnosed ME/CFS, and their families and carers"	Thank you for your comment. The areas raised by stakeholders will be used to inform the committee's

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			As PEM is an important symptom of many people with ME/CFS it is important to point out that patients have reported that trying to push too much and exercise may be counterproductive and hence that it would be sensible to add advice that patients with PEM should be particularly cautious about trying to ramp up exertion. The guideline should state explicitly that patients with ME/CFS should not be advised to 'try to exercise more' or 'go to the gym', as these are likely to cause harm.	decision making as they develop the review questions and protocols.
LocalME	7	6.1	Information, education, support needed – clear knowledge and understanding of the legislation, **Care Act, Children and Families Act**, of their responsibilities and obligations of the **Duty of Candour** and **Duty of Care** to support severely disabled People with ME/CFS.	Thank you for your comment. We agree and have included the question on information and support for health and social care professionals. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
F.O.R.M.E	7	7	That people with ME/CFS have physical symptoms, that it is not a psychological illness.	Thank you for your comment. We agree that people with ME/CFS have physical symptoms. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.
The ME Association	7	7	In view of the fact that there is a very serious problem with the lack of medical education about ME/CFS at both undergraduate and postgraduate levels, this is a subject that requires greater emphasis.	Thank you for your comment. We agree and have included the question on information and support for health and social care professionals.

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The Young Sufferers of ME Trust	7	7	Signposting to voluntary sector should be included in information and education.	Thank you for your comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	7	9	In addition to receiving education around their illness, its management and the best possible treatment, patients need support with accessing education, employment, benefits, homecare, OT assessments and home adaptations, mobility aids, blue parking badges. The severely ill and homebound need tailored support that they can physically access. Access to support groups is also helpful.	Thank you for your comment and information. The areas raised by stakeholders will be used to inform the committee's decision making as they develop the review questions and protocols.
Royal College of Paediatrics & Child Health	7	11	What about transition? There is no mention of the transition aspect. Given that some of them have this longer term, there should be some guidance on transition to adult services too.	Thank you for your comment. NICE has developed a guideline on 'Transition from children's to adults' services for young people using health or social care services'. We will refer to this guideline but can also highlight any specific issues for this guideline population as necessary.
The Young Sufferers of ME Trust	7	11	If the guideline intends to give specific consideration to children and young people we must include education professionals and local authority education-related professionals (attendance/education welfare officers/children missing from educations/children and families teams) or the agencies working on behalf of local authorities.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators,

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				occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
F.O.R.M.E	7	13	That people with ME/CFS have physical symptoms, that it is not a psychological illness. An understanding of this would prevent stigma and ignorance towards ME/CFS sufferers.	Thank you for your comment. We agree that people with ME/CFS have physical symptoms. We hope that a new guideline with more up to date reviews of evidence will improve understanding and care for patients and reduce any stigma. The guideline will address information, education and support for health and social care professionals.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	7	13	Education is also required for DWP and insurance assessors	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations

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				outside of the remit of the guideline would use the recommendations where appropriate.
Royal United Hospitals Bath NHS Foundation Trust	7	13	It will be very important to include senior representatives from the Department of Education, as the provision for severely affected children is woeful. They are effectively punished by the Education system for being ill. If their recovery takes many years, they may be deprived of their educational opportunities which impacts substantially on their futures. There is a need to look at good practice examples, where the state works with families to provide appropriate levels of support.	Thank you for your comment. NICE guidelines are developed for the NHS and can only make recommendations for health and social care organisations and professionals and do not have a remit outside of this. In the section,' who the guideline may also be relevant for' we have included a wider pool of professionals that includes educators, occupational health services and voluntary sector organisations. We would hope however that up to date guidance may help improve knowledge of all practitioners and would hope other organisations outside of the remit of the guideline would use the recommendations where appropriate.
University of Central Lancashire	7	13	With the knowledge and experience of almost 3 decades in clinical research, diagnosis and treatment of CFS/ME we could educate the primary health practitioners through day seminars. Doctors across the country could be easily taught the scientific rationale and how to examine patients for simple physical signs that could be used every day in surgeries and hospitals across the country.	Thank you for this suggestion.
Parents of children with ME/CFS Support Group	7	14	In line with our comments number 16 and 23, we recommend a point to be added 7 Information, education and support for education professionals	Thank you for your comment. The guideline is specifically directed to health and social care providers so we cannot add this question.

