

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

Consultation on draft guideline – deadline for comments 5pm on 22/12/20 email: cfs@nice.org.uk

	<p>Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.</p> <p>We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment.</p> <p>In addition to your comments below on our guideline documents, we would like to hear your views on these questions:</p> <ol style="list-style-type: none">1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.2. Would implementation of any of the draft recommendations have significant cost implications?3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) <p>See Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.</p>
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	#MEAction UK
Disclosure Please disclose any past or current, direct or	We have no past or current, direct or indirect links to, or funding from, the tobacco industry.

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indirect links to, or funding from, the tobacco industry.				
Name of commentator person completing form:		Sian Leary		
Type		[office use only]		
Comment number	Document [guideline, evidence review A, B, C etc., methods or other (please specify which)]	Page number Or 'general' for comments on whole document	Line number Or 'general' for comments on whole document	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	Guideline	General	General	<p>Overall, this Guideline is a significant improvement on the 2007 Guideline, and we would like to thank the committee members, and especially the lay members, for their extensive and hard work over the past couple of years.</p> <p>We are thrilled to see acknowledgement of the stigma people with ME have faced; the additional recommendations for people with severe or very severe ME and for children and young people; the recommendations on different ways to access care (such as phone, video conference or home visits); the recommendation to provide aids and adaptations without delay and also the acknowledgement that cognitive behavioural therapy is neither a treatment nor a cure for ME.</p> <p>In particular, we'd like to congratulate the committee on their recognition that graded exercise therapy has caused significant harm, and their decision to recommend against this therapy in the draft</p>

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				<p>Guideline. This particular change is a triumph of evidence based decision making that puts patient safety first, in the face of significant pressure from those with vested interests.</p> <p>We wish to convey the deep relief people with ME felt upon hearing this news, as Ben H, person with ME, wrote on twitter: “You'll never see so many patients so pleased and emotional about having no treatment for their illness. That's how unscientific, ineffective and harmful GET has been. No treatment is better than a harmful one.”</p> <p>All of us at #MEAction UK urge you to stand by this decision.</p> <p>While this draft Guideline is a major improvement, there is a need for clarification on some issues, and we remain concerned that certain recommendations could allow harmful practices to continue. We therefore argue for:</p> <ul style="list-style-type: none"> • Clarity around who will be providing care, and an explicit recommendation for a physician, preferably a consultant, to be part of every specialist team. • Strengthening and expanding the section on training, to ensure the paradigm shift this Guideline lays out works its way into practice. • Proactive follow up from a physician for those with suspected ME • Moving recommendations on safeguarding into the section on principles of care, as the stand-alone safeguarding section has already been misused. • The removal of the section on physical activity programmes, with access to specialist advice on physical activity instead being offered under the section on energy management. • Further downgrading of CBT, with broader guidance on the principles of any psychological support for people with ME and training required for any healthcare professional providing this. • The removal of language around goals and incremental increases in activity - stabilisation is key and the energy management approach already enables increases in activity where the person has improved. • A clear message from NICE that ambitious biomedical research is required
2	Guideline	General	General	We continue to oppose using the term chronic fatigue syndrome (CFS), and considering this committee is at present recommending new terminology such as PESE, energy envelope, energy management

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				<p>and more, we strongly urge them to make a recommendation that this disease is called myalgic encephalomyelitis (ME), with a note that it has formerly been known as CFS.</p> <p>As committee members have recognised, people with ME have faced significant stigma. The term CFS has contributed to this. We strongly urge the committee to take an active stance on this issue, instead of passively accepting an outdated misnomer.</p>
3	Guideline	1	9 - box	<p>“This Guideline will update NICE Guideline CG53 (published August 2007).”</p> <p>We have been assured by various NICE employees since 2017 that this new Guideline will replace CG53, not just update it. Please ensure this is clearly stated on the final Guideline.</p>
4	Guideline	2	1	<p>Whilst we acknowledge that this Guideline should not be used for those simply experiencing fatigue post-COVID 19, there is clear evidence from previous viral outbreaks that a significant minority will go on to develop ME.^{1,2,3} This box must make clear that having had COVID-19 does not exclude a patient from an ME diagnosis if they meet the criteria, and where a patient does meet the criteria, advice from this Guideline on exercise and energy management in particular should override other advice.</p> <p>Suggested addition: “However if a person does meet the criteria for suspecting or diagnosing ME/CFS after COVID-19, then this Guideline should be used, advice on energy management should be given, and investigations to exclude other conditions should continue.”</p> <ol style="list-style-type: none"> 1. Moldofsky, H., & Patcai, J. (2011). Chronic widespread musculoskeletal pain, fatigue, depression and disordered sleep in chronic post-SARS syndrome; a case-controlled study. <i>BMC neurology</i>, 11(1), 37. 2. Hickie, I., Davenport, T., Wakefield, D., Vollmer-Conna, U., Cameron, B., Vernon, S. D., ... & Lloyd, A. (2006). Post-infective and chronic fatigue syndromes precipitated by viral and non-viral pathogens: prospective cohort study. <i>Bmj</i>, 333(7568), 575. 3. Garcia, M. N., Hause, A. M., Walker, C. M., Orange, J. S., Hasbun, R., & Murray, K. O. (2014). Evaluation of prolonged fatigue post–West Nile virus infection and association of fatigue with elevated antiviral and proinflammatory cytokines. <i>Viral immunology</i>, 27(7), 327-333.
5	Guideline	4	4	<p>Add an additional bullet point here stating that ME can “affect any age group”.</p>

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				As the supporting documentation on children and young peoples finds, there is still significant stigma and disbelief that is unique to this group, it is therefore vital that all professionals begin with an understanding that ME can affect any age group.
6	Guideline	4	5	Agree.
7	Guideline	4	7	<p>We suggest that this is changed from “can have a significant impact on people’s quality of life” to “has a substantial impact on people’s quality of life”.</p> <p>We agree the impact on quality of life is very important to get across, and are pleased to see this sentence. Recommendation 1.2.3 p8 line 14 states that ME should only be suspected if “the person’s ability to engage in occupational, educational, social or personal activities is significantly reduced from pre-illness levels”, we believe it more accurate to state here that ME “has substantial” impact, instead of adding in the qualifier of “can have”.</p> <p>This change of wording is backed up by evidence that the quality of life for people with ME is lower than for many other debilitating illnesses.¹</p> <p>1. Falk Hvidberg, M., Brinth, L. S., Olesen, A. V., Petersen, K. D., & Ehlers, L. (2015). The health-related quality of life for patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). <i>PloS one</i>, 10(7), e0132421).</p>
8	Guideline	4	16	We strongly agree with this statement and the two bullet points below. It is vitally important that health professionals recognise this and actively work to remedy it. We especially appreciate the acknowledgement that people with ME may be hesitant to involve health and social care professionals because of the stigma they have faced. We thank the committee for including this.
9	Guideline	5	3	<p>The wording “Health and social care professionals should: “acknowledge to the person the reality of living with ME/CFS” does not go far enough. Both those who assume the illness is psychological and those who are aware of the science demonstrating biological dysfunction can readily acknowledge “the reality”.</p> <p>We suggest “acknowledge to the person the reality of living with ME and that, while not fully understood, research demonstrates pathophysiological abnormalities”.</p>

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10	Guideline	5	5	<p>Add “or rebuild” to this bullet point, so that it reads “take time to build or rebuild supportive, trusting and empathetic relationships”</p> <p>From the two community calls we held about the Guideline, we received strong feedback that many people who have been ill for a long period of time now have almost no contact with health professionals. As the stigma people with ME experience, acknowledged in 1.1.2, has driven some people away from the healthcare system, it should be noted that relationships may need to be rebuilt, not simply built.</p>
11	Guideline	5	7	<p>We very strongly support this recommendation.</p> <p>Many people with ME have told us stories of how their partners, parents or carers were excluded from appointments despite the person asking them to be present. We note that a young person quoted in the evidence you commissioned also tells of this experience referencing interactions which did not consider the impact on the participant. This included a need for family support as ME3 states in Supporting Documentation Appendix 1 p16 line 6: “my mum wasn’t allowed to come in with me... it was quite scary, it was the first time I’d ever been into a medical appointment without my mum”.</p> <p>Thank you for including this recommendation.</p>
12	Guideline	5	10	<p>We strongly support this recommendation for early and accurate diagnosis.</p>
13	Guideline	5	12	<p>We strongly support this recommendation, but raise concerns later in our response about who will carry out this monitoring and review.</p>
14	Guideline	5	18	<p>As various parts of the management plan that are laid out in recommendation 1.5.2 could not be described as an intervention, we propose changing the word intervention to “aspect” in this sentence.</p>
15	Guideline	5	20	<p>We strongly agree with this recommendation, including specifying “family, friends, health and social care professionals and teachers.”</p>
16	Guideline	6	7	<p>Under awareness of severe or very severe ME, add a further bullet point that ensures health professionals are aware a small minority of those with very severe ME die.</p>

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				<p>Suggested language: “Be aware that very severe ME can lead to death in a minority.”</p> <p>Deaths from ME are rare, and ME is rarely recorded on death certificates. Better understanding of ME as a serious disease and reporting of deaths would give more accurate figures. In England and Wales, between 2001 and 2016, 88 death certificates stated that the death was either partly or fully caused by myalgic encephalomyelitis/chronic fatigue syndrome,¹ which is less than six deaths per year.</p> <p>1. Mentions of postviral fatigue syndrome (benign myalgic encephalomyelitis), deaths registered in England and Wales, 2001 to 2016. (2018) ONS</p>
17	Guideline	6	8	<p>While we welcome the recognition of the range of debilitating symptoms that affect people with severe and very severe ME, in the feedback we received as we wrote this response, many people with moderate or even mild ME noted that they too experienced some or many of these symptoms.</p> <p>Be aware that people with severe or very severe ME may experience some of the following symptoms more severely and these can significantly affect their emotional wellbeing, communication, mobility and ability to interact with others and care for themselves:</p>
18	Guideline	6	8	<p>In the feedback we’ve received, and in evidence collated Greg and Linda Crowhurst,¹ people with severe or very severe ME report experiencing episodes of paralysis.</p> <p>Add paralysis to this list.</p> <p>1. Crowhurst, G., & Crowhurst, L. (2013) Paralysis, a qualitative study of people with Severe Myalgic Encephalomyelitis http://carersfight.blogspot.com/2013/08/paralysis-qualitative-study-of-people.html</p>
19	Guideline	6	22	<p>In the feedback we have received while writing this response, a few people requested the addition of diarrhoea to this list.</p>
20	Guideline	6	28	<p>This section, including the bullet points, is excellent and a vital inclusion in the Guideline.</p>
21	Guideline	7	8	<p>Consider expanding this bullet point to read: “need aids such as electric or manual wheelchairs, noise protection and dark glasses or eye masks”</p>

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22	Guideline	7	17	We strongly support this recommendation - having different professionals doing personal care can significantly exacerbate symptoms of people with ME. Awareness of the person's needs and consistency is very important.
23	Guideline	7	22	We strongly agree with this recommendation, and believe it could significantly help people with severe or very severe ME to access the care they need in the safest way possible.
24	Guideline	8	1	<p>We are pleased to see a section on suspecting ME and not just diagnosis, with recognition that early advice on symptom management can be critical. As Evidence Review D p53 line 5 states: "Early diagnosis is seen as critical to better care and may also improve prognosis. Appropriate advice on activity and rest given in the early stages of ME/CFS is seen as the key to prevent deterioration (see Evidence review E: pre diagnosis strategies)."</p> <p>We support the committee's decision to include a section on Suspecting ME/CFS.</p>
25	Guideline	8	2	We agree with this recommendation. We are pleased that the committee has not said this is a diagnosis of exclusion.
26	Guideline	8	6	We agree that a comprehensive clinical history should be taken
27	Guideline	8	7	We agree that a physical examination should be carried out.
28	Guideline	8	8	<p>This recommendation is unclear as to what exactly a psychological wellbeing assessment is, nor is this obvious from the evidence reviews or any rationale given as to why this is part of initial assessment.</p> <p>However Evidence Review C p20 line 29 states "Patients also expressed the opinion that their doctors ignored their physical symptoms and focussed more on the depressive symptoms, reporting that their more physical symptoms were disregarded in favour of any that could be described as pertaining to depression or to mental health issues."</p> <p>During our community call that discussed this issue, multiple attendees raised concerns that standardised depression questionnaires, such as the PHQ-9, could lead to misdiagnosis due to questions about energy levels, trouble concentrating and troubled sleep.</p>

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				<p>While it is important that people with depression get appropriate treatment and care, the issues around misattribution of symptoms should also be mentioned.</p> <p>We recommend you clarify what a psychological wellbeing assessment should include, and how misattribution of symptoms can be mitigated.</p>
29	Guideline	8	9	<p>What does the word ‘baseline’ here mean and why is it a necessary qualifier instead of simply saying assessment should include “investigations to exclude other diagnoses”? We recommend you remove the word “baseline” in this sentence.</p> <p>Many attendees to our community calls discussing the draft Guideline raised concern that doctors (including GPs) did not have the knowledge or experience to fully investigate symptoms. This is confirmed on page 72 line 2 of this Guideline where it states “many healthcare professionals lack the confidence and knowledge to recognise, diagnose and manage it”.</p> <p>Evidence Review C p43 line 31 reinforces this, stating that “Patients often felt they needed to take a proactive role in their care by doing their own research to persuade health-professionals to meet their needs, by asking for diagnostic tests, seeking treatment elsewhere, turning to private or alternative health services, and in some cases withdrawing from services and managing symptoms themselves.”</p> <p>This comes back to why it is so important specialist services have appropriate medical expertise as part of the staff team, especially when it comes to confirming diagnosis.</p>
30	Guideline	8	11	<p>We are happy with this recommendation.</p>
31	Guideline	8	16	<p>Some attendees to our community calls told us this would be more accurate if it stated: symptoms are new or had a specific onset” instead of “and”.</p>

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				<p>They reported that particularly in children and young people, a specific onset could be hard to define, with slow deterioration over time. They told us that requiring symptoms to be new <i>and</i> have a specific onset meant they wouldn't receive the support they needed.</p> <p>A simple change from “and” to “or” here would help these people.</p>
32	Guideline	8	17	<p>Symptoms: Debilitating fatigability is not defined in this box, whereas the other symptoms have a greater explanation. As the committee has agreed “there is a marked difference between ‘normal tiredness’ and the profound fatigue caused by ME/CFS and that the term fatigue does not reflect the actual symptoms that people with ME/CFS experience.” (Evidence Review D, page 50, line 29)</p> <p>We urge the committee to define fatigability in this box. Doing so only in the section on “Terms used in this guideline” is likely to lead to a common understanding of the term fatigue being used, without reference to the specific features that the committee has outlined.</p>
33	Guideline	8	17	<p>Symptoms: During our community call that discussed this draft Guideline, there were more people who agreed than disagreed that the term post-exertional symptom exacerbation was better than post-exertional malaise, however this was not unanimous.</p> <p>Overall, we agree with the committee’s assessment that the word malaise underplays the severity and impact of this symptom in people with ME.</p> <p>Our colleagues in the US expressed concern that adding a new term would create yet another long acronym: PEM/PESE. They noted that they are getting traction with US institutions using the terminology PEM at the moment, and felt a change may lead to greater confusion.</p> <p>We published a poll on our social media platforms to assess what term people preferred. Of 406 respondents, 49% supported the term PEM, 43% supported PESE and 8% supported other terms.</p>

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34	Guideline	8	17	<p>During our community calls, some attendees also said that, in their experience, PESE/PEM was not always delayed, and preferred the wording “can be delayed in onset by hours or days” to “is delayed...”.</p> <p>We agree that this symptom is disproportionate to the activity, and has a prolonged recovery time, and support the inclusion of these sentences in the definition.</p>
35	Guideline	8	17	<p>We agree with the inclusion of unrefreshing sleep.</p>
36	Guideline	8	17	<p>There has been debate about the inclusion of cognitive difficulties as a necessary symptom for diagnosis.</p> <p>Some people have told us they did not experience cognitive difficulties at the beginning of their illness, although generally these became more pronounced with time.</p> <p>We published a poll on social media asking about cognitive difficulties in people with ME. Of 500 respondents, 96% had cognitive difficulties at the onset of their illness, 6% did not, and 2% did not have ME. Albeit a minority, 6% is still significant.</p> <p>Overall, we strongly agree with narrower criteria than the 2007 NICE Guideline being utilised. However, we ask the committee to consider how they will mitigate against an initial presentation of ME without cognitive difficulties delaying diagnosis, advice and support. One option raised was the possibility of an atypical ME diagnosis, as is proposed in the International Consensus Criteria.</p> <p>We support the inclusion of a description of cognitive difficulties here, and agree with the specific presentations of cognitive difficulty the committee has laid out here.</p>
37	Guideline	9	3	<p>We are unsure if the term ‘exclusive’ is accurate here, as it implies that the symptoms in Box 1 are all exclusive to ME. This may be true in combination, but individually they are not.</p> <p>Could the committee remove the part in between commas, so that the sentence just reads “Be aware that the following symptoms may also be associated with ME/CFS:”</p>