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			7.1 What information, education and support do education professionals who provide education, services and provision for children and young people with ME/CFS need?	
#MEAction UK	7	15	Main Outcomes We are particularly concerned about this section and worry that if it is not improved, there could be serious negative consequences for the new guidelines.	Thank you for your comment. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions.
#MEAction UK	7	15	We ask: how will NICE ensure they can accurately assess the quality of evidence? Outcomes must be seen in the context of the trial that produced them: if the trial is not of a high standard, then its outcomes cannot be regarded as good quality evidence. We ask that the GDG and those who assess evidence will read full papers as well as any commentary or critique related to them. NICE should be concerned with whether the trial protocol was pre-published and the quoted results match that protocol. In the PACE trial, reported outcomes exaggerated success when compared with those in the published protocol. Issues of protocol changes have also been raised with the SMILE and GETSET trials. This suggests that a careful analysis of the methodologies and reliability of reported outcomes is needed.	Thank you for your comment. The guidelines development process uses GRADE to assess quality and this process requires detailed assessment of study characteristics and outcomes.
#MEAction UK	7	15	Studies that use the Oxford criteria should be excluded because they are too imprecise to be considered studies of ME. According to a 2017	Thank you for your comment and this information.

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			paper, the Oxford criteria designated CFS in 25.5% of 2004 men and 19.9% of 1954 women. Based on quadrant analysis, 85% of Oxford-defined cases were inappropriately classified as CFS (Baraniuk, 2017). The US Agency for Healthcare Research and Quality has stated that use of the overly broad Oxford criteria in trials has resulted in the inclusion of 'patients who may have an alternate fatiguing illness' and called for the Oxford definition to be retired (Agency for Healthcare Research and Quality, 2014). In 2015, the US National Institutes of Health called for Oxford to be retired because it could 'impair progress and cause harm' (Green, 2015).	
Forward ME	7	15	The main outcomes listed are nearly all subjective judgements. Why not measure return to work/education on a full or part-time basis or joining civil society for example? Adverse effects and the impact of treatment or management strategy should be added to the main outcomes to be assessed.	Thank you for your comment. The outcomes are not specifically intended to be subjective. Physical and cognitive functioning may be measured by using objective measures as you describe. The guideline committee will inform the more detailed list used in the evidence searches. We have added adverse reactions to the list.
LocalME	7	15	**3.6 Main Outcomes**	Thank you for your comment.
ME Research UK	7	15	There should be some consideration of the influence on outcomes of comorbid conditions such as inflammation, autoimmunity, thyroid conditions, mast cell activation syndrome, postural orthostatic hypertension syndrome and Ehrler-Danlos syndrome. These conditions	Thank you for your comment. The outcomes listed are those from research evidence. We recognise that outcomes from an individual patient will be influenced by many other factors including co-morbid conditions.

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			will also need repeated testing throughout what might be a lifetime of fragile health.	
ME Research UK	7	15	Are there other metrics that could be considered here, such as those required by social and educational services, and those related to symptoms, care pathways, specific areas of patient difficulty, life limitations and impacts, social wellbeing, and the need for assistance/aids?	Thank you for your comment. The outcomes listed here are those likely to be most commonly reported in research studies. The list is not exhaustive and will be augmented with more detail by the committee.
Patient Advisory Group to the CMRC (CFS/ME Research Collaborative)	7	15	The criteria used to recruit participants for research studies should be considered. The results of studies which do not require post exertional malaise cannot be applied to patients who experience this symptom. It must be made clear in the guidelines which group of patients any advice applies to. Extreme care should be taken when considering studies which only report subjective measures. Objective measures of improvement should be required.	Thank you for your comment.
Royal College of Psychiatrists	7	15	Healthcare utilisation, such as frequency of attendance, may also be relevant under outcomes.	Thank you for your comment.
Science for ME	7	15	"3.6 Main outcomes" To our minds there are serious issues with this section and if it stands like this it could have a serious negative impact on the guidelines being developed. Many of the proposed outcomes are subjective and issues have been raised concerning the use of such subjective outcomes (i.e. views	Thank you for your comment. This list is not intended to be exhaustive and will be augmented by outcomes specific to individual questions such as the use of objective biomedical data where appropriate. The methods used in guideline development will assess blinding as part of quality assessment.

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			expressed in questionnaires) when used in open label trials. This concern is increased where interventions (such as CBT/GET/Lightning process) aim to change the way patients think about their symptoms and how much they can do. This can result in considerable reporting bias. This issue of the reliance on subjective outcomes has been one of the major criticisms of the PACE trial. For example, in http://journals.sagepub.com/doi/full/10.1177/1359105317700886 Edwards states: *"Yet the trial has a central flaw that can be lost sight of: it is an unblinded trial with subjective outcome measures. That makes it a non-starter in the eyes of any physician or clinical pharmacologist familiar with problems of systematic bias in trial execution."* In a different piece looking at the PACE trial http://journals.sagepub.com/doi/full/10.1177/1359105317700885 Wilshire reflects on some of the evidence around the unreliability of subjective outcomes when used without blinding. *"Again, the problem here is that, in a non-blinded study, self-report measures are highly vulnerable to response bias. The size of this bias is not trivial. A recent meta-analysis of clinical trials for a range of disorders calculated that when participants were non-blinded to treatment allocation, self-reported improvements associated with treatment were inflated by an average of 0.56 standard deviations relative to comparable blinded trials. Importantly, no such inflation was observed when the outcomes involved objectively measurable indices (Hróbjartsson et al., 2014). Therefore, in order to securely demonstrate the efficacy of any*	

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			intervention within a non-blinded design, researchers need to show that self-reported improvements are supported by evidence based on more objectively measurable outcomes." Further Stoutens http://journals.sagepub.com/doi/full/10.1177/1359105317707531 does an analysis of the PACE data concluding the more subjective the measure the bigger the reported effect. *"To further investigate the hypothesis that objective data produce less favourable results for CBT, I computed the treatment effects for the aforementioned studies by Prins et al. (2001), Stulemeijer et al. (2004) and White et al. (2011), see the Online Appendix. The results in Figure 1 show that the effect sizes of CBT with respect to the control groups are the smallest for objective measures of physical functioning. When the subjectiveness of the outcomes increase, the effect sizes increase to medium and even large."* *criteria such as PEM were "blatantly missing.""* When assessing trials on patients with ME/CFS care needs to be taken around this issue of subjective outcomes in non-blinded trials. The proposed measures here are likely to be unreliable and if used are likely to exaggerate the success of interventions tested in trials without blinding and where interventions encourage patients to view their symptoms differently. Hence lead to unreliable guidelines.	
Science for ME	7	15	We would recommend that the methodology and outcomes of trials being assessed are looked at carefully. Not only taking concern about	Thank you for this information.

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			subjective outcomes but also whether the trial protocol was pre-published and the quoted results match that protocol. Here again issues have been reported in the PACE trial where the reported outcomes exaggerated success when compared with those in the published protocol. Equally issues of protocol changes have been raised with the SMILE and GETSET trials. This suggests that a careful analysis of the methodologies and reliability of reported outcomes needs to be carried out.	
Science for ME	7	15	"Main Outcomes" Given the fluctuating nature of the illness outcomes (including objective ones) measured over too short a period may not indicate real lasting improvements.	Thank you for this information.
Science for ME	7	15	"Main Outcomes" Even with objective outcomes care should be taken: Are the outcomes really objective (say self-reported school attendance vs school records) and hence subject to bias? Often objective outcomes (such as a walking test) have higher dropout rates and given the exertion required it is likely that data is not missing at random but rather reflecting patient difficulties. Thus, objective outcomes with high dropout rates could over play treatment effects.	Thank you for this helpful information.

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			Hence the need for a careful and detailed consideration of the evidence.	
Science for ME	7	15	"Main Outcomes" Assessment of adverse effects seems to be part of the standard NICE process although missed out here. There may be little formal evidence and adverse effect reporting systems do not exist for CBT and GET; however, there are patient surveys from the ME Association and Action for ME. In addition, adverse effects are often in the form of a relapse and worsening of symptoms rather than new side effect symptoms. Thus, this should be looked at but taking account of the issues with subjective measures mentioned in other comments.	Thank you for your comment. We have added adverse reactions to the list of outcomes and can use alternative methods to formal reviews to inform these.
Science for ME	7	15	When assessing ME/CFS trials it is important to understand the range of different recruitment criteria (Oxford, CDC, CCC, ICC, etc) that maybe applied. An evidence-based review by the AHRQ was concerned about the use of a very general (Oxford) definition of CFS and found very different results when discounting trials using these criteria. Whilst entry criterial such as the Oxford criteria may seem to apply to many patients caution needs to be applied. Where a trial is known to involve activity or GET patients who suffer PEM may well be much less likely to volunteer and thus bias randomisation. This could result in treatments that do not help or even harm a very large subset based on a	Thank you for this information.