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38	Guideline	9	3	<p>This list is a helpful addition to the symptoms laid out in Box 1, and we strongly support its inclusion in the Guideline.</p> <p>We are surprised to see no mention of gastrointestinal symptoms (nausea, incontinence, constipation and bloating) on this list though. Evidence demonstrates an increased prevalence of gastro-intestinal symptoms in ME,¹ and both the International Consensus Criteria² and the Canadian Consensus Criteria³ note these symptoms.</p> <p>We recommend adding gastrointestinal symptoms (nausea, incontinence, constipation and bloating) to this list.</p> <p>We also see that gastrointestinal symptoms are noted on page 6, line 22 under “Awareness of severe or very severe ME/CFS”, but cannot find evidence to suggest these symptoms are only present in severe or very severe ME.</p> <ol style="list-style-type: none"> 1. Maes, M., Leunis, J. C., Geffard, M., & Berk, M. (2014). Evidence for the existence of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) with and without abdominal discomfort (irritable bowel) syndrome. <i>Neuroendocrinol. Lett</i>, 35, 445-453. 2. Carruthers, B. M., van de Sande, M. I., De Meirleir, K. L., Klimas, N. G., Broderick, G., Mitchell, T., ... & Bateman, L. (2011). Myalgic encephalomyelitis: international consensus criteria. <i>Journal of internal medicine</i>, 270(4), 327-338. 3. Carruthers, B. M., Jain, A. K., De Meirleir, K. L., Peterson, D. L., Klimas, N. G., Lerner, A. M., ... & Sherkey, J. A. (2003). Myalgic encephalomyelitis/chronic fatigue syndrome: clinical working case definition, diagnostic and treatment protocols. <i>Journal of chronic fatigue syndrome</i>, 11(1), 7-115.
39	Guideline	9	17	We agree with this recommendation.
40	Guideline	9	21	<p>We agree with this recommendation that testing should continue, however as we have previously mentioned:</p> <p>Some attendees of our community call to discuss the draft Guideline felt it would be helpful to list investigations that should be done, whilst others felt this might limit what is done just to those investigations listed.</p>

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				<p>It was generally felt that a list of possible differential diagnoses could be helpful, with a proviso that the list is not exhaustive and the healthcare professional should consider what is necessary to rule out based on symptomatology.</p> <p>We also request that this recommendation notes that co-existing conditions may be present.</p>
41	Guideline	10	2	<p>It would be helpful to define who this specialist is, and whether the suggestion is to seek advice from an ME specialist, or a specialist in the specific sign or symptom that there is uncertainty about.</p> <p>We support the referral of people with ME to other specialties where there is uncertainty in interpreting signs and symptoms. We particularly urge that symptoms should not be assumed to be ME without thorough investigations.</p>
42	Guideline	10	4	<p>We are pleased to see an additional section on children and young people with suspected ME here.</p>
43	Guideline	10	7	<p>We support the recommendation to refer children and young people to a paediatrician. However again we recommend that you add a list of differential diagnoses with the proviso that the list is not exhaustive.</p>
44	Guideline	10	9	<p>We suggest changing this recommendation to “offer to write to the child or young person’s place of education or training...” (our addition in bold).</p> <p>This would ensure that the child or young person, along with their parent or carer, maintains a role in leading their care.</p>
45	Guideline	10	11	<p>We support the inclusion of a section on advice for people with suspected ME.</p>
46	Guideline	10	15	<p>We agree that personalised advice on symptom management should be available.</p>
47	Guideline	10	17-21	<p>We strongly agree with these bullet points, particularly the mention of rest which we strongly urge the committee to retain.</p>

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				<p>We recommend adding, after line 19, that “the amount of activity they can manage without triggering PESE may be lower than they initially expect”</p> <p>In our experience, people are often surprised by how tiny activities can cause PESE, especially early on in their illness.</p>
48	Guideline	10	22	<p>During online and community call discussions, some participants raised concerns that this recommendation could be taken in isolation. Therefore, we recommend that you add to the beginning of this line: “After giving advice on symptoms, energy management, rest and diet, explain to people with suspected ME/CFS...”</p>
49	Guideline	11	1	<p>We strongly agree with the recommendation that people with suspected ME can return for a review if they develop new or worsened symptoms, and to ensure they know who to contact for advice.</p> <p>However this recommendation puts the onus on the person with suspected ME to manage accessing an appointment for diagnosis and referral to specialist care. Considering the long term implications of ME, the physician (most likely GP) should proactively follow up with the person at 3 months.</p> <p>Other guidelines by NICE give clear recommendations of timescales that should be adhered to in the provision of care, and this committee has found that early diagnosis and information can improve outcomes, it is vital the committee makes an explicit recommendation that the healthcare professional arranges a follow-up appointment at 3 months in order to reassess and refer forwards to the specialist team for confirmation of diagnosis if the person continues to experience all of the persistent symptoms in Box 1.</p> <p>Change this to: “Explain to people with suspected ME that their diagnosis can only be confirmed after 3 months of persistent symptoms, and arrange a follow up appointment for that time. Reassure them that they can return for a review before then if they develop new or worsened symptoms, and ensure they know who to contact for advice.”</p>

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50	Guideline	11	3	<p>There appear to be three levels of diagnosis in this Guideline. Provisional diagnosis for those with suspected ME, diagnosis at 3 months, and then confirmation of diagnosis by a specialist team.</p> <p>The differential diagnosis seems more complex than is reasonable to expect a GP to do and not miss comorbidities or rarer alternatives.</p> <p>Recommendations 1.4.2 and 1.5.1 appear to define a referral pathway, with confirmation of diagnosis by a specialist. However this could be made clearer, and we therefore recommend adding a new step under Assessment and care planning by a specialist ME team (section 1.5) that states “Confirm diagnosis or refer for further investigations.” We have made this recommendation as a separate comment on section 1.5 as well.</p>
51	Guideline	11	7	<p>For many long term conditions GPs will often refer, with a suspected diagnosis, to a specialist team, seeking a more detailed assessment, which may include a range of specialist tests, confirmation and a management plan which they will be part of.</p> <p>Evidence Review I p24 line 5 states: “The committee acknowledged that GPs did not have enough time to carry out the assessments needed to confirm a diagnosis of ME/CFS or to develop a management plan in a single standard appointment. The committee recommended that once someone with suspected ME/CFS has had persistent symptoms indicating ME/CFS for 3 months the person should be referred to a specialist team for confirmation of the diagnosis.”</p> <p>However this recommendation is unclear, and must be explicit that the diagnosis of ME should be confirmed by a specialist.</p> <p>Change this to: “Refer adults directly to a specialist ME team to confirm the diagnosis of ME and to develop a management plan.”</p>

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52	Guideline	11	9	<p>We agree that it is important that paediatric specialist team members should be experienced in ME, however to create the change in service provision truly needed this sentence must also specify that paediatric specialist team members have training in accordance with this Guideline.</p> <p>Change to: “If ME is diagnosed in a child or young person after assessment by a paediatrician (based on the criteria in recommendation in 1.2.3), refer them directly to a paediatric specialist team with experience in ME and training in accordance with this Guideline to develop a management plan.”</p>
53	Guideline	11	20 - general	<p>Section 1.8 “Access to care” should be moved to before this section (1.5). This would ensure that health professionals assessing people with ME are aware of the recommendations on access to care.</p>
54	Guideline	11	15	<p>The pathway to a confirmed diagnosis is unclear here, with a simple reference to “After confirming diagnosis of ME/CFS”.</p> <p>This needs to be a step of its own, that is taken after the holistic assessment, not before the clinician even takes a history.</p> <p>Add a new recommendation after these bullet points: “Confirm diagnosis or refer for further investigations.”</p>
55	Guideline	11	17	<p>We are concerned that this recommendation does not specify what “relevant symptoms” are. More guidance needs to be given on this to ensure that the correct questions are asked and relevant history is explored thoroughly in order to identify symptoms.</p>
56	Guideline	12	4	<p>We are concerned that the language of psychosocial wellbeing could be seen as reductive here, excluding areas such as housing and benefits, and for this reason believe “overall wellbeing” would be a more appropriate term.</p> <p>We agree with the language of “impact of symptoms on...”, and are pleased to see the committee considering it in this way.</p>

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				Reword to “the impact of symptoms on their overall well-being.”
57	Guideline	12	10	We support the recommendation to develop a personalised management plan based on the holistic assessment of the person’s needs
58	Guideline	12	13-30	We agree with all the bullet points here, We particularly agree with the recommendation that all people with ME should have “details of the health and social care professionals involved in the person’s care, and how to contact them.” We have only one comment on the sections of the Guideline referred to in the symptom management bullet point - see next point
59	Guideline	12	25-26	The current reference to recommendations for symptom management excludes the recommendations on orthostatic intolerance which start at section 1.11.24. The recommendations should be changed to start at 1.11.24. The current reference to recommendations on symptom management includes recommendations on CBT (recommendation 1.11.50). CBT should not be included as it is not a way of directly managing symptoms of ME. Recommendations should be changed to end with 1.11.42
60	Guideline	13	1	We strongly agree with the recommendation that the specialist team should recognise the person with ME is in charge of the aims of their management plan.
61	Guideline	13	9	The recommendation states that copies of the management plan should be given to the person: we suggest that there should be additional text here saying the copy of the management plan should be provided in paper and online to the person with ME. This would ensure it is accessible.
62	Guideline	13	12	We are concerned that the recommendation of home visits for the holistic assessment is only for those with severe or very severe ME. This service should be available for those with moderate ME who may be unable to visit the specialist team in person. We cannot see any evidence in Evidence Review A or Evidence Review G that supports the recommendation only to offer home visits for assessments to severe/very severe.

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63	Guideline	13	12	This recommendation should specify who within the specialist team should carry out home visits in order to ensure that it is a member of the team with relevant skills and experience.
64	Guideline	13	13	The box below this line appears to reference the wrong evidence review
65	Guideline	15	9	<p>The rationale for this section refers to the importance to patients of having information for people with ME to share with ‘employers’ (Guideline p54 line 23), but no mention of this information is made in section 1.6 Information and Support p13.</p> <p>Recommendation 1.6.7 says: “Give families and carers of people with ME/CFS information about the condition and ways they can help the person.” Please add a further recommendation saying: “Give people with ME/CFS information suitable for sharing with employers (see recommendations section 1.9 on supporting people with ME/CFS in work, education and training)”</p>
66	Guideline	13	16	<p>We are concerned that this section on Information and Support does not address the issue that non-English speaking people face in obtaining a diagnosis and accessing care - see (Evidence Review C p72 line 1-10).</p> <p>Although there is reference to the relevant NICE Guideline in this section, we suggest that this important point should be highlighted in the Guideline with the addition of a sentence such as that used in the relevant Guideline: “Difficulties with reading, understanding or speaking English are addressed so that the patient is able to participate as fully as possible in consultations and care.”¹</p> <p>1. Patient experience in adult NHS services: improving the experience of care for people using adult NHS services Guidance NICE</p>
67	Guideline	14	2	<p>We are concerned that this recommendation does not consider the needs of children or young people with severe or very severe ME. The word ‘symptoms’ should be added after ‘any disabilities’ to make sure that the needs of those with severe ME are considered.</p> <p>Edit the second sentence to: “Use interactive formats tailored to their individual needs, such as:”</p>

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68	Guideline	14	4	The evidence does not support the recommendation of group discussions for children as a format for providing information to them as the evidence cited is based on studies of adults. See Evidence review A p25 line 14-15 for evidence on positive benefit of group sessions for adults. There is evidence (Evidence Review A p32 line 49) that young people find it beneficial to meet and talk to “others with CFS” , but this does not support the recommendation of group discussions as a format to provide information to children and young people.
69	Guideline	14	5-7	It is good to see alternative formats suggested for providing information to children and young people, but not all are suitable for those with severe ME who may have noise and light sensitivities.
70	Guideline	14	16	We support the recommendation to explain that ME is a ‘fluctuating medical condition’ and are pleased to see this explained here. We would like to see this emphasised in subsequent sections, particularly the section on Access to care page 17 line 20.
71	Guideline	14	23-24	Wording on recovery should be amended to make it clear that even those who recover or have a long period of remission from ME have to live their lives with caution so they do not have a relapse. The wording should also say ‘most’ will need to adapt (rather than ‘many’).
72	Guideline	14	26-27	We agree with the wording that ME can have a major impact on the people’s lives, however to then state that “they may need to adjust how they live” underplays the significant debilitation even people with mild ME suffer. We request the committee changes this to: “can have a major impact on people’s lives, including their daily activities, family and social life, and work or education, and usually requires significant adjustments in how they live”
73	Guideline	14	29	It is apparent that the common theme running through all of these triggers is overexertion of some description. It would be helpful to explicitly include overexertion here as a trigger. While it is helpful to include childbirth as an example of a stressful event (as mentioned in the Equality Impact Assessment) it would be good to include other common triggers too. e.g. "Examples include traffic accidents, major operations involving general anaesthesia and childbirth"

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74	Guideline	15	6	<p>We fully support referring people to support groups and suggest that these bullet points are expanded to address the issues faced by black and minority ethnic groups. Evidence Review C p17 and p22 identifies the specific issues faced by the BME community.</p> <p>We suggest adding a bullet point to this list saying “community outreach groups which work with services to help and support black and minority ethnic groups to access healthcare, community and other resources”.</p>
75	Guideline	15	8	<p>Information on financial support is vital for people with a chronic illness and we are pleased to see it included here, but it is very rare that medical or social care staff can keep up with the ever changing landscape of benefits. It is therefore important to also signpost to organisations that can provide tailored advice, such a Citizens Advice Bureau. We suggest adding “and signpost or refer them to other organisations that provide advice and support on these areas, such as Citizens Advice Bureau”.</p>
76	Guideline	15	11	<p>We strongly agree that social care should be discussed with the person with ME, and that a referral to social services should be offered.</p>
77	Guideline	15	23	<p>We agree with these recommendations on supporting families and carers of people with ME.</p>
78	Evidence Review A	6	23	<p>Evidence Review A looks at the evidence on information and support for people with ME. On page 6 line 23, it states “No evidence was identified for social care professionals caring for people with ME/CFS.” This major gap should surely warrant a research recommendation.</p>
79	Guideline	16	5	<p>Although we recognise the good intentions behind including a safeguarding section to guard against past abuses by health and social work professionals who do not have expertise with ME, this section could be misused as the safeguarding approach taken for ME patients has been in the past.</p> <p>Univadis, a publication and resource for health professionals, has produced an ME/CFS clinical guidance summary based upon this draft guideline.¹ As one of 6 key bullet points on the management of ME/CFS they state “Conduct safeguarding assessment.” There is no qualifier that this should only be done when required. It is stated as part of the management approach for all people with ME. This may</p>

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			<p>be a misinterpretation of the Guideline, however it demonstrates how easily this section can be misused.</p> <p>The issue of children's families being threatened by social services with the accusation of Fabricated or Induced Illness(FII)/Munchausen by proxy must be addressed but this section is unclear in its intent. An explicit acknowledgement of the historical misuse of safeguarding must be added towards the end of the section on "Principles of care for people with ME/CFS" with a statement that an ME diagnosis is NOT grounds for a safeguarding assessment, sectioning or child protection order.</p> <p>In Evidence Review B p57 line 24 "The committee agreed it was important that recommendations address some of the common misconceptions that may have led to child protection concerns, and to provide guidance on this topic."</p> <p>In the feedback we have received, parents of children with ME are very concerned that instead of addressing common misconceptions, by inserting a section on safeguarding, the committee are inadvertently implying that abuse of children with ME is common, contrary to any evidence to suggest this.</p> <p>We have heard too often that the NICE Child Maltreatment Guideline² has been misused against children and young people with ME and their families. For a poorly understood disease such as ME section 1.1 on Physical Symptoms has been used to launch safeguarding investigations at a disproportionate rate, leading to accusations of Fabricated and Induced Illness against families of children and young people with ME.³</p> <p>FII is a rare form of child abuse,⁴ with any connection between this rare occurrence and ME entirely unfounded in evidence.</p> <p>We very strongly urge the committee to clearly state that this issue lies with misuse of safeguarding procedures, not with abuse of children with ME by parents.</p> <p>Considering the above, we ask the committee to take action to mitigate against seriously damaging unintended consequences of this section.</p>
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				<p>While there have been varying views expressed in discussing this section of the Guideline, with some pleased to see the inclusion of certain recommendations, we have ultimately concluded, in consultation with experts in this area, that a standalone section on safeguarding in a medical Guideline is not the way to address this.</p> <p>We therefore recommend moving recommendations within this section, many of which are important and highly welcomed, into the section on principles of care.</p> <ol style="list-style-type: none"> 1. O’Shea, D. New NICE guidance on chronic fatigue syndrome: the key points. (2020) <i>Univadis</i> https://www.univadis.co.uk/viewarticle/new-nice-guidance-on-chronic-fatigue-syndrome-the-key-points-732697 2. Child maltreatment: when to suspect maltreatment in under 18s (2017) <i>NICE</i> https://www.nice.org.uk/guidance/cg89 3. Colby, J. False Allegations of Child Abuse in Cases of Childhood MyalgicEncephalomyelitis (ME) (2014) <i>Argument and Critique</i> https://www.tymetrust.org/pdfs/falseallegations.pdf 4. Fabricated or Induced Illness (2019) NHS https://www.nhs.uk/conditions/fabricated-or-induced-illness/
80	Guideline	16	6	<p>Neither the MS or Childhood Asthma Guideline or the majority of Guidelines on individual biomedical illnesses have a safeguarding section. It is counterproductive to have one here as this section of the draft Guideline is already being interpreted as an alert that ME indicates safeguarding concerns. See Univadis clinical guidance summary where they recommend, on the basis of this draft Guideline, conducting a safeguarding assessment for all people with ME.</p> <p>By stating that “safeguarding assessments... should be carried out...” this committee appears to be recommending a terrifying and dangerous protocol.</p> <p>If retained this recommendation should state: “If a safeguarding assessment <i>is required</i> in people with confirmed or suspected ME/CFS it should be carried out or overseen by health and social care professionals who have training and experience in ME/CFS <i>in accordance with this Guideline.</i>”</p> <p>The misuse of safeguarding procedures has caused distress to families and children and exacerbation of symptoms for people with ME, and we understand this is what the committee is attempting to ward against. However, this section has already done the opposite.</p>