Stakeholder	**Page no.**	**Line no.**	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
			PEM symptom (The main symptom in the Institute of Medicines latest definition).	
South London & Maudsley NHS Foundation Trust	7	15	Healthcare utilisation, such as frequency of attendance, may also be relevant under outcomes.	Thank you for this suggestion.
The 25% ME Group	7	15	Adverse effects / impact of treatment intervention or management strategy should be added to the main outcomes to be assessed.	Thank you for your comment. We have added adverse reactions to the list of outcomes.
VIRAS	7	15	"3.6 Main outcomes The main outcomes that may be considered when searching for and assessing the evidence are: 1 Quality of life (for example, EQ-5D, SF-36) 2 Pain 3 Fatigue 4 Physical and cognitive functioning (a person's ability to do everyday tasks and activities) 5 Psychological wellbeing 6 Care needs 7 Sleep" The list omits the following objective signs of change: • return to employment or study, (or increase in work/study hours per week)	Thank you for your comment, information and references. This list is not intended to be exhaustive and will be augmented by outcomes specific to individual questions. The committee will need to consider the issues you outline in their decisions about outcomes they consider important.

Stakeholder	Page no.	Line no.	**Comments** Please insert each new comment in a new row	**Developer's response** Please respond to each comment
			• Change in sickness and disability benefits • Change in social services provision • Change to pre-illness activities (i.e., resumption of hobbies and sports) • 2, 6, or 12 minute walk tests • Step test • Actometer recording • Peak O2 exercise challenge (with day 2 repetition) (important because the IOM report states that published research into this test validates PEM) • Blood lactic acid (mitochondrial function) • ADP, ATP recycling (mitochondrial function) • Tilt-table test (POTS) • Nerve conduction studies • Spect scan (changes to punctate lesions) Number 1 and 4 need clearer specifications. In some M.E./CFS research (and other disabling diseases), it is the SF-36 *Physical Function subscale* (PF) which is used to measure impairment. The scope must be clear about which it is utilising and if it is the PF scale then it should be included in #4. HOWEVER, NICE MUST TAKE INTO ACCOUNT EVIDENCE THAT THE SF-36 IS NOT AN ACCURATE MEASURE IN M.E./CFS.	

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			Writing on the 'Prognosis of ME/CFS',[43] Dr David Bell referred to his and his colleague's studies of patients who became ill with CFS in their youth. At the 25 year follow-up they observed: "All studies employed the Rand-36 (SF-36), a questionnaire is (sic) common use. The first question of this instrument is 'how would you rate your health?' Many of the patients rated their health as 'good', while the rest of the questionnaire demonstrated how poorly they were actually functioning." Dr Bell concluded his essay: "Forty year old adults who had an acute onset during their teenage years have the activity of seventy year old adults." (Bell D. Prognosis of ME/CFS. Open Medicine Foundation. https://www.omf.ngo/2016/08/01/prognosis-of-mecfs/. Accessed Jul 25th 2018) FURTHERMORE, ME/CFS research and researchers disagree and contradict themselves and each other regarding what an SF-36 PF subscale rating means: **SF-36 Physical Function subscale.** **Interpretations of thresholds in CFS and normative data from the general population**	

Authors	**Rating**	**Interpretation according to the author(s)**
Bowling et al[12]	**58**	Average for 75 to 84 years old
Bleijenberg & Knoop[13]	**60**	Recovery from CFS
White et al[1]	**60**	Normal Range (successful treatment of CFS)
White et al[14]	**60**	Normal Range (successful treatment of CFS)
Bleijenberg[15]	**65**	Severe functional impairment
White et al[16]	**65**	Diagnosis of CFS
White et al[17]	**65**	Abnormal levels of physical function in CFS
Knoop[18]	**70**	Severely disabled
Reeves[19]	**70**	Diagnosis of CFS
Wearden et al[20]	**70**	Diagnosis of CFS
White et al[21]	**70**	Diagnosis of CFS
Wearden et al[22]	**75**	Clinically significant improvement in CFS
White et al[23]	**75**	Positive outcome in CFS
White et al[24]	**85**	Recovery from CFS
Jenkinson et al[25]	**78.3**	Gen. pop. reporting long-standing illness
Jenkinson et al[26]	**92.5**	Gen. pop. not reporting long-standing illness

Perhaps NICE plan to add their own interpretation to this list of confusion.

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			REFERENCES 1. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. Lancet. 2011 Mar 5;377(9768):823-36. doi:10.1016/S0140-6736(11)60096-2. 12. Bowling A, Bond M, Jenkinson C, Lamping DL. Health Survey England 1996. J Public Health. (1999) 21 (3):255-270. 13. Bleijenberg G, Knoop H. Where to PACE from here? Lancet. Volume 377,No.9768,p786–788. 5 March 2011. doi:10.1016/S0140-6736(11)60172-4. 14. White PD, Goldsmith K, Johnson AL, Chalder T, Sharpe M. Recovery from chronic fatigue syndrome after treatments given in the PACE trial. Psychol Med. 2013 Oct; 43(10):2227-2235. doi:10.1017/S0033291713000020. 15. Stulemeijer M, de Jong LWAM, Fiselier TJW, Hoogveld SWB, Bleijenberg G. Cognitive behaviour therapy for adolescents with chronic fatigue syndrome: randomised controlled trial. BMJ. bmj.38301.587106.63v1. 10.1136/bmj.38301.587106.63. 16. See 14. 17. See 14. 18. Tummers M, Knoop H, van Dam A, Bleijenberg G. Implementing a minimal intervention for chronic fatigue syndrome in a mental health centre: a randomized controlled trial. Psychol Med. 2012 Oct;42(10):2205-15. doi:10.1017/S0033291712000232.	