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				<p>Considering that, and in discussion with other experts in this field, we do not think a separate section on safeguarding should be included, and urge the recommendations on safeguarding to be moved into the section on principles of care, with appropriate wording to clarify that the committee’s concern is about misuse of safeguarding procedure by professionals.</p> <p>Evidence Review A p44 line 3 - ‘The committee considered that some people may be reluctant to or have reservations about engaging with social care support services due to previous disbelief about the severity of the illness and the level of impact on day-to-day functioning. They noted there are sensitivities in this area, particularly with children and young people and their families.’</p>
81	Guideline	16	8	<p>We would welcome staff who have received training based on the new guidance, however this must be made clear to ensure the change in paradigm that this draft Guideline lays out.</p> <p>Any change in approach to managing ME, hinges on both the content of new training and the ability of those undertaking it to accept and alter their views accordingly. They need to recognise and agree that "ME/CFS is a serious, chronic, complex systemic disease that often can profoundly affect the lives of patients and ... is not, as many clinicians believe, a psychological problem."¹</p> <p>In a quote from Supporting Documentation Appendix 1, a young research participant says “The specialist person didn’t listen to me, she even wrote things that weren’t right, she was always trying to make things sound better than they were. She made me feel bad, I hated going.” This type of experience must never happen again.</p> <p>Add the section in bold: “who have training in accordance with this Guideline and experience in ME.”</p> <p>1. Komaroff, A. L. (2015). Myalgic encephalomyelitis/chronic fatigue syndrome: A real illness. <i>Annals of internal medicine</i>, 162(12), 871-872. https://www.acpjournals.org/doi/10.7326/m15-0647</p>
82	Guideline	16	9	<p>We strongly agree with the inclusion of this sentence in the Guideline, and the implied recognition of wrongful allegations or abuse or neglect.</p>

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				<p>However this recommendation as it stands will not stop people with severe or very severe ME from being wrongly sectioned, as has happened to some in our community.</p> <p>Sectioning in the UK is based upon the person having a “mental disorder” (Mental Health Act 1983).</p> <p>Based on our experience in this community, people with severe or very severe ME are in danger of having their physical symptoms misinterpreted as psychological problems e.g. an inability to swallow or digest food being wrongly attributed to an eating disorder. Any professional involved with these patients should have extensive training on the problems that people with severe and very severe ME can suffer and on the new Guideline.</p> <p>To ensure people with ME are not wrongly sectioned, there must be an additional statement here that simply says “ME is not a mental disorder.”</p> <p>This will ensure that those who do have a severe coexisting mental disorder can receive the treatment they require, while those without a coexisting mental disorder will not be wrongly sectioned.</p> <p>This recommendation would therefore become: “Recognise that people with ME/CFS, particularly those with severe or very severe ME, are at risk of their symptoms being confused with signs of abuse or neglect. ME/CFS is not a mental disorder.”</p> <p>As the recommendations on safeguarding laid out in the draft Guideline have already been misused we recommend that this should instead come under “principles of care” section to avoid further suffering being inflicted on people with ME and the Safeguarding section removed.</p>
83	Guideline	16	12	<p>We strongly agree with this recommendation in principle. However in practice many healthcare professionals retain incorrect assumptions about ME based upon stigma and bad science. Professionals involved in the care of people with ME should receive training that is in accordance with this Guideline before they can continue or start working with people with ME, especially in an area where the patient's wishes may be overridden.</p>

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				<p>We urge the committee to add the bolded wording: “If an assessment under the Mental Health Act 1983 or the Mental Capacity Act 2005 is needed, involve health and social care professionals who have training and experience in ME/CFS in accordance with this Guideline..”</p>
84	Guideline	16	17	<p>This section on Children and Young People under Safeguarding was undoubtedly put here to protect children, young people and their families from unjustified safeguarding procedures. Unfortunately, it gives the impression that safeguarding concerns are indicated in people with ME. This is already being briefed to doctors; e.g univadis.co.uk.</p> <p>We can find no other Guideline for a biomedical illness that includes a safeguarding section and having it here gives the impression that safeguarding procedures are justified and should be commonplace in ME care, even with the caveats.</p> <p>We strongly urge the committee to remove the Safeguarding section.</p> <p>If it is not removed we recommend that a statement is added saying “Be aware that a diagnosis of ME/CFS in a child or young person is not grounds for suspecting abuse or neglect.”</p> <p>Due to the misuse of this section, we also urge the committee to move the recommendations in 1.7.6 to the section on principles of care.</p>
85	Guideline	17	8	<p>Saying “not necessarily a sign of abuse” leaves a broad range of doubt to the interpretation from “unlikely to be” to “may be but are not definitely”. We suggest rewording to: “Recognise that the following are established features of ME and the following should not be taken as a sign of abuse or neglect in children and young people with confirmed or suspected ME:”</p> <p>Having this section under Safeguarding implies that abuse and neglect is a problem to be addressed for children and young people with ME and will be used to continue making unfounded allegations about this vulnerable group. It would be less damaging to children, young people and their families who</p>

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				have suffered stigma and prejudice if this section was moved to “Additional principles of care for children and young people with ME/CFS” and we recommend that this is done.
86	Guideline	17	20	Section 1.8 Access to Care should be moved to before Section 1.5 Assessment and Care Planning. This would ensure that the specialist teams treating ME patients are aware of how to ensure that people with ME can access their services. .
87	Guideline	18	1	<p>The recommendation on adapting appointments is very useful. GPs and patients find the constraints of 10 minute appointments do not work when dealing with a complex illness such as ME so should be guided to offer longer appointments to this group of patients.</p> <p>Evidence Review C line 32 - ‘Patients highlighted the limited time for consultation as a barrier to appropriate care provision and another reason for seeking support outside the NHS. Health professionals recognised that a 10-minute consultation can be challenging due to the variety and complexity of ME symptoms.</p>
88	Guideline	18	8	We request that email is added to the list of providing care flexibly as some people can’t speak but can write emails in a paced manner to communicate with HCPs.
89	Guideline	18	10	The ‘do not discharge’ recommendation is warmly welcomed. We would add that HCPs should explore other ways that people with ME can access healthcare; e.g. video or phone.
90	Guideline	18	13	Thank you for including this important point. People with ME are rarely seen at their worst and often ration energy to attend appointments. We suggest following up several days after any appointment to check if it has triggered PESE.
91	Guideline	18	15	The word ‘fear’ is unhelpful and inaccurate. We request that it is replaced by ‘possibility of’ or ‘concern regarding’ or “risk”
92	Guideline	18	17	This is a very welcome addition to the Guideline as patients are likely to have prepared for the appointment with preemptive resting and will do less in the days afterwards to minimise PEM/PESE.

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93	Guideline	18	20	<p>The proactive and flexible recommendations for people with severe and very severe ME are welcome. We ask you to add that the time of day that appointments are offered should also accommodate the needs of this group.</p> <p>We would like to stress the importance of home visits for these patients who may be not able to access telephone or video appointments. As one mother of a severely ill young woman said, ‘in seven years of severe illness, my daughter has had no home consultations or visits from NHS specialist ME staff.</p> <p>However, we strongly urge that this flexibility is offered to people with moderate ME as well who are defined in the Guideline as having ‘reduced mobility and are restricted in all activities of daily living’ and often have great difficulty accessing care. In any other illness this level of disability would be regarded as severely affecting their lives and we feel that ‘moderate’ underplays the level of disability that this group experiences. In the supporting documentation Appendix 1 Children and Young People (p18 line 27) ME11 stated: “I think doctors should do home visits if the patient isn’t well enough to go. Because a lot of the times like the doctors ... like we’ve had to travel to my consultant before because they’ve moved him, and at times it’s been tough getting to him cos of I’ve just been unwell.”</p>
94	Guideline	19	1	<p>We welcome this suggestion and would add that flexibility around timing of routine tests should be offered.</p>
95	Guideline	19	4	<p>We also urge that people with ME who are ill enough to need hospital care need a single room regardless of their illness level as the extra exertion, noise, light and medical examinations on top of any comorbid illness can cause a relapse and severe PESE.</p>
96	Guideline	19	8	<p>We welcome these recommendations on hospital care for people with severe or very severe ME but urge that they are also offered to people with mild or moderate ME. The evidence from review A quoted below applies to all patients with ME.</p> <p>Evidence Review A p26 line 30 - “Patients who had hospital care also described their need for designated wards for ME, with environments adapted to their needs, as in keeping light and noise</p>

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				levels low. Some highlighted the limited time for consultation as a barrier to appropriate care provision and another reason for seeking support outside the NHS.”
97	Guideline	19	20	The Guideline says to ‘aim to provide a single room if possible ’ for people with severe or very severe ME. However, a single room is essential for a person with severe or very severe ME, as it is impossible to keep light, sound, and movement to a low level in a ward setting. We would urge that these patients are a priority for a single room and reword the recommendation to ‘provide a single room as a priority ’.
98	Guideline	19	21	The advice on keeping stimuli to a minimum is welcome and we thank the committee for including this. We suggest one addition, there should be reference to the fact that dimming lights may not be enough and windows will need to have blinds drawn and also may need additional measures such curtains to block out sufficient light as blinds on their own may not be adequate. Hospitals may need to work with families and carers to determine the level of light that the person with ME can withstand.
99	Guideline	20	20	We welcome the recommendation for provision of aids and adaptations without delay. This will help people avoid PEM/PESE and relapses.
100	Guideline	20	23	We warmly welcome this recommendation.
101	Guideline	20	26	We welcome this recommendation on providing aids and adaptations for people with moderate, severe or very severe ME. Electric wheelchairs should be specified as the exertion involved in propelling a manual wheelchair can make their use impossible for people with ME. We also recommend that this provision is extended to include people with mild ME if needed. Levels of ability can fluctuate daily and aids and adaptations for people with mild ME/CFs can prevent PESE, relapses and degradation of function.
102	Guideline	21	4	We welcome the advice to people with ME that there may be times when they are unable to continue with work or education, some people find that going back to work, school or college worsens their symptoms and they may be able to access reasonable adjustments or adaptations. We would strengthen this wording as in the ‘Living with the impact of ME’ survey undertaken by Action for ME in 2019, 83% of people had to stop or reduce work and 77% had to stop work entirely.

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				We suggest rewording from “there may be times when they are unable to continue with work or education” to ‘there will often be times when they are unable to continue with work or education.’
103	Guideline	21	11	<p>We welcome this suggestion. Liaising with employers etc is a valuable and welcomed service.</p> <p>We request that insurers be added to this list for people unable to return to work.</p> <p>The Department of Work and Pensions should be included in this list as they are a gatekeeper for benefits and disbelief in ME as a serious disease means that people are often denied benefits.</p> <p>Due to the fluctuating nature of ME people often struggle to gain accommodations from employers or benefits from the DWP as illustrated in Evidence Review C p72 line 27: “The committee discussed that the unpredictability of the severity of people’s symptoms can sometimes prevent reliable planning ahead meaning that scheduled appointments (or work) may be missed or cancelled with little notice.”</p>
104	Guideline	21	15	<p>This is an important provision.</p> <p>However an additional recommendation is required here. Children and young people with ME are often pressured to increase school attendance as shown in the following evidence:</p> <p>Supporting Documentation Appendix 1 p13 line 3 “Often the school concerned would initially require the participant to attend lessons or restrict the ability to rest.”</p> <p>Evidence Review A p33 line 13 - “Young people felt that better support from education systems could have helped. They described schools and colleges as inflexible, unhelpful, un-empathetic and invalidating.”</p>

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				<p>Evidence Review A p33 line 21-23 - “letter provided by the ‘CFS/ME’ service confirming a diagnosis enabled mothers to legitimately take their child out of school, request funding for home schooling and more generally inform and gain support from teachers when managing reduced attendance.”</p> <p>Evidence Review C p55 line 39 - “Both teachers and families identified the diagnosis as a catalyst to the school taking the health concerns seriously and implementing the necessary support. Teachers emphasised that at an organisation/policy level, teachers needed this formal diagnosis to implement treatment recommendations, such as reduced timetables.”</p> <p>Further to this, specialist services are often seen as unhelpful or as doing harm to children and young people with ME, as Evidence Review A p30 line 45 states: “Young people appeared to experience difficulty with a lack of understanding and awareness around the condition from medical professionals involved.” In the patient survey “Your Experience of ME Services” by #MEAction UK, the overwhelming experience of respondents of all ages attending specialist clinics was negative, a trend that is especially pronounced in the experience of children and young people. There are over 140 negative comments from young people or their carers recounting their treatment by the specialist clinics and fewer than 10 positive or neutral ones.</p> <p>Children, young people and their families report to us that they need to attend services to obtain letters giving them access to home/online tuition or to reduce attendance, as local authorities will commonly refuse to accept letters that are from their GP. This is problematic as access to consultants can be limited or take a long time, delaying access to the support children and young people require. Guidance should be provided to education authorities and local authorities that a letter from a GP is sufficient evidence that a child is either ‘unfit for school’ or needs accommodations.</p> <p>We therefore urge the committee to add an additional recommendation stating that: “Training and education services should accept letters from either GPs or consultants that the child or young person is “unfit for school” or requires accommodations.”</p>
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105	Guideline	21	20-22	A balance of activities is important for children and young people. We would like to see these listed so there is clarity around the subject and for this to include education and training, home and family, hobbies and social activities.
106	Guideline	22	3	<p>A flexible approach to training and education is an excellent provision. Acknowledging the value of home or online education as a means of ensuring that children and young people can access education is very welcome as this has been a major barrier for children and young people with ME.</p> <p>We are pleased to see this included considered the important evidence identified, such as:</p> <p>Supporting Documentation Appendix 1 p13 line 3 - “Often the school concerned would initially require the participant to attend lessons or restrict the ability to rest.”</p> <p>Evidence Review A p46 line 3 - “It was highlighted by the committee that there is a legal responsibility to ensure children receive an education, but this does not mean that they must attend a school.”</p> <p>Evidence Review C p53 “There is often a lack of sufficient or direct communication between schools, families and health-care professionals, implicating the care of children with ME/CFS and the importance of such an ongoing communication across settings is acknowledged by all parties.”</p>
107	Guideline	22	6	Advice on applying for education, health and care plans will be welcomed by parents and carers. The inclusion of a note on confirming the eligibility of children with ME/CFS for EHCPs is needed here along with notification of the same to local authorities.
108	Guideline	22	14	We acknowledge the lack of evidence identified to inform recommendations on multidisciplinary care, and that therefore the committee has made these recommendations based upon their own experience and consensus views.