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			19. Reeves, W., Wagner, D., Nisenbaum, R. et al. Chronic Fatigue Syndrome - A clinically empirical approach to its definition and study. BMC Med. 2005;3:19. 10.1186/1741-7015-3-19. 20. Wearden AJ, Riste L, Dowrick C, Chew-Graham C, Bentall RP, Morriss RK, Peters S, Dunn G, Richardson G, Lovell K, Powell P. FINE Trial Protocol. BMC med. 2006,4:9. doi: 10.1186/1741-7015-4-9. 21. White PD. PACE Trial Registration. MRC. Online: http://web.archive.org/web/20030611144353/http://controlled-trials.com/isrctn/trial/%7C/0/54285094.html. Accessed 10 December 2016. 22. See 20. 23. See 8. 24. See 8. 25. Jenkinson C, Coulter A and Wright L. Short form 36 health survey questionnaire: normative data for adults of working age. BMJ. 1993 May 29;306(6890):1437-1440. PMCID: PMC1677870. 26. See 25. FUTHERMORE, in the PACE Trial, 111 participants across all groups met the author's 'normal range' thresholds for both the fatigue scale and the SF-36 physical function subscale. Yet only 22 of these participants met 'normal range' for the 6 minute walk test, and 9 of those were still diagnosed with CFS. This shows a major discrepancy between SF-36 PF ratings and the more objective measure of ability to walk.	

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			AND FURTHERMORE, in the PACE Trial, the 111 participants who met the author's 'normal range' thresholds for both the fatigue scale and the SF-36 physical function subscale, had an average 6 minute walk test distance of 414 meters. This is 100 meters LESS than the average for people aged 70-80 years in Casanova et al. (Casanova C, Celli BR, Barria P. et al. The 6-min walk distance in healthy subjects: reference standards from seven countries. Eur Respir J. 2011 37: 150-156; doi: 10.1183/09031936.00194909.) NICE must consider if the SF-36 is a valid outcome measure for patients with M.E./CFS especially if it suggests improvement. If NICE decide to go ahead and use this measure, then trial data for the measure must be critically analysed and validated by a more objective measure. This applies especially if any of the interventions used could have resulted in bias, e.g., individual therapy claimed to treat the illness in the form of cognitive therapy or exercise.	
#MEAction UK	7	18	SF-36 has limited use for ME. People with ME experience floor effects for the physical aspects which makes it impossible to accurately distinguish severity and improvement (Davenport et al, 2011). Members of our team completed the SF-36 in order to inform our response and found that our physical scores were 0. Many people with ME are far more severely affected than we are but the SF-36 would miss this range. Improvement within this range would be missed by trials using the SF-36.	Thank you for this information.

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			The SF-36 perhaps has some use as a comparison between different conditions or to compare physical and emotional health, which is often in stark contrast in ME (with emotional health being within the range of error of that of healthy controls (Unger et al., 2017)). However, the SF-36's limitations should be kept in mind if physical health measured by the SF-36 is a primary outcome of a study. We note that the disease specific ME/CFS Fatigue Types Questionnaire (MFTQ) may be more appropriate (Jason et al, 2011); however, objective outcomes are always preferable over questionnaires.	
Hope 4 ME Fibro Northern Ireland	7	18	**Quality of Life:** We are concerned that subjective questionnaires should not be the only means of measuring life-quality outcomes. Objective measures should be explored.	Thank you for your comment. Objective measures will be used where possible.
Parents of children with ME/CFS Support Group	7	18	We argue that the draft scope does not currently include any indications of how the measurements will be adapted for children and young people. We argue that any quality of life measurement tools need to be appropriately adapted for children and young people, to include, for example, capacity to access to education instead of capacity to volunteer or work.	Thank you for your comment. The outcomes are stated in general terms in the scope and will be adapted for children and young people.
Respect for ME	7	18	SF-36 and the Chalder Fatigue Scale (https://www.s4me.info/docs//CFQ-Critique-S4me.pdf) have severe weaknesses in capturing the full clinical picture in ME. Where the use of questionnaires is absolutely essential, we would recommend ME/CFS Fatigue Types Questionnaire (MFTQ) instead (Jason et al, 2011). In general, however, subjective measures	Thank you for this information.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			are only useful if combined with objective measures that verify their accuracy.	
Royal College of Psychiatrists	7	18	The Work and Social Adjustment Scale is an important outcome measure of quality of life / functioning Also anxiety, depression specifically and return to school or employment are important.	Thank you for these suggestions.
South London & Maudsley NHS Foundation Trust	7	18	The Work and Social Adjustment Scale is an important outcome measure of quality of life / functioning Also anxiety, depression specifically and return to school or employment are important.	Thank you for these suggestions.
#MEAction UK	7	19	We express concern about how 'fatigue' and 'pain' would be assessed as outcomes. Subjective reports of such measures (especially in non-blinded trials) are not specific or reliable.	Thank you for your comment. The blinding of outcomes is assessed as part of the GRADE system and unblended outcomes would be downgraded.
Buckinghamshire Healthcare NHS Trust	7	19	Pain is one of the main outcomes here specified, the guidelines should have specific management advice relating to pain (and can be incorporated in section 3.5 p6, 22-31). The analgesic ladder may differ from other types of chronic pain and offer a cost saving opportunity.	Thank you for this suggestion.
Stonebird	7	19	**P7 line 19** It is not clear how the Scope will provide an outcome for pain, as stated as one of the the main outcomes, given it also says that neuropathic pain in adults has separate guidance and chronic pain assessment and management and headache guidance is being developed and so will not	Thank you for your comment. We have altered the wording in the scope to clarify that we will not address

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			be covered under these guidelines. This is a huge omission and also a large contradiction. New head ache and head pain, for example, is a part of ME that should therefore be covered under ME Guidance, because of its unique nature. In Severe ME it is very difficult to impossible to manage pain, better recommendation, specifically for ME pain could help, because the pain must be understood within the context of the whole illness. Pain in ME must be viewed in the context of the whole illness experience and complexity of symptoms. Drug sensitivity is also a specific ME issue when looking at pain control.	management of other conditions where these are covered by other NICE guidance. Pain is included in the list of outcomes so that it is included as a specific part of ME/CFS illness experience
#MEAction UK	7	20	Fatigue should not be a main outcome**.** Reliance on an improvement in fatigue is based on a misunderstanding of ME as a disease. With skilful use of pacing, people with ME can be severely limited in energy without being fatigued. Energy limitation is not a synonym for fatigue and the symptoms we experience when we crash after exceeding our energy limitation do not necessarily include fatigue. The scales used to quantify fatigue in the ME literature are inadequate, with many mild patients scoring as poorly as severe patients -- e.g. the Chalder fatigue scale (Morriss, 1998). A more substantial critique of the Chalder fatigue scale notes that few items appear clearly related to fatigue, the focus is on change in fatigue rather than intensity, physical and mental components	Thank you for your comment and this information. Following stakeholder comment we have altered the scope to more clearly outline that fatigue is not necessarily considered an appropriate term for symptoms associated with ME/CFS. Fatigue is included in the list of outcomes as we are aware it has been used as an outcome. The guideline methods and the committee decisions allow for downgrading of outcomes where they are not considered valid or objective.

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			are arbitrarily weighted, there is an incompatibility of the two scoring systems and a failure to directly measure fatigue intensity. This is on top on the ceiling effect. (Wilshire & McPhee, 2018) Since a key aspect of ME is energy limitation and exertion intolerance, objective measures which indicate increased activity without relapse are critically important, such as ongoing increased steps per day, or a return to work.	
Science for ME	7	20	When assessing fatigue, we have been particularly concerned about the use of the 'Chalder Fatigue Questionnaire'. We believe it to be a particularly poor questionnaire. Language is used in a confusing way particularly when asking for a comparison with a sometimes-distant reference point. It also uses two incompatible marking schemes where, for example, in both the PACE and FINE trials some subjects improved with one marking scheme but got worse with another. We believe that particular care should be taken when relying on results using this questionnaire. We have written a more detailed critique available here: https://www.s4me.info/docs//CFQ-Critique-S4me.pdf Measuring fatigue is difficult - It is perfectly possible for a patient who is very severely disabled by ME/CFS to experience little fatigue most of the	Thank you for this information and link.