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				<p>However these recommendations on multidisciplinary care do not provide the clarity required for commissioning of services, and do not align with the recommendation that the specialist team should confirm diagnosis of ME. There is no explicit mention in this section that a physician should be included in the team, although this will be necessary to confirm diagnosis.</p> <p>Where evidence cannot be found for a specific disease it is appropriate to explore more broadly. A report by the Academy of Medical Royal Colleges found that “the consistency of the association between consultant involvement and improved outcomes across many studies in many specialties is compelling.” On the basis of further systematic review they conclude “there is considerable internationally shared professional knowledge, expert opinion and considerable secondary evidence to support decision-making with regard to future policy making on consultant-delivered care. This body of knowledge and expertise recognises the complications that arise from a lack of consultant presence, failure to care by non-consultant staff and it supports the concept of consultant-delivered care.”</p> <p>Evidence from surveys of people with ME supports the appointment of physicians to any multidisciplinary specialist team.</p> <p>An ME Association survey found that when asked, “Which health professionals and organisations do you want to be involved?”, the GP was most favoured, then a consultant physician.</p> <p>#MEAction UK’s survey report “Your Experience of ME Services”, undertaken in response to this committee’s call for evidence, found that when respondents were asked who they would most want on a multidisciplinary team “consultant was the most common choice, with 76% choosing this as one of their top 3 [professions].”</p> <p>In both surveys, psychologists were amongst the least preferred profession to support management of this illness. Similar sentiment was also expressed by participants of the community calls #MEAction UK held to discuss this draft Guideline, who felt that specialist teams should not be led by psychiatrists or psychologists.</p>
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				<p>Evidence Review I p24 line 5 states: “The committee acknowledged that GPs did not have enough time to carry out the assessments needed to confirm a diagnosis of ME/CFS or to develop a management plan in a single standard appointment. The committee recommended that once someone with suspected ME/CFS has had persistent symptoms indicating ME/CFS for 3 months the person should be referred to a specialist team for confirmation of the diagnosis.”</p> <p>This acknowledgment is very important to the make-up of a multidisciplinary team, as it requires there is a physician with expertise in ME in order to confirm diagnosis.</p> <p>This committee must therefore add an explicit recommendation for the presence of at least one physician, preferably a consultant, within every multidisciplinary team.</p> <p>We also note that the committee could find no evidence as to which specialty ME should be managed under, and the input we’ve received from community members on this varies widely. We therefore ask the committee to consider a research recommendation on which specialty should take managing people with ME.</p>
109	Guideline	23	7	<p>We strongly agree with the inclusion of a named contact to help people with ME access support. This is particularly important during a relapse and should go some way to stop people with ME being forgotten by the medical establishment, particularly those with severe ME.</p>
110	Guideline	23	12	<p>We strongly agree with the inclusion of a named contact to help children and young people with ME access support. This is particularly important during a relapse and should go some way to stop children and young people with ME being forgotten by the medical establishment, particularly those with severe ME. It should also be used to ensure that children are not refused education due to not being able to attend school.</p>

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111	Guideline	23	12	<p>Evidence Review I page 25 line 10 says: “The committee noted this was particularly important for children and young people and they should be involved in the decision making about their key worker.” (our emphasis)</p> <p>We recommend adding the part in bold to this recommendation: “Provide parents and carers of children and young people with ME/CFS with details of a named professional in the specialist team who they can contact with any concerns about their child’s health, education or social life. Involve children and young people with ME/CFS in choosing this named professional.”</p>
112	Guideline	23	17	<p>Transition to adult services for young people with ME is often very slow or non-existent and the care provided is unsuitable to their needs. In a recent community call one parent who has struggled to get any care for their adult child remarked, “Transitions from paediatric care to adult care is a huge issue. A good paediatrician can coordinate care, but this disappears in adults and GPs don’t have the same authority and links that consultants have.” This means that there is no joined up approach to care, which has a particularly negative impact on managing comorbid conditions.</p> <p>We urge that young people can opt to remain under the care of their existing team until a suitable care pathway is found for them.</p>
113	Guideline	24	4	<p>We strongly agree with including this statement but are very surprised it doesn’t come with a related research recommendation. We hope you will rectify this major omission.</p>
114	Guideline	24	6	<p>We are pleased to see energy management forming the basis for other recommendations.</p>
115	Guideline	24	11	<p>The statement “with” support from a healthcare professional is inaccurate. For many, strategies around energy management are learned and undertaken alone. We cannot find evidence that support from a healthcare professional is a necessary part of energy management. We strongly agree that people should have support from appropriately trained healthcare professionals where they want it, but think this language should be changed from “with” to “can include”.</p>

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116	Guideline	24	13	<p>The point of the energy envelope is to manage overall energy expenditure - saying it “can be applied to all types of activity” implies a level of separation between different types of activity and misses the key aspect of the approach.</p> <p>Suggest changing this to “includes all types of energy expenditure”</p>
117	Guideline	24	14	<p>We strongly agree with this statement, especially that overexertion can cause a worsening of symptoms</p>
118	Guideline	24	16	<p>We strongly agree with this statement.</p>
119	Guideline	24	18	<p>We agree with this statement.</p>
120	Guideline	24	21	<p>This statement assumes that there will be periods where symptoms are improved, and then only suggests pulling back when symptoms are worse, not before they may get worse, despite another recommendation for pre-emptive rest.</p> <p>We do however agree that the approach should be flexible. Suggest changing this to “uses a flexible approach so that activity changes dependent on symptom severity, and reduces activity when symptoms are or may be about to get worse”</p>
121	Guideline	25	1	<p>Again this bullet point assumes that increases in tolerance or activity are possible and to be aimed for. We are particularly concerned by the use of the word “tolerance” here.</p> <p>Instead change to “is a long-term approach that aims to reduce the chances of flares and relapses”</p>
122	Guideline	25	3	<p>Despite significant evidence to the contrary, this statement of assumption still allows for the possible interpretation that ME/CFS could be caused by deconditioning. In evidence review G p335 line 50, the language used is “recognises that deconditioning is not the cause of ME/CFS.”</p> <p>Why have the committee not used this more accurate language in the Guideline itself? We recommend changing this to: “recognises that deconditioning is not the cause of or a perpetuating factor of ME/CFS.”</p>

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123	Guideline	25	4	<p>We agree that people with ME should be offered an assessment to develop an energy management plan with realistic expectations, however remain concerned about the language of “goals”.</p> <p>Evidence Review G p336 line 26 states: “The committee noted that where goals are rigid and unrealistic this can result in false starts, flares and relapses. The committee commented on the findings in the qualitative evidence that people had felt pressured and blamed when they could not complete the programme even though it was making their symptoms worse. The committee acknowledged the controversy around the setting of fixed unrealistic goals and the importance of understanding realistic goal setting by both the person with ME/CFS and the healthcare professional supporting any programme.”</p> <p>Where there is evidence of harm from goal setting, including relapses that “can lead to a long-term reduction in the person’s energy envelope” (Guideline p44 line 29) there must be very strong evidence of benefit to recommend such a strategy even with the caveats of “realistic” attached. Such evidence is not presented in the evidence reviews.</p> <p>“and goals” should be removed from this sentence, and doing so would have no adverse impact on the Guideline or people with ME.</p>
124	Guideline	25	7	We agree with all of these bullet points
125	Guideline	25	12	Can this bullet point on rest and relaxation be linked to the specific recommendations around rest made at 1.11.23?
126	Guideline	25	15	This implies that the management plan can be established by the healthcare professional alone, add in “work with the person to establish...”
127	Guideline	25	18	We agree this should be a first step.
128	Guideline	25	19	We strongly agree with the recommendation for pre-emptive rest.
129	Guideline	25	21	While this may help some, we have heard from others that this can take more energy. We don’t know of an evidence base for this, and cannot find one in the evidence reviews. We would suggest adding

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				the word “consider” at the beginning of this bullet point to make it clear this may only be helpful for some.
130	Guideline	25	25	We strongly agree with this statement.
131	Guideline	25	27	We strongly agree with this statement.
132	Guideline	26	1	It is unclear if all three of these bullet points must be met, or if only one of them should be. However we agree that specialist and not generic services are required for people with ME.
133	Guideline	26	4	Physical activity advice from a specialist should be available to any person with ME who needs it, whether they are increasing or decreasing activity. As in other places in this Guideline, this sentence once again puts a focus on progressing physical activity, without a clear evidence base for doing so. Change this to: “Would like support in changing their physical activity pattern to match their current energy envelope”.
134	Guideline	26	6	This sentence again suggests that people with ME simply need to want to incorporate physical activity programmes into their life for it to be appropriate - without consideration for whether their current energy envelope would allow for this. During our community calls to discuss this draft Guideline, that were attended by over 70 participants, people expressed offence at this language. One participant told us that of course she “would like” to do physical activity, of course she “would like” to do new activities, of course she “would like” to return to her previous levels of health and fitness - but her energy envelope and ability to do these activities had nothing to do with what she “would like”. This was met with agreement from other participants. This sentence plays into tropes that people with ME simply need to undertake physical activity to recover, tropes that you have recognised to be problematic and inaccurate in the evidence reviews and supporting evidence. We very strongly urge the committee to remove all language suggesting people with ME simply need to “like” an activity programme, for it to be appropriate.

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				Remove this sentence.
135	Guideline	26	9	We agree that more specialist advice is required for people with severe or very severe ME, but only where they would like it.
136	Guideline	26	14	<p>“That changes in activity should be smaller and any increases (if possible) much slower.” - Once again we see a focus on increases where the aim of energy management should be stabilisation and reduction of flares and relapses.</p> <p>Change this sentence to: “that changes in activity should be smaller (unless decreasing activity significantly to reduce symptom severity), and should focus on stabilisation and remaining within the person’s energy envelope”</p>
137	Guideline	26	16	<p>We are pleased to see the inclusion of this section in the Guideline.</p> <p>It is important to recognise the impact ME can have on general health, and work to mitigate that in ways that recognise the harm of overexertion itself.</p> <p>However it seems important that an additional recommendation is added to this section - in our experience, it is common that people will search for and read just the part of a Guideline that is relevant to them on that particular day. When read alone this section implies that normal management advice relating to muscle strength and other areas could be appropriate.</p> <p>We strongly agree with the definition of physical maintenance laid out on page 44. Incorporating all or part of this here would make it significantly clearer what the aim of physical maintenance is.</p> <p>We particularly note the helpful and clarifying statement on page 44 line 15 that states: “Such activity is undertaken within the person’s energy envelope and avoids pushing through boundaries of tolerance.”</p> <p>We therefore strongly urge the committee to at least add a statement that says:</p>

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				<p>“Be aware that any activity undertaken as part of physical maintenance should be within the person’s energy envelope and should avoid pushing through the boundaries of tolerance. Consider the person’s other activities of daily living when giving advice.”</p> <p>Bringing this important aspect in from the definition of physical maintenance will ensure this recommendation is in line with other advice and doesn’t harm people with ME by generalised and inappropriate advice being given.</p>
138	Guideline	26	22	We would recommend the removal of the word endurance here. In healthy people, increasing endurance is generally achieved by repeatedly exceeding one’s capacity - something this committee has explicitly warned can cause PEM/PESE and relapses for people with ME.
139	Guideline	27	3	We agree with this recommendation.
140	Guideline	27	8	We agree with this recommendation.
141	Guideline	27	14	We agree with this recommendation.
142	Guideline	27	20	<p>We support the inclusion of a section on physical activity, due to the significant reports of harm from programmes relating to physical activity in the evidence reviewed, and our personal experience of such therapies and programmes.</p> <p>Considering the harm caused by past recommendations, and that other sections of this Guideline make clear statements not to offer medicines, CBT or anything else as a treatment or cure for ME, we see it as equally if not more important that this is reiterated here.</p> <p>Add a sentence: “Be aware that physical activity and/or exercise is not a treatment of cure for ME, and may worsen their symptoms.”</p>
143	Guideline	27	21-23	Remove the word “unstructured”. The evidence reviews provide significant evidence that structured exercise (as in the form of graded exercise therapy) is in fact also harmful.

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				<p>There is also a double negative in the sentence that leads to confusion. People with ME clearly should not be advised to take part in unstructured exercise even as part of a supervised programme.</p> <p>We suggest rewording this sentence to: “Do not advise people with ME to undertake generalised exercise, such as telling them to go to the gym or exercise more, because this may worsen their symptoms”</p>
144	Guideline	27	24	<p>This is a very helpful addition that we strongly agree with overall. Thank you to the committee for taking the reports of harm seriously, and actively following the evidence base.</p>
145	Guideline	28	1	<p>We strongly agree with this bullet point, and consider it an important part of the overall Guideline.</p>
146	Guideline	28	3	<p>We strongly agree with this bullet point, but the use later on of the term “physical activity programme” for people with ME makes this less clear. We suggest keeping this bullet point as is, but changing the language of “physical activity programme” used later in this Guideline. We will make a separate comment about this.</p>
147	Guideline	28	6	<p>This recommendation is a necessary and clear repudiation of a paradigm that has caused very significant harm. As you have found in the evidence reviews, trials commonly did not measure adverse events, outcomes were switched and the quality of evidence was almost entirely very low. Yet data from surveys of many thousands of patients demonstrated significant harm from such approaches. It is vital that this committee have taken into account the grey literature on these areas, and we urge them to retain this statement.</p> <p>We would change just one thing in this sentence - removing the word fixed. According to Oxford Languages, the definition of incremental is “relating to or denoting an increase or addition, especially one of a series on a fixed scale”. This language of “incremental increases” already covers what is necessary here, without the additional qualifier of ‘fixed’.</p> <p>Incremental increases have been the core part of activity programmes provided to people with ME in the past, however the terminology of fixed has not previously been used. In the 2007 CFS/ME Guideline, it states: “People with mild or moderate CFS/ME should be offered GET that includes</p>

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				<p>planned increases in the duration of physical activity. The intensity should then be increased when appropriate...”</p> <p>The Guideline also states: “Encourage them to undertake this exercise for at least 5 days out of 7, or build up to this level if and when possible.”</p> <p>Language was already included that allowed for some level of flexibility in increasing exercise, yet it is under this Guideline that so much damage has been caused.</p> <p>The Oxford Brookes Survey Report (2019), which specified therapy must have been received since 2007 as an inclusion criteria, demonstrates that over two thirds of respondents who underwent this therapy whilst the 2007 Guideline was in place deteriorated. Further survey data support this finding. It is quite clearly not only “fixed” incremental increases in activity that have caused harm, but an approach that’s basis is any type of incremental increases.</p> <p>We do not wish to take away from the incredible step that a recommendation against graded exercise therapy is for the wider community, but do urge the committee to remove the word “fixed” from this sentence.</p>
148	Guideline	28	8	<p>While we strongly agree with the sentence, it could be better said as “activity or exercise programmes as a cure or treatment for ME, including any programmes based on deconditioning as a cause or perpetuating factor of ME.”</p>
149	Guideline	28	10	<p>We very strongly agree with this recommendation, in particular the recommendation against using the Lightning Process, that has no evidence base and draws on techniques, such as activities outside the person’s energy envelope, that are contraindicated for people with ME.</p> <p>In #MEAction UK’s community calls to discuss this draft Guideline, and in emails we’ve received, some people with ME have raised concerns about osteopathy being included alongside life coaching, neurolinguistic programming, and the Lightning Process, and so we wished to pass this along to the committee. It is unclear if this recommendation means therapies derived from combinations of osteopathy, life coaching and neurolinguistic programming, or each of these sources alone.</p>

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150	Guideline	28	12	<p>In the 2007 Guideline advice was given for people with ME to increase their activity and exercise, this included sentences such as “People with mild or moderate CFS/ME should be offered GET that includes planned increases in the duration of physical activity. The intensity should then be increased when appropriate...” and “Encourage them to undertake this exercise for at least 5 days out of 7, or build up to this level if and when possible.”</p> <p>In spite of language that includes qualifiers of “when appropriate” and “if and when possible” many people with ME have been harmed by these recommendations. It is clear the committee has understood and recognised the extensive harm caused, and there is very significant relief that the lived experience of so many people has not been ignored.</p> <p>This recommendation for physical activity programmes, while adding more qualifiers than the 2007 Guideline, appears likely to lead to the same outcomes of harm, deterioration, resultant distrust in healthcare professionals and therefore worse overall care for people with ME.</p> <p>It is right that people with ME, alongside those with other debilitating illnesses, have access to specialist support around physical activity when requested, especially as this aspect appears key in preventing relapses.</p> <p>However, in their recommendation of “physical activity programmes” the committee appear to have made up an entirely new management approach that is not backed by the evidence base, be that research literature or qualitative data.</p> <p>The committee has acknowledged that graded exercise therapy has done harm, and has explicitly recommended against this. Under ‘Other Exercise Interventions’ (Evidence review G, page 154-165), not a single outcome rates higher than ‘very low’ on the quality of evidence, nor has any qualitative evidence been identified.</p> <p>We therefore strongly question why the committee has created a newly defined ‘physical activity programme’ in the Guideline.</p>
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				Our strong recommendation here is to remove this non-evidence based ‘programme’ from the Guideline in its entirety, and instead provide greater access to specialist advice and support on energy management, as this should include support in managing fluctuations in a person’s energy envelope anyway. This would enable access to physical activity advice for all people with ME, and not just those who “are ready” or “would like” to “progress their physical activity”.
151	Guideline	28	12-14	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>Why has the committee chosen to call this a programme?</p> <p>Programme is defined in Oxford Dictionaries as “a set of related measures or activities with a particular long-term aim.” To us, this has connotations of expected change, yet that very clearly cannot be guaranteed.</p> <p>The committee could choose language without connotations of expected change and ultimately improvement, such as “Physical Activity Advice”, Physical Activity Support” or a “Physical Activity Plan”.</p> <p>Why the difference here between an Energy Management <i>Plan</i> and a Physical Activity <i>Programme</i>?</p> <p>We very strongly urge the committee move away from the language of a programme.</p>
152	Guideline	28	14	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>Evidence Review G p336 line 44 states: It was the opinion of the committee that a physical activity or exercise programme can be beneficial for people who have chronic fatigue (not ME) and in a subset of people with ME who have already begun to improve and feel they want to do more.” (Our bolding)</p>