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			time because they are pacing themselves and restricting their activities to remain below their fatigue-triggering threshold. Similar difficulties that arise when measuring fatigue and fatiguability, designing as well as assessing treatment trials are recently also being discussed in much better researched and understood conditions like MS (see e.g. Rudroff, Thorsten, Kindred, John H, Ketelhut, Nathaniel B.; Fatigue in Multiple Sclerosis: Misconceptions and Future Research Directions, Frontiers in Neurology 2016 Aug 2;7:122. doi: 10.3389/fneur.2016.00122, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969300/).	
#MEAction UK	7	21	Outcomes that matter most to people with ME and reflect a genuine improvement in health are: objective measures of physical and/or cognitive functioning over a sustained period of time. This is of utmost importance. We suggest changing this outcome to: "Physical and cognitive functioning (objective measures, including return to employment/education and/or actimetry)". It is crucial that technical staff prioritise objective data. The apparent (though unimpressive) effects of CBT or GET in some trials can be explained solely by poor study design: an unblinded trial using self-reported measures (Helmfrid, 2016) and research using this	Thank you for your comment. We have not changed the terminology in the outcomes list as the intention at this stage is to provide important headings. The methods used by the technical teams in guideline development, including GRADE, do assess blinding as you describe when examining quality of evidence and will downgrade subjective outcomes.

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			combination should be downgraded in GRADE (see comment #31). This is supported by the Stouten paper which showed that "the more objective the outcome, the worse the result for CBT and GET" (2017). This is particularly a concern for psychological trials. Evidence is lacking that GET or CBT produce any improvement in patients' physical capabilities in objective measures, such as return to work (McPhee G 2017) and are more likely just changing beliefs[3] about health. We assert that this combination of unblinded and subjective measurement creates a biased dynamic of participants being trained to answer the questionnaires 'better' rather than ensuring that the patients actually get better. As (Stouten 2017) has stated, "Though patients think they are able to walk more after CBT, they fail to actually do so". Thus, NICE and the committee must understand that subjective outcomes from open-label trials cannot be used as evidence of effectiveness for an intervention:	

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[3] For example, in the PACE trial, participants were sent newsletters while the trial was still in process. A 2008 newsletter included very positive feedback from participants about their 'therapy' and therapists (social proof). It also appealed to authority by including positive feedback from a participant's doctor and Number 10 Downing Street. These social proof and authority statements would have **increased placebo effect risk of bias for the intervention groups**, but not for the SMC group.

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			"Again, the problem here is that, in a non-blinded study, self-report measures are highly vulnerable to response bias. The size of this bias is not trivial. A recent meta-analysis of clinical trials for a range of disorders calculated that when participants were non-blinded to treatment allocation, self-reported improvements associated with treatment were inflated by an average of 0.56 standard deviations relative to comparable blinded trials. Importantly, no such inflation was observed when the outcomes involved objectively measurable indices (Hróbjartsson et al., 2014). Therefore, in order to securely demonstrate the efficacy of any intervention within a non-blinded design, researchers need to show that self-reported improvements are supported by evidence based on more objectively measurable outcomes." (Wilshire, 2017.) Substantial reporting bias is a problem in such instances, especially where interventions (like CBT, GET or the Lighting Process) are designed to change the way people with ME think about, and describe their symptoms. [2] For example, in the PACE trial, participants were sent newsletters while the trial was still in process. A 2008 newsletter included very positive feedback from participants about their 'therapy' and therapists (social	

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			proof). It also appealed to authority by including positive feedback from a participant's doctor and Number 10 Downing Street. These social proof and authority statements would have increased placebo effect risk of bias for the intervention groups, but not for the SMC group.	
Respect for ME	7	21	Objective measures have been completely missed from this list. Actimeters, step test, return to work or school records (rather than patient-reported attendance) and other objective measures should be the cornerstone of any evidence review.	Thank you for your comment. This list is not intended to be exhaustive and will be augmented by outcomes specific to individual questions such as the use of objective biomedical data where appropriate.
Royal College of Occupational Therapists	7	21	As well as physical and cognitive function it would be helpful to include social function as this can be equally debilitating. Some studies also use employment/occupation as an outcome measure.	Thank you for your comment. Physical and cognitive functioning is meant as a general term which could include social functioning such as employment and school attendance.
Hope 4 ME Fibro Northern Ireland	7	23	**Psychological Wellbeing:** We are concerned that psychological wellbeing should not be one of the main outcomes for consideration. ME is not a psychologically based condition, thus psychological wellbeing should only be considered as secondary to the symptoms of ME.	Thank you for your comment. We agree that this was unclear and we have removed it from the list of outcomes.
Royal United Hospitals Bath NHS Foundation Trust	7	23	This line should be changed to **Psychological wellbeing *and* Mental Health.** All chronic illness (diabetes, asthma, chronic pain disorders) may lead to problems with Psychological wellbeing but also increase the risk for the development of Psychiatric disorder significantly. Please do not ignore the mental health needs of this population group because of outdated mind-body duality. A successful guideline would be one which makes recommendations for physical and mental health.	Thank you for your comment. We have removed psychological wellbeing from the list of outcomes as the meaning was unclear. We agree that all chronic conditions increase the risk of psychiatric disorder. NICE already has a number of guidelines for psychiatric disorders and we will cross refer to these where appropriate.

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Stonebird	7	23	**P7 line 23** The Scope should clarify what it means by psychological well being ? It needs specifying that ME is not being considered in any way as a Mental Health Condition itself. This level of clarity is required. What exactly does physical wellbeing mean in the context of an incurable untreated disease and unrelenting physical torment? NICE needs to answer this.	Thank you for your comment. We agree that this was unclear and we have removed it from the list of outcomes.
#MEAction UK	7	25	In 'Social Value Judgements: Principles for the development of NICE guidance' you define non-maleficence as one of your moral principles, and state "any treatment or intervention can potentially have adverse consequences" (National Institute for Health and Clinical Excellence, 2008). Other scopes include a main outcome relating to adverse effects. Considering reports of harm from the ME community, the patient surveys reporting a majority deteriorate after graded exercise therapy (Geraghty, 2017; Kindlon, 2011) and the numerous papers reporting adverse consequences of exertion in ME (Cook, 2017; Loy, 2016; Rutherford et al 2016) we find this omission disturbing. We ask for: "Adverse effects of treatment" to be added as an outcome (this is the wording used in the multiple sclerosis scope.) For people with ME, avoiding post-exertional malaise and long term deterioration should be considered a crucial outcome in GRADE (see comment #31). Recording of harm in GET studies is considered	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes. The NICE process does include consideration of patient experience and the results of patient surveys will be taken into consideration.

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			inadequate with "Issues involving the heterogeneity of subjects and interventions, tracking of adverse events, trial participants' compliance to therapies, and measurement of harms using patient-oriented and objective outcome." (Kindlon, 2011). Therefore, survey data is the strongest available evidence about the adverse effects of GET. It should be taken into account that the combined samples of patient surveys are much larger than trial evidence and show that adverse outcomes are the most common type of response after GET (Geraghty, 2017). The discrepancy between patient surveys and trial reports of harm should be taken seriously when weighing up the evidence. This inconsistency can likely be explained by the bias and indirect case criteria in the GET trials.	
Parents of children with ME/CFS Support Group	7	25	We argue that the draft scope excludes evidence of Post-Exertional Malaise when considering outcomes and recommend that an additional point be added: 8 Evidence of Post-Exertional Malaise	Thank you for this suggestion. The list specifically relates to outcomes from evidence reviews and is not intended to be exhaustive. The importance of post-exertional malaise has been added to the scope and the committee will consider how this will be measured when finalising the protocols for the review questions.
Parents of children with ME/CFS Support Group	7	25	We argue that the draft scope excludes objective, biomedical evidence in the list in section 3.6 and recommend that an additional point be added: 9 The use of objective biomedical data	Thank you for your comment. This list is not intended to be exhaustive and will be augmented by outcomes specific to individual questions such as the use of objective biomedical data where appropriate.

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Respect for ME	7	25	There is no question for outcomes relating to harms. Although there is sadly no formal way for patients to record harms from GET or CBT (the Yellow Card Scheme has refused to consider any reports), there are large patient surveys that record iatrogenic harm. Additionally, there are papers that explicitly address exercise and exertion intolerance in ME. These must be included by the NICE evidence review.	Thank you for your comment. We will include outcomes on harms in all the review protocols and have added adverse effects to the list of outcomes.
Royal United Hospitals Bath NHS Foundation Trust	7	25	Sleep is a fundamental factor when assessing and managing fatigue; it would be useful to get contributions from Sleep Disorder Specialists in both the Adult and Paediatric Services.	Thank you for this suggestion. NICE are developing a guideline on sleep disordered breathing which includes assessment methods and we will cross-refer to this guideline. Sleep is included in the list of outcomes. We will also consider seeking additional expert testimony from sleep specialists.
Royal United Hospitals Bath NHS Foundation Trust	7	18,24	Quality of life and functional evaluation tools need to be appropriate for the age group/developmental needs ie child friendly and validated for children and young people. Also specific questionnaires for Parents / families and carers should be done and taken into consideration when establishing the needs of the individual. Support needs to be based around the individual and the impact on the family / support system.	Thank you for your comment. We agree that tools should be appropriate to the population and that perspective of carers is also important. This list is not intended to be exhaustive and will be augmented by more detail and the inclusion of outcomes specific to individual questions. The technical team will ensure the areas you raise are brought to the attention of the committee when they are considering the final review questions and protocols.