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				<p>Despite this, the Guideline says “Only consider a physical activity programme for people with ME/CFS who are ready to progress their physical activity beyond their current activities of daily living, or would like to incorporate physical activity into the management of their ME/CFS.”</p> <p>This difference between “and” and “or” here is vital. By defining the prerequisite for undertaking this newly defined programme as something a person simply would like to do, instead of also being ready to do, it opens up the possibility for significant harm.</p> <p>We very strongly request that “or” is changed to “and” in this sentence.</p>
153	Guideline	28	17	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>It is under the purview of health professionals trained in ME that such significant harm has occurred and at present this recommendation does not go far enough to support the paradigm shift needed to halt the harm.</p> <p>We recommend adding: “by a physiotherapist or occupational therapist with training and expertise in ME as per this Guideline.”</p> <p>The shift required will mean many practitioners who wish to stay working in healthcare relating to ME retraining per this Guideline. It is simple enough for the committee to make this clear.</p>
154	Guideline	28	20	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p>

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				<p>Qualitative evidence quite clearly demonstrates that most people with ME deteriorate following graded exercise therapy, furthermore Evidence Review G acknowledges that most clinical trials did not record harm from this therapy. Taking this into account, we find it perplexing that the committee has recommended to “Explain that some people with ME/CFS have found that physical activity programmes can make their symptoms worsen, for some people it makes no difference and others find them helpful.” (Our bolding)</p> <p>It would be more accurate to write that “many” or “most” people with ME have found the physical activity programmes can make their symptoms worsen.</p>
155	Guideline	28	23	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>Again, we disagree with the terminology of “programme” here. We agree that physical activity should be personalised.</p>
156	Guideline	28	25	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>We agree that not worsening symptoms should be the highest priority. The committee could make this clearer by adding a first bullet point that simply states: “should not worsen symptoms”.</p> <p>If advice or a programme is worsening symptoms, it is not fit for purpose, yet for the past 13 years this has been considered acceptable.</p> <p>We urge the committee to take a very clear stance that this is not acceptable.</p>

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157	Guideline	28	27	<p>We recommend that this non-evidenced based and newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>We agree that any physical activity should remain inside the person’s energy envelope, unfortunately this bullet point suggests that this only needs to happen at the start. The Guideline does state that any increases should be within the energy envelope later, but this is a key principle that must not be understated.</p> <p>The committee could make this clearer by stating that any physical activity programme should “start by reducing the person’s activity to within their energy envelope and stay within their energy envelope throughout”.</p>
158	Guideline	28	28	<p>We recommend that this non-evidenced based and newly defined physical activity programme be removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>The Guideline recognises that the person with ME/CFS is the “best judge of their own limits” (page 24, line 17). Surely this should be considered in this bullet point, beyond just that ability to maintain their baseline activities.</p> <p>If the person judges that they have not yet reached their limit, then minor increases may be appropriate, however if the person feels they are at their limit, or that they have other life events ahead that require energy expenditure, this must be taken into account - decreases in physical activity may be just as appropriate as increases dependent on circumstances. This is recognised in Evidence Review G p336 line 25 where it says “Another finding highlighted the need for programmes to fit into their lives accounting for essential life activities.”</p>

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				We recommend changing this bullet point to: “Adapt to changes in circumstance or the person’s energy envelope by decreasing or increasing activity as appropriate.”
159	Guideline	29	1	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>“Use flexible increments” - albeit slightly different language, this is ultimately what the 2007 CFS/ME Guideline also advised, and is what has caused such harm.</p> <p>Increments implies additions or increases. However this will not be appropriate for all people. We question why the committee has decided to focus so strongly on increments instead of words such as “changes” that encompass the wider range of possibilities people with ME confront in living with this chronic condition.</p> <p>The focus of “want to improve their physical abilities” is yet again deeply offensive to the majority who are too ill to do this, as if wanting to is the only barrier.</p> <p>We urge the committee to remove this bullet point. It has no place in ME care.</p>
160	Guideline	29	3	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>We agree that recognising flares or relapses early is important. It would be helpful if such terms were defined at the beginning of the Guideline instead of the end, as the nuanced difference is currently lost.</p>

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				<p>We also agree that outlining how to manage a flare or relapse is important. It would be helpful for the committee to recommend that this outline should be defined before the flare or relapse occurs.</p> <p>Simply adding the bold words to the recommendation: “recognise a flare or relapse early and outline how to manage it before it occurs...” would help make sure any advice incorporated this.</p>
161	Guideline	29	5	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>We agree that regular reviews are important, but would add that the professionals should record any flares or relapses that have taken place.</p> <p>We therefore suggest the bullet point is changed to include the part in bold: “incorporate regular reviews and record any flares or relapses.”</p>
162	Guideline	29	6	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>This recommendation could be suggesting that agreement on how to manage flares or relapses is considered once the person is in a flare or relapse. This is too late.</p> <p>Change to: “Agree with the person in advance how to adjust their physical activity after a flare or relapse.”</p>
163	Guideline	29	9	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p>

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				<p>On page 28 the Guideline recommends “a physiotherapist or occupational therapist with training and expertise in ME/CFS” should be involved in physical activity advice. However this recommendation now mentions a specialist physiotherapy service. Is this service relating to flares and relapses intended to be different from the support given in the initial stages of considering physical activity with the person with ME?</p> <p>Why is occupational therapy mentioned previously but not here?</p> <p>Should the person contact this service instead of their named contact as per recommendation 1.10.3 that also mentions support during a relapse?</p>
164	Guideline	29	10	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>We agree that reducing activity is vital during a flare or relapse.</p>
165	Guideline	29	12	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>There must be a bullet point making clear that avoiding another flare or relapse is the highest priority. There is also concern that “establishing a new physical activity baseline” doesn’t explain that this should be reduced, nor that cycles of physical activity and flare are more likely to lead to relapse.</p> <p>We would therefore recommend replacing this bullet point with: “identifying what may have caused the flare or relapse and changing physical activity levels to prevent this in future.”</p>

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				<p>Continuing with physical activity programmes after flares or relapses have occurred should ideally be advised against and, if undertaken, the risks of further flares or relapses should be clearly discussed.</p> <p>While this sentence should be replaced, the use of the word “and” is an important qualifier that should not be changed if the committee decides to keep such a sentence: “only once symptoms stabilise and the person feels able to resume physical activity, ...”</p>
166	Guideline	29	14	<p>We recommend that this non-evidenced based and entirely newly defined physical activity programme is removed from the Guideline.</p> <p>In case the committee does not take this step, here are our further comments:</p> <p>This recommendation appears confused. In the section “Terms used in this Guideline” a flare is defined as transient, and typically resolves after a few days. Yet this recommendation says “Advise people with ME/CFS after a flare that the time it takes to return to the level of physical activity they had before the flare varies from person to person.”</p> <p>We actually believe this is more accurate than the 1-3 days timeline proposed in the “Terms used in this Guideline” however note that for some people they may never return to the level of physical activity they had before the flare - in this case it should be considered a relapse, and the person with ME should also be advised of this as a possible outcome.</p> <p>Change this recommendation to: “Advise people with ME/CFS that the time it takes to return to the level of physical activity they had before a flare varies from person to person, and that when a flare develops into a relapse this can lead to a long-term reduction in the person’s energy envelope.”</p>
167	Guideline	29-33	17 - General	<p>We recommend this section be edited to include more details on symptoms and symptom management. We understand the reasons why the recommendation is that there is no overall treatment for ME, but in our experience specific symptomatic treatment can significantly improve our quality of life. It would be helpful for GPs to be given a clearer steer as to what can be offered, rather</p>

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				than assuming relevant knowledge. Suitable prescriptions might include amitriptyline for pain and reverse body clock; betahistine for nausea and dizziness, antihistamine based sleeping tablets, etc. It would be helpful for patients and GPs to be given a list of suitable examples like this.
168	Guideline	29	17	We recommend the addition of a referral to a sleep clinic in cases where other approaches do not help. A sleep clinic can determine whether the person has additional problems such as sleep apnoea and recommend appropriate treatments.
169	Guideline	29	18	This section should further explain the role of rest, and discuss interventions for more severe sleep issues, providing specific advice for people with ME including pharmaceutical interventions.
170	Guideline	29	19	The word 'sleep' should be added to this sentence alongside the word 'rest'. Daytime sleep is discouraged by clinics at the moment but is often vital for energy management.
171	Guideline	29	20	We strongly agree that rest periods are a part of all management strategies for ME and are pleased the committee has made such a clear statement on this.
172	Guideline	30	3	An additional research recommendation on treatment of orthostatic intolerance in people with ME should be made, due to the paucity of evidence here. Further training in testing and interventions for orthostatic intolerance for healthcare professionals treating people with ME should also be required.
173	Guideline	30	4	We agree with this recommendation.
174	Guideline	30	10	We agree that people should be referred to secondary care for orthostatic intolerance if the professional treating ME is not trained in orthostatic intolerance.
175	Guideline	30	10	We strongly agree with the recommendation to follow advice on neuropathic pain in adults, and not the new Guideline on chronic pain in adults that recommends treatments contraindicated in ME.
176	Guideline	30	10	We agree that the NICE guidance on headaches should be referred to.

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177	Guideline	31	2	Nausea could be caused by a variety of factors, including comorbid conditions. The origin of the nausea should be investigated and addressed accordingly. We recommend this section be edited accordingly.
178	Guideline	31	2	There are specific anti-nausea medications. A general reference to them should be included here. We recommend the following be added at 1.11.28: “Where nausea is not remedied by fluid intake and eating habits: <ul style="list-style-type: none"> ● Consider standard antiemetics ● Consider revisiting the energy management plan as nausea may be induced by over-exertion”
179	Guideline	31	6	Evidence review F makes a much clearer statement on the use of medicines for symptom management than is given here: “The committee acknowledged that while there are not any current pharmacological treatments or cures for ME/CFS, people with ME/CFS have found some drugs when used appropriately with advice and support from health care professionals can be helpful in managing the symptoms of ME/CFS and they could be discussed on an individual basis.” (p94 line 30) We urge the committee to include a recommendation in line with these remarks, that where a physician or person with ME believes that a medicine may provide symptomatic relief, their GP should offer advice and support, and prescribe it if in their judgement there is potential benefit with low risk for harm. Some over-the-counter interventions may mitigate symptoms despite not treating or curing the root cause(s) of ME. We recommend that use of low-risk, low-cost interventions be supported in the Guideline if the doctor and person with ME agree. Add a recommendation: “Be aware that some medicines or supplements can be helpful in managing the symptoms of ME and should be discussed and prescribed on an individual basis.”
180	Guideline	31	17	We would like the word “paediatrician“ to be replaced by “paediatrician with training in accordance with this Guideline and experience of ME.”

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				It is vital that all those involved in the prescribing of care for people with ME, and especially children and young people, have an understanding of ME based upon this Guideline.
181	Guideline	32	1	We would like to see a recognition that many people experiment with diet to try and gain some relief from symptoms. As with medication and supplements, we would like to see a recommendation that healthcare professionals take a supportive attitude, advising on potential harms and benefits if they are qualified, or referring the person to a dietician if not.
182	Guideline	32	8	Some people with ME experience weight gain rather than loss. We recommend this be taken into account for this section of the Guideline. Many people find that excluding certain foods can help reduce symptoms. We recommend the following to be added to the end of this sentence: “.. or wish to try excluding certain foods from their diet”.
183	Guideline	32	11	We agree with this recommendation, including reference to those who are predominantly housebound or bedbound.
184	Guideline	32	15	We recommend the following wording to be added to this recommendation: “Where a person wishes to try vitamin or mineral supplements, be supportive but advise on safe limits and any possible harms or side effects.”
185	Guideline	32	21	We agree with this recommendation, however would add to the end “and has training in accordance with this Guideline.”
186	Guideline	33	4	We agree with this recommendation, however would add to the end “and has training in accordance with this Guideline.”
187	Guideline	33	6	We agree with this recommendation.
188	Guideline	33	15	We agree with this recommendation, and all the bullet points, especially the reference to possible “oral nutrition support and enteral feeding”.

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189	Guideline	34	1 - General	<p>While we agree that people with ME may need psychological support and should have access to this, we argue below that the focus on CBT alone in this guideline is not evidence based and will lead to less access to support than is desirable and necessary. We recommend changing the title of this section to just “Psychological support”, and creating recommendations that cover all therapies people with ME may receive for psychological support.</p> <p>Looking through Evidence Review H - we note that out of 161 outcomes of CBT that were assessed, 113(70.2%) had a rating of very serious risk of bias and the remaining 48(29.8%) had a serious risk of bias. The vast majority (143/88.8%) received a quality rating of very low, with the remaining outcomes (18/11.2%) receiving a quality rating of low.</p> <p>In looking at Evidence Review H, Appendix J we also note that the minimal important difference (MID) used throughout appears to have been 0.5xSD. We cannot find any analysis of a minimal important difference of one standard deviation, but considering the inconsistent results we believe using a slightly higher MID would have led to every or almost every outcome being considered not clinically important.</p> <p>In the overall summary in Evidence Review G for cognitive behavioural therapy the committee found that “most of the clinical evidence showed no clinical difference” (p323 line 28) and that where they did find “evidence of benefit [this] was not consistent” (p325 line 42).</p> <p>The committee discussed that there was a “lack of clarity over the intervention components” (p325 line 48) and that “harms [...] were rarely included as an outcome and reported” (p326 line 6).</p> <p>Overall they concluded that various factors meant it was “difficult to make confident conclusions about the evidence.” (p326 line 5)</p> <p>The committee goes on to note that CBT “is one type of supportive psychological therapy which aims to improve wellbeing and quality of life” (p326 line 11 - emphasis added). Yet in the next sentence note that “benefits to quality of life and psychological status were not demonstrated in the clinical effectiveness evidence.” (p326 line 14)</p>
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			<p>Despite this lack of evidence, “[t]he committee agreed that CBT has a role in helping to manage the psychological effects of a chronic illness such as ME/CFS and can be particularly helpful for improving ‘secondary disability’ such as sleep, depression, and dietary issues” (p326 line 20) - yet we then see that no outcomes on dietary issues were assessed, and “[m]ost of the evidence showed no clinical difference compared to usual care or waiting list for [...] psychological status [...] and sleep quality.” (p323 line 28)</p> <p>The aspects of CBT that were apparently more helpful included:</p> <ul style="list-style-type: none">• “[t]hemes of validation, relationship with the therapist, individualised care, self-management support and ongoing support” (p342 line 41)• providing support for people (p325 line 3)• “The simple act of talking to someone was of benefit” (p325 line 5)• “people were comforted by the knowledge that the therapist was available if they needed help” (p325 line 6)• With the last two findings being “closely related to the theme of the relationship with the therapist and likely to be dependent on the establishment of a good therapeutic relationship” (p325 line 8)• “Benefits of tailored care to people with ME/CFS” (p327 line 16) <p>Each of these aspects are “common across other interventions” (p324 line 42).</p> <p>In discussing other psychological/behavioural interventions the committee found three findings in which they had moderate confidence: “There was moderate confidence in the finding that learning about the diagnosis, symptoms, possible causes and prognosis increased understanding and confidence in adults who had experienced education/information interventions. There was moderate confidence in the finding that an evidence-based source of information was welcomed due to issues with identifying reliable information on the internet and some felt more able to assess information about the illness and treatments more critically. There was moderate confidence in the finding that some people realised that they had to focus on acceptance and coping with the illness rather than curing it.” (p330 line 8)</p> <p>These aspects are common to generalised support that we strongly believe every person with ME/CFS should have access to.</p>
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Looking beyond ME to other chronic or long-term illnesses, where there is also a need to support some patients in dealing with the impact of their symptoms and living with their illness, there is at least some evidence that psychological interventions other than CBT can produce positive outcomes for patients. There is also support within that evidence for tailored psychological interventions, which may utilise different formats, durations and facilitators, recommended based on the person's illness and symptoms.

For example, a randomised control trial (RTC) published in 'The Oncologist' looked at the one-year effect of a nurse-led psychosocial intervention on depressive symptoms in patients with head and neck cancer¹, and found that levels of depressive symptoms were significantly lower in the intervention group. The authors note that "several meta-analyses and reviews have shown that psychosocial interventions are effective in diminishing depressive symptoms in the general cancer population... [but that] There is no evidence that one intervention is superior to another."

Similarly, a rapid systematic review of RTCs published in BMC Psychology looked at the effectiveness of psychological interventions to improve quality of life in people with various long-term conditions,² reviewing studies encompassing a variety of psychological interventions, and found promising results for utilising psychological interventions to improve quality of life for patients with long-term conditions. The authors noted the importance of "actively involving patients in their care and tailoring [...] interventions to patients' needs".

Other studies have been conducted into the utility of different psychological interventions in various long-term conditions, including: a randomised clinical trial finding positive results from caregiver-assisted coping skills training in lung cancer patients³; a systematic review of psychological interventions for adolescents and young adults living with chronic illness⁴; and a Cochrane Review of psychological interventions for coronary heart disease⁵.

We strongly support people with ME receiving the support they want and require to adapt to this devastating illness, including the psychological support that has ironically long been denied them through "inappropriately delivered" CBT (p326 line 27).

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			<p>By elevating CBT as the only therapy recommended this perpetuates the idea that people with ME necessarily need to manage their thinking and behaviour in order to manage their symptoms, in contradiction with the evidence laid out above.</p> <p>Based upon the evidence presented by the committee and additional evidence of psychological support and therapies in other physical illnesses, we can only conclude that this section should be rewritten</p> <p>A more general recommendation should be made to consider and discuss with the patient whether psychological support might be helpful - CBT could be included as one of many therapies. This section on psychological support could then lay out factors that would apply to any psychological support delivered to people with ME. It should recommend that all psychological support be given by a professional with training in accordance with this Guideline, and experience of ME. General pointers relating to what the therapy should and shouldn't include would then address all the types of therapy people with ME might seek out and receive, meaning that even private therapists would have a resource to turn to.</p> <p>This could retain the excellent recommendations this committee has made, such as:</p> <ul style="list-style-type: none">● Psychological therapy “should be only delivered by a healthcare professional with appropriate training and experience in-[...] ME/CFS, and under the clinical supervision of someone with expertise in [...] ME/CFS.” (Guideline p34 line 6)● Psychological support “is not curative” (Guideline p34 line 12)● “takes a non-judgemental, supportive approach to the person’s experience of symptoms and the challenges these present” (Guideline p34 line 19)● “developing a shared understanding with the person about the main difficulties and challenges they face” (Guideline p35 line 1)● Regular review (Guideline p35 line 9)● “Involve parents or carers in the therapy wherever possible” (Guideline p35 line 19)● “adapt therapy to the child or young person’s cognitive and emotional stage of development” (Guideline p35 line 20) <p>This approach could provide people with ME who want psychological support with the guidance they deserve, without “pigeonholing” them into an approach that can never be one-size-fits all.</p>
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				<ol style="list-style-type: none"> 1. van der Meulen IC, May AM, Ros WJ, Oosterom M, Hordijk GJ, Koole R, de Leeuw JR. One-year effect of a nurse-led psychosocial intervention on depressive symptoms in patients with head and neck cancer: a randomized controlled trial. <i>Oncologist</i>. 2013;18(3):336-44. doi: 10.1634/theoncologist.2012-0299. Epub 2013 Feb 21. PMID: 23429740; PMCID: PMC3607532. 2. Anderson N, Ozakinci G. Effectiveness of psychological interventions to improve quality of life in people with long-term conditions: rapid systematic review of randomised controlled trials. <i>BMC Psychol</i>. 2018;6(1):11. Published 2018 Mar 27. doi:10.1186/s40359-018-0225-4 3. Porter LS, Keefe FJ, Garst J, et al. Caregiver-assisted coping skills training for lung cancer: results of a randomized clinical trial. <i>J Pain Symptom Manage</i>. 2011;41(1):1-13. doi:10.1016/j.jpainsymman.2010.04.014 4. Sansom-Daly, U. M., Peate, M., Wakefield, C. E., Bryant, R. A., & Cohn, R. J. (2012). A systematic review of psychological interventions for adolescents and young adults living with chronic illness. <i>Health Psychology</i>, 31(3), 380–393. https://doi.org/10.1037/a0025977 5. Richards SH, Anderson L, Jenkinson CE, Whalley B, Rees K, Davies P, Bennett P, Liu Z, West R, Thompson DR, Taylor RS. Psychological interventions for coronary heart disease. <i>Cochrane Database of Systematic Reviews</i> 2017, Issue 4. Art. No.: CD002902. DOI: 10.1002/14651858.CD002902.pub4. Accessed 12 December 2020.
190	Guideline	34	2	<p>As we understand it, NICE has two levels of recommendation - “offering” and “considering”.</p> <p>Based on the fact that 88.8% of outcomes of CBT assessed received a quality grade of very low, and the remaining 11.2% received a grade of low, there can be no justification for the committee recommending this at the “offer” level, even within the given qualifiers. If this recommendation remains it must be downgraded to the “consider” level.</p> <p>Furthermore the evidence does not support the recommendation of CBT for “people with ME/CFS who would like to use it to support them in managing their symptoms.”</p> <p>Evidence review G p323 line 28 clearly states: “Most of the evidence showed no clinical difference compared to usual care or waiting list for quality of life, cognitive function, physical function, psychological status, pain and sleep quality.”</p> <p>The only evidence of benefit in symptom presentation was highly inconsistent, with some studies showing a benefit and others no clinical difference, and based upon “general symptom scales”. Furthermore “evidence was not stratified by diagnostic criteria used, so theoretically, studies including</p>

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				<p>potentially different populations could have been combined.” - this is of particular concern in a disease defined by its symptoms, and once again undermines the effectiveness of CBT when there is no clinical difference for the actual symptoms of ME that were individually assessed: cognitive difficulties, unrefreshing sleep, and pain.</p> <p>Finally, in grading the quality of evidence every single CBT outcome was rated as having serious or very serious population indirectness, as PEM was not a mandatory symptom for inclusion (Evidence Review H). The importance of this cannot be understated when considering evidence of symptom benefit, and most of the studies can, therefore, be discounted.</p> <p>The focus on symptom management in this recommendation is consequently in contradiction of the evidence.</p> <p>Even a focus on psychological distress is non-evidence based here.</p> <p>We cannot conclude anything other than that CBT should not be recommended as clinically and cost effective in this Guideline.</p> <p>However if the committee do decide to retain CBT we must urge them to change this recommendation to: “Only consider cognitive behavioural therapy (CBT) for people with ME/CFS who would like to use it to support them in managing their symptoms of ME/CFS and to reduce the psychological distress associated with having a chronic illness. Do not offer CBT as a treatment or cure for ME/CFS.”</p>
191		34	6	<p>As noted in the Evidence Review G there was a “lack of clarity over the intervention components” (p325 line 48) and a “potential for harm when inappropriately delivered” (p326 line 27).</p> <p>Considering this potential for harm, the low and very low quality of evidence, and the commonality of the positive aspects of CBT with other psychological therapies, we conclude that experience in CBT for ME/CFS is not the issue here, but access to generalised psychological support is. We therefore, again recommend that the committee recommends access to psychological support tailored to the person with ME, without making a recommendation of CBT over other modalities.</p>

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				<p>If the committee decides to retain the recommendation for CBT, it must make absolutely clear that training must be in accordance with this Guideline, to safeguard against further harm from inappropriate delivery. See edit in bold below:</p> <p>“CBT should be only delivered by a healthcare professional with appropriate training in accordance with this Guideline and experience in CBT for ME/CFS, and under the clinical supervision of someone with expertise in CBT for ME/CFS.”</p>
192	Guideline	34	11	<p>Evidence Review G p325 line 22 states: “Regarding the effect of CBT on symptom improvement, the response in adults was mixed, with some reporting a gradual improvement which did not reach a pre-morbid level of functioning, some reporting no change and some reporting a worsening of symptoms.” However a recommendation that simply advises to “discuss... the potential benefits and risks” falls far short of this detailed information which is needed to enable people with ME to make informed decisions and consent to this therapy.</p> <p>As with physical activity, there must be a clear acknowledgement of each of these outcomes. Recommendation 1.11.19 states: “Tell people about the risks and benefits of a physical activity programme. Explain that some people with ME/CFS have found that physical activity programmes can make their symptoms worsen, for some people it makes no difference and others find them helpful.”</p> <p>We strongly urge the committee to include an equivalent statement on CBT - e.g. “Tell people about the risks and benefits of cognitive behavioural therapy. Explain that some people with ME/CFS have found that cognitive behavioural therapy can make their symptoms worsen, for some people it makes no difference and others find it helpful.”</p> <p>Any recommendation of CBT should come with the caveat that it may be counterproductive and harmful for some sufferers, particularly those in the severe or very severe category but also those in the moderate and mild categories. The exertion required to talk, think and attend sessions, even online sessions, may lead to a worsening of symptoms.</p>

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193	Guideline	34	12	This is an important inclusion that we agree must be mentioned when discussing whether the person with ME/CFS should consider CBT.
194		34	13	Evidence Review G (p326 line 14) states: “benefits to quality of life and psychological status were not demonstrated in the clinical effectiveness evidence.” There is a serious problem when a therapy is “designed to improve wellbeing and quality of life” as this bullet point states, yet there is no clinical effectiveness evidence to suggest this outcome actually occurs. Remove this bullet point.
195	Guideline	34	14	The phrase ‘aims to improve functioning’ is not evidence based in the context of ME/CFS. Evidence Review G (p323 line 28) states: “Most of the evidence showed no clinical difference compared to usual care or waiting list for... physical function”. In keeping this “aim” the committee sets people with ME/CFS up to fail. We urge them in the strongest way possible to remove the first limb of this bullet point, leaving: “aims to reduce the psychological distress associated with having a chronic illness.”
196	Guideline	34	16	We strongly urge the committee to reword this bullet point to “recognises that ‘abnormal’ illness beliefs and behaviours are not an underlying cause of ME/CFS” The second limb of this bullet point directly undermines the first. There is an implication that thoughts, feelings and behaviours could be a perpetuating or causal factor in ME, which is not proven. Furthermore, due to the paucity of evidence of clinical benefit from CBT, for which the central tenet is behavioural change, this could actually be considered disproven. We strongly request you remove this part, the next bullet point covers what is said here far more appropriately.
197	Guideline	34	19	We agree with this bullet point, and are pleased to see it’s inclusion.

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198		34	23	<p>Under positive experiences of CBT identified in the qualitative evidence it is found that: “people were comforted by the knowledge that the therapist was available if they needed help as a form of safeguard.” (Evidence Review G p325 line 6)</p> <p>By defining CBT as a time-limited intervention this removes one of the few positive experiences identified. Again, it appears that generalised psychological support is more appropriate than this intervention, as it more broadly covers the wants and needs of people with ME and can provide an ongoing relationship with a therapist.</p>
199		34	25-27	<p>The phrase "to work towards meaningful goals" is very problematic. It implies that ME sufferers can control improvement over time, when this is not supported by the evidence presented. We would suggest, after 'help the person to', substituting with '..adapt to living with long-term illness'.</p>
200		34	28	<p>We agree with this bullet point.</p>
201		35	1	<p>We agree with this bullet point.</p>
202		35	3	<p>We cannot find an evidence base to support this bullet point. The phrase “exploring their personal meaning of symptoms and illness” is unclear. None of the positive aspects of CBT identified appear to relate to “personal meaning of symptoms”. Furthermore we are concerned that inclusion of this could lead to therapists imposing their own stigmatised views and meanings onto the person with ME - as Evidence Review G (p325 lines 33-38) notes that experiences of CBT included perceptions of CBT as ‘controlling, patronising and a form of brainwashing’.</p> <p>Remove this bullet point.</p>
203	Guideline	35	8	<p>This bullet point creates significant confusion, as this Guideline has already advised a management plan be devised in collaboration with a specialist team.</p> <p>We therefore recommend changing this bullet point to: “working together to adjust and refine strategies to adapt to living with a long-term illness”</p>
204	Guideline	35	9	<p>In recommendation 1.11.46 this Guideline states that CBT is a “time-limited intervention”.</p>

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				<p>However, this recommendation states that CBT should include “reviewing their plan regularly to see if their self-management strategies need to be adapted, for example if their symptoms or functioning change”</p> <p>In Evidence Review G one of the themes relating to a positive experience of CBT was ongoing support - “people were comforted by the knowledge that the therapist was available if they needed help.” (p325 line 6)</p> <p>This factor is important, and is common across other modalities of psychological support. It should not be explicitly excluded by the use of a time-limited therapy simply because more research has been done on CBT, not because it is shown to be more effective. Again, focusing only on CBT in this section would mean the omission of this important point for professionals considering support for people with ME.</p> <p>As the term “management plan” has already been used under recommendation 1.5.2 and is separately defined in this Guideline, we strongly urge the committee to focus in this section instead on the development of strategies. It is the case that a plan is generally fixed until the situation changes whereas good strategies for adapting to symptoms will always be good strategies. Reviewing and changing a plan only after symptoms or functioning have changed could cause additional harm if the person’s energy envelope has reduced.</p> <p>Change this sentence to: “reviewing their strategies regularly to see if they need to be adapted, and ensure the strategies are appropriate if they experience a change in symptoms or functioning”</p>
205	Guideline	35	12	<p>“Therapy blueprint” appears to be an obscure term that most non-experts will not understand. As this Guideline is intended for people with ME, general health professionals and the public, we see its use as unhelpful.</p> <p>We therefore request the use of plain English here instead.</p>

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206	Guideline	35	15	<p>We note again that there is not a clear statement on the risks here, meaning that health professionals without in-depth knowledge will not be able to give their patients the information they need in order to give informed consent.</p> <p>We were particularly alarmed to find in Evidence Review G that “[t]asks were often initially very hard to achieve, and parents found it challenging to watch their children push themselves.” (p325 line 20) This directly contravenes the advice on energy management this committee has agreed is key.</p> <p>A statement similar to that made for physical activity should be included here too; e.g. “Explain that some people with ME/CFS have found that cognitive behavioural therapy can make their symptoms worsen, for some people it makes no difference and others find it helpful.”</p>
207	Guideline	35	19	<p>We strongly agree that parents and carers should be involved wherever possible, and urge the committee to retain this sentence.</p>
208	Guideline	35	22	<p>Given that the severity of the cohorts assessed was usually unclear, the evidence base for the use of CBT in severe or very severe ME is in even muddier waters. Many of the studies required attendance at a clinic, which excludes most people with severe or very severe ME from inclusion. Moreover, the effort and energy involved in getting out of the house and to a clinic increases the risk of an adverse response to the intervention.</p> <p>We therefore request that a caveat be inserted here that acknowledges CBT can be unsuitable and harmful for people with severe and very severe ME.</p> <p>Evidence Review C (p73 line 36) shows that hypersensitivity to noise can make CBT impossible for many severe sufferers: “The committee discussed the importance of energy management for people with ME/CFS and the prioritisation of daily activities. They commented that this is heightened in people with severe and very severe ME/CFS where even the smallest action or interaction may result in worsening of symptoms. People with severe or very severe ME/CFS report they can be hypersensitive to noise and even people whispering can be very painful.”</p>

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				<p>Add a recommendation such as: “Be aware that if cognitive behavioural therapy is outside the person with ME’s energy envelope it is contraindicated.”</p>
209	Guideline	35	25-26	<p>Again, we strongly advise against the use of the term ‘goals’.</p> <p>Evidence Review G (p336 line 26) states: “The committee noted that where goals are rigid and unrealistic this can result in false starts, flares and relapses. The committee commented on the findings in the qualitative evidence that people had felt pressured and blamed when they could not complete the programme even though it was making their symptoms worse. The committee acknowledged the controversy around the setting of fixed unrealistic goals and the importance of understanding realistic goal setting by both the person with ME/CFS and the healthcare professional supporting any programme.”</p> <p>Whilst this was in relation to physical activity, the term remains problematic across the board. We are particularly surprised that the committee have not even included the term ‘realistic goals’ here.</p> <p>This sentence would be more appropriate if it removed mention of goals leaving: “Healthcare professionals delivering CBT to a person with severe or very severe ME/CFS should adjust the process and pace of CBT to meet the person’s needs. This might include shorter and less frequent sessions.”</p>
210	Guideline	35	General	<p>We remain concerned that unless there is a significant effort to retrain existing healthcare professionals delivering services, the recommendations here will make little difference to the service provided.</p> <p>We acknowledge that energy management in people with ME could theoretically be supported via CBT but it is unlikely that people previously trained to use CBT to treat ME would simply switch to this approach, and considering the “lack of clarity over the intervention components” this acknowledgement remains entirely theoretical.</p>

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				We request that when considering these recommendations prior to publication of the final Guideline, the committee takes account of the level of shift required to achieve high quality care and support for people with ME.
211	Evidence Review H	98	General	The formatting has gone wrong here - we can't read part of the effectiveness evidence on the PDF version.
212	Evidence Review G	326	20	<p>“The committee agreed that CBT has a role in helping to manage the psychological effects of a chronic illness such as ME/CFS and can be particularly helpful for improving ‘secondary disability’ such as sleep, depression, and dietary issues”</p> <p>We question why sleep has been included here under ‘secondary disability’ when unrefreshing sleep is a core symptom of ME. We recommend you remove sleep from this list.</p>
213	Guideline	36	7	<p>We welcome the signposting to guidance on multimorbidity, thyroid disease and coeliac disease.</p> <p>However, in the feedback we have received as we have written this response, people with ME have requested the addition of further conditions here. A study of comorbidity in ME/CFS concluded that “[o]ver 80% of a large population-based cohort of Spanish patients with ME/CFS presented comorbidities” and that “a thorough assessment of comorbidities is mandatory in view of their specific involvement in the deterioration of the quality of life of these patients.”¹ Another study found that 97% of ME/CFS subjects had been diagnosed with at least one of 43 listed medical conditions.²</p> <p>This must be emphasised in order to ensure that symptoms are not wrongly assumed to relate to ME.</p> <p>As Evidence Review C states, “Patients often felt they needed to take a proactive role in their care by doing their own research to persuade health- professionals to meet their needs, by asking for diagnostic tests, seeking treatment elsewhere, turning to private or alternative health services, and in some cases withdrawing from services and managing symptoms themselves.”</p> <p>This is reflected in Evidence Review D (p65 line 37): “The committee agreed the importance of performing relevant tests for differential diagnoses, both pre- and post-diagnosis of ME/CFS. It was</p>

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				<p>considered that new symptoms can develop after a diagnosis and that these should still be fully investigated rather than immediately attributed to ME/CFS. During investigation of new symptoms, both differential and comorbid diagnoses should be considered where appropriate.” (Our emphasis.)</p> <p>Overall, the input we’ve received suggests that GPs rarely have the time or experience to thoroughly investigate and manage coexisting conditions, and that without a more extensive list of these, accurate identification of differential and coexisting conditions will remain limited.</p> <p>Serious consideration should be given to diagnosing and treating common comorbid conditions, such as those laid out in the International Consensus Criteria³ or Canadian Consensus Criteria⁴.</p> <ol style="list-style-type: none"> 1. Castro-Marrero, J., Faro, M., Aliste, L., Sáez-Francàs, N., Calvo, N., Martínez-Martínez, A., ... & Alegre, J. (2017). Comorbidity in chronic fatigue syndrome/myalgic encephalomyelitis: a nationwide population-based cohort study. <i>Psychosomatics</i>, 58(5), 533-543. 2. Chu, L., Valencia, I. J., Garvert, D. W., & Montoya, J. G. (2019). Onset patterns and course of myalgic encephalomyelitis/chronic fatigue syndrome. <i>Frontiers in pediatrics</i>, 7, 12. 3. Carruthers, B. M., van de Sande, M. I., De Meirleir, K. L., Klimas, N. G., Broderick, G., Mitchell, T., ... & Bateman, L. (2011). Myalgic encephalomyelitis: international consensus criteria. <i>Journal of internal medicine</i>, 270(4), 327-338. 4. Carruthers, B. M., Jain, A. K., De Meirleir, K. L., Peterson, D. L., Klimas, N. G., Lerner, A. M., ... & Sherkey, J. A. (2003). Myalgic encephalomyelitis/chronic fatigue syndrome: clinical working case definition, diagnostic and treatment protocols. <i>Journal of chronic fatigue syndrome</i>, 11(1), 7-115.
214	Guideline	36	2	<p>While we agree with what is included here, consideration must also be given to energy management, especially where existing treatment modalities are contraindicated in ME - such as taking regular physical exercise for depression.</p> <p>We ask that you add the part in bold to this recommendation: “Take into account the recommendations in the section on principles of care for people with ME/CFS, the section on access to care and the section on energy management when managing coexisting conditions in people with ME/CFS.”</p>
215	Guideline	36	12	<p>To make it clear that depression, anxiety or other mood disorders are responses to living with a debilitating disease we recommend changing the word “associated” to “reactive” here.</p>

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216	Guideline	36	14	<p>As this ME Guideline is literally about a chronic physical illness, the inclusion here of the Guideline on depression for those without a chronic physical health problem is superfluous.</p> <p>Furthermore, inclusion of this Guideline is problematic because standard questionnaires used for assessment of depression currently include questions relating to having little energy, trouble concentrating and trouble sleeping and can give rise to a mistaken diagnosis of depression in people with ME.</p> <p>We request you remove this bullet point.</p> <p>NICE must recommend that while it is possible for people with ME to be depressed, doctors must take note of whether reported symptoms associated with depression are in fact symptoms of ME itself. Comparison of SF-36 physical function, social role function, and emotional role function to more simplistic depression questionnaires may be salutary.</p>
217	Guideline	37	3	<p>During discussion online and during the community calls #MEAction UK ran to discuss this draft Guideline, some felt the term “flare” was acceptable while others did not.</p> <p>There was a general feeling that “crash” was the terminology most used by people with ME, and this should at least be mentioned alongside the term “flare”. This is especially true as people also use this term when speaking with healthcare professionals, and they therefore need to be aware of this.</p> <p>Some questioned why an additional term of flare was being used as well as PESE, and felt it would be simpler to replace flare with PESE throughout.</p> <p>We also note that in the input we have received, multiple people have said their experience of PEM/PESE or flares is longer than a few days.</p> <p>In the definition of this term, we note the committee states “it may not be clear in the early stages of a symptom exacerbation whether it is a flare or a relapse.” (Guideline p44 line 26)</p>

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				<p>If this recommendation around flares is retained, it must therefore include an additional sentence stating: “Be aware that it may not be clear in the early stages of symptom exacerbation whether it is a flare or relapse.” This will ensure the potential long term impacts of relapse are considered at the earliest possible time point.</p>
218	Guideline	37	12	<p>We suggest the use of the term ‘resuming’ in place of ‘increasing’.</p>
219	Guideline	38	1	<p>We are concerned here that this recommendation comes too late for many people. Once in a relapse, accessing services and support will be significantly harder for the person with ME.</p> <p>Having strategies in advance of a relapse is key here. We recommend adding an additional recommendation stating: “Give all people with ME information on strategies to use in a relapse, and discuss how they may utilise these, such as:</p> <ul style="list-style-type: none"> ● reducing, or stopping, some activities ● increasing the frequency or duration of rest periods ● re-establishing a reduced energy envelope to stabilise symptoms” <p>During a relapse, offer to discuss these strategies.”</p>
220	Guideline	38	5	<p>The Guideline recommends “re-establishing a new energy envelope to stabilise symptoms.”</p> <p>The use of the term “energy envelope” here is incorrect - as per the definition on page 42, the energy envelope is “the amount of energy a person has to do all activities without triggering an increase in their symptoms.”</p> <p>This is not something that can be established by the person with ME; instead we suggest using language from the section on energy management that discusses activity patterns. It is also important to emphasise here that the energy envelope will have reduced, and a concurrent reduction in activity is required to guard against further relapses.</p>

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				This should state: “re-establishing a reduced activity pattern to stabilise symptoms.”
221	Guideline	38	12	<p>This section deals with treatment after a relapse but seems to assume that it is safe for people taking part in a physical activity programme to resume, even at a lower level. This is dangerous advice for someone with ME. The aim of any programme should be to stabilise and to reduce relapses that often cause a decline in function. If a physical activity programme causes relapses or flares then it has no place in a Guideline on ME.</p> <p>There remains an underlying assumption in this Guideline that ‘increases’ or ‘goals’ have a part in the management of ME. However, the core principle of care and management should be ‘stabilisation’. This will reduce or avoid worsening of symptoms.</p>
222	Guideline	39	1	Have the committee given consideration to recommending GP practices keep a register of people diagnosed with ME, and especially those with severe or very severe ME, in order to aid review and care of this population in line with the other recommendations made here?
223	Guideline	39	2	We strongly agree with the recommendation of a yearly review and would like to see home visits or online appointments offered to moderate as well as severe patients as the effort involved in attending appointments can cause PEM/PESE and lead to a relapse.
224	Guideline	39	15	It is important to include here that new symptoms should always be investigated as a possible comorbidity and not just assumed to be part of ME. Symptom labels for ME can be broad and may overlap with other energy limiting chronic conditions.
225	Guideline	39	23	It should be specified that advice should be sought from an appropriate ‘clinical’ specialist.
226	Guideline	39	27	We welcome the recommendation in 1.14.6 that children should receive six monthly reviews and would like to see home visits or online appointments offered to moderate, as well as severe, patients, because the effort involved in attending appointments can cause PEM/PESE and lead to a relapse - as outlined in Evidence Review G p256 line 16: “There were reports that travel to the hospital site for appointments contributed to setbacks, which worsened fatigue in some young people.”

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227	Guideline	40	11 - general	<p>We strongly agree with the inclusion of a section on training in this guideline, and commend the committee for taking this step.</p> <p>As both the evidence reviews and expert testimony identify, training for healthcare professionals on ME is often superficial or non-existent.</p> <p>During #MEAction UK's community call to discuss this Guideline, training of healthcare professionals was identified as one of the key aspects of this Guideline that could lead to improved care for people with ME - but only if this training is compulsory, includes retraining for professionals who are already working in this area and is adopted wholesale rather than piecemeal. Participants agreed that each GP practice should have at least one member with more extensive training on ME, as well as all specialist team members undertaking such training.</p> <p>Any change in approach to managing ME hinges on both the content of new training and the ability of those undertaking it to accept and alter their views accordingly. Healthcare professionals need to recognise and agree that "ME/CFS is a serious, chronic, complex systemic disease that often can profoundly affect the lives of patients and [...] is not, as many clinicians believe, a psychological problem."¹ This is confirmed by Evidence Review C p68 line C which shows that there is a lack of medical legitimacy with limited health professional knowledge and understanding of ME/CFS underpinned by insufficient medical training. Evidence Review A p42 line 8 states explicitly "disbelief of the legitimacy of the condition" is a consistent theme in all of the qualitative reviews conducted for this Guideline. In her expert testimony, Dr Nina Muirhead states "The incongruity between current education of professionals and the experience of patients compromises the relationship between patients and health and social care professionals. Or worse has the potential to cause harm" (Appendix 3 p18).</p> <p>Current training modules need to be withdrawn immediately and replaced by new ones that are in accordance with this Guideline. Evidence Review B p51 line 23 notes that Dr Muirhead's testimony supports the weaknesses in the current training of medical staff. "Her experience has been that the information, education and support provided by medical bodies is mostly outdated, misleading and not</p>
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¹ Ganiats, T. G. (2015). Redefining the chronic fatigue syndrome. <https://www.acpjournals.org/doi/10.7326/m15-0647>

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				<p>in line with patient experience. In particular, she expressed concerns that ME/CFS training and education is not mandatory, is often merged with other medically unexplained symptoms and is based on theories of deconditioning and fear avoidance of exercise.” Such a wholesale change needs action at a high level within the NHS, CCGs and health boards.</p> <p>It is essential that NICE urgently communicates the new recommendations on training to all current specialist clinics, all medical colleges and professional organisations of all health and social care professionals, to prevent further harm.</p> <p>This needs to be expedited as soon as possible alongside the production of the new Guideline.</p> <p>Overall we believe this section should be strengthened and expanded to emphasise the need for training/retraining of all staff, stress that the training should be based on these Guidelines and recommend that previous training should be withdrawn immediately as it has the potential to cause harm to patients.</p>
228	Guideline	40	12-13	<p>The phrase “access to training” suggests that training is optional, and we suggest it should be replaced by “mandatory” or “compulsory”. We strongly agree that training should reflect current knowledge: for this Guideline to effect change for people with ME the development of completely new training is essential.</p> <p>We suggest that the recommendation is reworded to state “Health and care providers should provide compulsory training that reflects current knowledge in ME/CFS (including understanding what ME/CFS is, diagnosis and management) for all health and social care staff who deliver care to people with ME/CFS”.</p> <p>We suggest a sentence is added to this recommendation stating that health providers should immediately withdraw current training based on the old Guideline in order to avoid harm to patients (Appendix 3 p18).</p>

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229	Guideline	40	17	<p>We agree that training programmes must provide evidence-based content and training methods.</p> <p>It is great that NICE has embraced the fundamental importance of patient involvement in the understanding of this disease and development of new training programmes, however we urge the committee to include specific mention of input from ME organisations as well as from individual people with ME.</p> <p>Change this to: “provide evidence-based content and training methods (developed and supported by specialist services with input from people with ME and patient organisations)”</p>
230	Guideline	40	18	<p>We welcome the recommendation that training should be developed with input from people with ME, however we urge that this recommendation includes the involvement of ME organisations and charities.</p> <p>It is imperative that any new training programme is co-produced by professionals who have already adapted their approach to ME, based on a biomedical understanding, and ME organisations, such as the CMRC Medical Education group. Without this involvement there is a high risk of inadequate and misleading information being produced once more. This would not only be a waste of money and resources but fail to improve the care of people with ME/CFS.</p>
231	Guideline	40	19	<p>As noted in the Context section p72 line 7 of these Guidelines, there remains a "lack of belief and acknowledgement from health and social care professionals" both within many "specialist" clinics and more widely.</p> <p>Considering the major changes in practice and understanding this Guideline sets out, we believe patient organisations are best placed to lead on new training and should again be noted here.</p> <p>We recommend changing this to: “are run by trainers with relevant skills, knowledge and experience, and led by or involving patients and patient organisations”</p>
232		40	20	<p>We agree with this recommendation.</p>

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233		40	22	<p>We agree with this recommendation, but feel that where possible, training should also involve speaking with people with ME in person.</p> <p>We request this is changed to: “represent the experiences of people with ME/CFS, either in person or using video and other resources.”</p>
234	Guideline	41	1	<p>We recommend that the word 'All' be added here so it reads ‘All health and social care professionals’. This reflects Evidence review B page 51 line 47 which states that the committee made a recommendation suggesting access to training should be provided for all staff that have contact with or deliver care for people with ME.</p> <p>We welcome the recommendation that health and social care professionals undertake training. It is vital that this training is based on the new Guideline and that patient organisations are involved in preparing training materials.</p>
235	Guideline	41	1	<p>The reference to training of health and social care professionals who provide care for people with ME needs to be expanded to address the specific need for the training of professionals heading up paediatric services.</p> <p>We urge that NICE recommends that training programmes clearly illustrate the debilitating effects this disease has on children and young people. Anyone involved with the care of this vulnerable group must understand and accept the diverse symptoms of this disease and the limitations it imposes on daily life. They need to realise that a snapshot view, either in a clinic or online, does not reflect the daily reality and limitations of ME. They need to listen and believe young people and their parents.</p>
236	Guideline	41	9	<p>We agree with this definition of activity, and consider it important to retain in the final Guideline.</p>
237	Guideline	41	12	<p>We agree with this definition of advocate.</p>

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238	Guideline	41	18	<p>We find this definition to be very problematic. By defining carers as “unpaid” this explicitly excludes carers or PAs who may be provided by social services, and makes an incorrect assumption that all people with ME/CFS will have family, partners or friends who are able to take on this role.</p> <p>Many people with ME will need adult social care to enable them to live independently, and these people should not be excluded from the recommendations around carers being allowed to join the person with ME during appointments etc.</p> <p>This is especially important for people with significantly reduced cognitive capacity, where excluding paid carers from information and support needs, access to appointments, etc., could lead to serious adverse impacts on care.</p> <p>We very strongly urge the committee to change this definition to: “In this Guideline, a carer refers to someone who provides care and support to a family member, partner, friend or client with ME.”</p>
239	Guideline	42	1	We agree with this definition.
240	Guideline	42	4	We agree with this definition.
241	Guideline	42	7	We agree with this definition.
242	Guideline	42	10	We agree with this definition.
243	Guideline	42	14	We agree with this definition.
244	Guideline	42	25	<p>During discussion online and during the community calls to discuss this Guideline, some felt the term “flare” was acceptable while others did not.</p> <p>There was a general feeling that “crash” was the terminology most used by people with ME, and we suggest that this should at least be mentioned in this definition.</p>

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				<p>Some questioned why an additional term of flare was being used as well as PESE, and felt it would be simpler to replace flare with PESE throughout.</p> <p>We cannot find evidence that supports the involvement of a timescale in this definition. In the input we have received, multiple people have said their experience of PESE or flares is longer than 1-3 days. We recommend removing this timescale.</p> <p>It would be helpful to cross reference to the term “relapse” here, stating: “It may not be clear in the early stages of a symptom exacerbation whether it is a flare or a relapse; a relapse is defined below.”</p>
245	Guideline	43	3	<p>In feedback that we have received as we write this submission, some felt that “management plan” overstated what is possible, and that “support plan” (as used in the NICE MS Guideline) would be more appropriate.</p> <p>In case the committee considers changing this term to “care plan”: this does not appear appropriate as this terminology is already in use by social services.</p>
246	Guideline	43	4	<p>This definition of a management plan appears quite different from that laid out in recommendation 1.5.2 We strongly urge the committee to change this to:</p> <p>“The personalised management plan is developed by the specialist team after the confirmation of a diagnosis of ME/CFS and a holistic assessment. Based on the person’s needs, it includes: information and support needs; support for activities of daily living; aids and adaptations; education, training or employment needs; self-management strategies; physical maintenance; symptom management; guidance on flares and relapses; and contact details for a named health and social care professional. It is the basis for all other assessments and plans.”</p>
247	Guideline	43	9	<p>There has long been debate about the terminology used to differentiate between different severity levels of ME.</p>

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				<p>Many feel that the term “mild”, when considered against other chronic illnesses such as asthma, underplays the severity of ME.</p> <p>Some felt a change of term would be appropriate here, however there was no clear consensus on what that should be.</p> <p>Suggestions ranged from changing to a grade/level 1-4 type terminology, or to scrapping mild and renaming this moderate, renaming moderate to severe, severe to very severe, and very severe to extremely severe.</p> <p>Others, including some who are would fit into this definition, felt okay with the term mild.</p> <p>#MEAAction UK therefore cannot make a clear recommendation on changing the term from mild to something else or not. However as we cannot find a rationale for why this has been used, we felt it important to raise this point and ask the committee to consider, alongside other feedback, if this is indeed the most appropriate term.</p>
248	Guideline	43	10	<p>We request that the committee adds a note that “Mild ME/CFS has a significant impact on quality of life.”</p>
249	Guideline	43	15	<p>We agree with the first sentence in this definition.</p> <p>We also agree with the statement: “They have usually stopped work, school or college and need rest periods, ...”</p> <p>However we cannot find an evidence base to support the assertion relating that to rest periods: “often resting in the afternoon for 1 or 2 hours.” We feel this is an unhelpfully limiting part of the definition, that doesn’t represent the broad experience of when and how much rest a person may need. We would remove this specific part of the definition.</p>

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				<p>By including the statement on sleep being poor quality and disturbed in the definition of moderate but not mild or severe ME, it implies a difference in symptom presentations. Furthermore this is not accurate for every person with moderate ME - some may sleep fine, but wake unrefreshed. It would be better to focus on functioning in the definitions of mild and moderate ME. We recommend removal of the sentence on sleep.</p> <p>We recommend adding a sentence to state that people with moderate ME usually have difficulty leaving the house and some are mostly housebound.</p>
250	Guideline	43	20	<p>As this definition differs significantly from that used elsewhere, we are curious as to why the committee has focused on inability to regulate blood pressure and cerebral flow.</p> <p>While these can be causal factors in orthostatic intolerance, the definition of orthostatic intolerance itself normally focuses on increased symptoms, or new symptoms, on standing or sitting upright. We therefore feel it would be helpful to add an initial sentence stating this broader definition of the impact of orthostatic intolerance, before what is already defined here.</p> <p>“Orthostatic intolerance is an increase in symptoms or the development of new symptoms on standing, or in some cases sitting, upright. This can be caused by the inability to regulate blood pressure and cerebral blood flow when upright. It may lead to postural tachycardia, hypotension and alterations in consciousness (such as fainting). This may include postural orthostatic tachycardia syndrome (a significant rise in pulse rate when moving from lying to standing) and postural hypotension (a significant fall in blood pressure when moving from lying to standing).”</p>
251	Guideline	43	27	<p>We agree with this definition of physical activity, and particularly the sentence: “For many people, physical activity has a health benefit but in people with ME physical activity may make their symptoms worsen.”</p> <p>We strongly urge the committee to retain this important fact in the final version.</p>

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				It would be helpful to note the extremely low levels of physical activity that can lead to PEM/PESE in some people with ME. We recommend the inclusion of a final sentence that states “For some people with ME physical activities such as brushing their teeth, speaking briefly, or turning over in bed will be their main physical activities of the day.”
252	Guideline	44	6	<p>This is an excellent definition. We are particularly pleased to see the last sentence “Such activity is undertaken within the person’s energy envelope and avoids pushing through boundaries of tolerance.”</p> <p>We have made a separate comment on the physical maintenance section that this explicit statement should also be included there, to ensure those who do not read through the definitions of terms understand this.</p>
253	Guideline	44	18	<p>There are mixed views about introducing the new term PESE into use, and because of this we do not feel we can make a clear recommendation as an organisation.</p> <p>Participants on our community call discussed this section of the draft Guideline, and generally agreed the term post-exertional symptom exacerbation was better than post-exertional malaise, however this was not unanimous.</p> <p>Overall we agree with the committee’s assessment that the word malaise underplays the severity and impact of this symptom in people with ME.</p> <p>Our colleagues in the US expressed concern that adding a new term would create yet another long acronym: PEM/PESE. They noted that they are getting traction with US institutions using the terminology PEM at the moment, and felt a change may lead to greater confusion.</p> <p>To assess general support of this change in terminology we published a poll on our social media platforms which, out of 406 respondents indicated support for the term PEM from 49%, with PESE gaining 44% and other terms 8%.</p>

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254	Guideline	44	19	<p>We agree with the first sentence of this definition, and the note that this is also referred to as post-exertional malaise.</p> <p>During our community calls some attendees raised the point that in their experience PESE/PEM was not always delayed, and preferred the wording “symptoms can worsen 12 - 48 hours...” over “symptoms typically worsen 12 - 48 hours...”</p> <p>Others noted that they experienced some symptoms only during PEM/PESE, and therefore felt that language such as “and development of different symptoms” should be added into this statement.</p>
255	Guideline	44	23	<p>We agree with this definition overall. It is important to note that relapses can lead to long-term reduction in the person’s functioning.</p> <p>We are unsure about the sentence “The person’s symptoms and level of disability may be similar to illness onset.”</p> <p>We cannot find an evidence base to support this, nor do we recognise this in our lived experience. For some, symptoms at onset are severe, however for others symptoms gradually get worse. We recommend removing this sentence.</p>
256	Guideline	45	1	<p>Overall we support this definition, particularly the inclusion of two levels of severity here; severe and very severe.</p> <p>While of course there is so much more that could be said about severe and very severe ME, this gives a simple but clear overview of how debilitating they are.</p>
257	Guideline	45	11	<p>Therapy blueprint is an obscure term that should not be used in this Guideline.</p> <p>Again there is a focus on goals for the future, despite a clear statement that CBT, under which this term is mentioned, is not a treatment or cure for ME. The committee found evidence that goal setting has been harmful for people with ME, yet do not present evidence to show that the language they are proposing to use will mitigate this, nor have they even used the language of “realistic goals” which they</p>

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				<p>specify elsewhere. In the face of evidence of harm, there must be very clear evidence that benefit outweighs the harm of such approaches. We cannot see that the committee has done their due diligence in this respect.</p> <p>It is not clear what “warning signs” mean here, nor why it is in quotation marks. We encourage the committee to remove this term from the whole Guideline.</p>
258	Guideline	45	17	<p>We cannot find any evidence that describes unrefreshing sleep as a light sleep. Nor can we find significant evidence to suggest that ‘light sleep’ truly describes the experience of unrefreshing sleep for most people with ME. In Box 1 in the section on Symptoms for suspecting ME/CFS, it is instead described as ‘feeling exhausted, flu-like and stiff on waking’ and as ‘broken or shallow sleep, altered sleep pattern or hypersomnia’.</p> <p>We therefore suggest the removal of this first sentence and believe it is instead best to stick to the facts in the second two sentences.</p>
259	Guideline	45	21 - general	<p>We welcome the section of Recommendations for research, but are disappointed by how sparse these recommendations are.</p> <p>As this committee has found, biomedical research into ME is fragmented and small-scale because of lack of funding. Although a lot of useful research has been done, there is a need for well-funded, targeted research which in many areas will involve large-scale, carefully designed and controlled trials. Making funding available for these should be a key recommendation. Investment in research would be a sound economic investment. With 250,000 estimated sufferers in the UK, 75% of whom cannot work, effective management or treatment tools would save healthcare costs and boost tax returns.</p> <p>NICE needs to send a clear message that ambitious biomedical research is needed now.</p>

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				<p>In particular, this committee must make a recommendation for research into the causes of ME. While NICE may usually focus on treatment and management of illness, in this case research into treatments has stalled in part because the “pathophysiology is unclear.” (Guideline p4 line 6)</p> <p>It is only with a clearer understanding of the pathophysiology that treatments and eventually a cure will be found.</p> <p>We strongly urge the committee to add a recommendation such as: “What are the causal mechanisms of ME that may lead to effective treatments?”</p>
260	Guideline	45	24	<p>We strongly welcome the two key recommendations for research into diagnostic tests and a core outcome set.</p> <p>The core outcome set in particular is vital to be able to standardise research findings, to ensure objective measures are used as well as any subjective measures, and to ensure findings of minimal clinical difference genuinely reflect what people with ME consider important changes in their health and wellbeing.</p>
261	Guideline	46	4	<p>The other research recommendations for diagnostic criteria and dietary strategies are helpful, but otherwise these recommendations relate to “management” and “non-pharmacological” interventions. There is a lack of research recommendations relating rigorous biological science, looking for causes, mechanisms and treatments, many of which will likely be pharmacological.</p> <p>In particular participants in our consultation process have commented on the need to move towards objective measures and away from subjective measures as the primary outcome of ME studies. One participant said “By the next review we need much better quality research as evidence, not another decade of wasting the limited money available.”</p>
262	Guideline	46	4	Add recommendation:

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				<p>What is the clinical and cost effectiveness of medicines and supplements in the management of symptoms in ME?</p> <p>While the committee found many small trials on pharmacological treatment, quality of evidence was often low, sample sizes small, and outcomes therefore dubious. Further research is needed here urgently, as this could be the first area to create significant improvements in the quality of life of people with ME.</p>
263	Guideline	46	4	<p>Add recommendation: What is the clinical and cost effectiveness of treatments for orthostatic intolerance in ME?</p>
264	Guideline	46	4	<p>Add recommendation: What is the clinical and cost effectiveness of treatments for nausea in ME?</p>
265	Guideline	46	4	<p>Add recommendation: What conditions commonly coexist alongside ME?</p>
266	Guideline	46	4	<p>Evidence Review A p6 line 23 states “No evidence was identified for social care professionals caring for people with ME/CFS.”</p> <p>Add two recommendations:</p> <ul style="list-style-type: none"> • What information and training do social care professionals caring for people with ME require? • How can social care professionals caring for people with ME best meet their needs?
267	Guideline	46	4	<p>The Equality Impact Assessment states that “the groups identified in the equalities impact assessment during scoping were considered through the development of the guideline, however there was no or limited evidence identified for these groups and it was agreed no separate recommendations for these groups were to be made”. (These groups are listed as: Older people; Pregnant women; Black and Minority Ethnic people; and Men, as well as those from low socioeconomic backgrounds and those living in rural settings. Equality Impact Assessment questions 1 & 2.)</p>

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				In light of this concerning lack of evidence, we recommend adding a research recommendation considering access to care and outcomes for people with ME in groups with potential equality issues.
268	Guideline	46	5	<p>Due to the cognitive difficulties and severely limited energy people with ME experience, it would be helpful to add specific mention of automated technologies to this research recommendation.</p> <p>We recommend this is changed to: “What is the clinical and cost effectiveness of self-monitoring techniques, such as automated technologies, apps and wearables, in guiding energy management in ME?”</p>
269	Guideline	47	2	<p>This recommendation is quite concerning, as it seems to suggest a behavioural approach to managing ME, without recognition of the evidence found by this committee that demonstrates behavioural approaches have very poor outcomes. This recommendation doesn’t even apply to managing symptoms in ME, but to managing ME as a whole. We have anecdotal reports, and experience within our team, that past use of sleep management strategies have harmed people with ME, including children and young people.</p> <p>We strongly recommend this recommendation is changed to “What is the clinical and cost effectiveness of medications to manage unrefreshing sleep and other features of abnormal sleep in ME?”</p>
270	Guideline	71	9	We welcome the inclusion of the context section.
271	Guideline	71	12	<p>We dispute that there being “little pathological evidence of brain inflammation[...] makes the term ‘myalgic encephalomyelitis’ problematic.”</p> <p>In our experience, people with ME have experienced far greater problems in having a disease with multiple names, including “chronic fatigue syndrome”, a name that is trivialising and focuses on one symptom at the expense of many others.</p> <p>Various diseases have historical names that do not accurately describe the disease entity, malaria being one such example that is a contracted form of <i>mala aria</i> ‘bad air’.</p>

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				<p>We continue to oppose using the term chronic fatigue syndrome (CFS), and considering this committee is at present recommending new terminology such as PESE, energy envelope, energy management and more, we strongly urge them to make a recommendation that this disease is called myalgic encephalomyelitis (ME).</p> <p>As committee members have recognised, people with ME have faced significant stigma. The term CFS has contributed to this. We strongly urge the committee to take an active stance on this issue, instead of passively accepting an outdated misnomer that they recognise here to be considered “too broad, simplistic and judgemental.”</p>
272	Guideline	71	15-17	We agree with the inclusion of this sentence on prevalence.
273	Guideline	71	19	<p>We strongly urge the committee to replace “emotional wellbeing” with “physical functioning” here.</p> <p>The focus on emotional wellbeing is unfounded, with some evidence suggesting that, “[p]erhaps surprisingly, mental health was less affected in patients with CFS.”¹</p> <p>In fact across multiple studies considered in a 2010 systematic review, “role emotional” and “mental health” sub-domain scores on the SF36 showed the smallest difference from non-ill controls.² Physical functioning is the factor that brings down quality of life scores so significantly, with a 70.1 point difference out of a total of 100 for the “role physical” sub-domain of the SF36.²</p> <p>This must be the focus of this sentence.</p> <ol style="list-style-type: none"> 1. Maroti, D., & Bileviciute-Ljungar, I. (2018). Similarities and differences between health-related quality of life in patients with exhaustion syndrome and chronic fatigue syndrome. <i>Fatigue: Biomedicine, Health & Behavior</i>, 6(4), 208-219. 2. Jason, L., Brown, M., Evans, M., Anderson, V., Lerch, A., Brown, A., ... & Porter, N. (2011). Measuring substantial reductions in functioning in patients with chronic fatigue syndrome. <i>Disability and Rehabilitation</i>, 33(7), 589-598.
274	Guideline	71	20-22	We agree with the inclusion of these sentences.

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275	Guideline	71	23	The sentence noting the lower quality of life of people with ME compared with other severe chronic conditions is an important issue in the context of ME. We would like to see this noted in the principles of care section on p4 line 8.
276	Guideline	71	26	This is an important paragraph to include and we are pleased to see it here. We believe it would also be helpful for clinicians suspecting ME to be aware that it can be triggered by an infection, and would like to see this stated in the section on Suspecting ME/CFS p8 line 1.
277	Guideline	72	1	We agree with the inclusion of the first sentence of this paragraph.
278	Guideline	72	3-6	We suggest deletion of the part of this sentence struck out. “Fatigue associated with another chronic disease may be confused with ME/CFS and some practitioners are reluctant to positively diagnose ME/CFS when no other causes are found. ” Even in the 2007 Guideline, diagnosis was made on the presence of a defined symptom set. It was not and is not a diagnosis purely of exclusion. This sentence leads to confusion, and would be clearer noting the factual statement that practitioners are reluctant to positively diagnose ME. We hope this Guideline will go some way to changing that.
279	Guideline	72	7-9	Beyond what is written here, the lack of belief and acknowledgement from professionals may lead to worse outcomes. We recommend adding the parts in bold: “People with ME/CFS report a lack of belief and acknowledgement from health and social care professionals about their condition and related problems, which may lead to worse outcomes, and to them being dissatisfied with care and disengaging from services.”
280	Guideline	72	12	We believe this paragraph should be removed. While it may have been important to the context during the scoping phase, it is no longer needed here, and sows confusion around the recommendations this committee has made. The ME community needs a clean break from a presentation of these therapies as controversial, and to be enabled to move forwards to campaign and advocate for research into treatments that will lead to a cure.

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281	Guideline	72	19	We very much welcome the commitment from NICE to review this Guideline once further evidence has emerged from recently started studies.
282	Guideline	72	22	We agree with this final paragraph.
283	Equality Impact Assessment	1	Question 3.1	<p>The Equality Impact Assessment states that “the groups identified in the equalities impact assessment during scoping were considered through the development of the guideline, however there was no or limited evidence identified for these groups and it was agreed no separate recommendations for these groups were to be made”. (These groups are listed as: Older people; Pregnant women; Black and Minority Ethnic people; and Men, as well as those from low socioeconomic backgrounds and those living in rural settings. Equality Impact Assessment questions 1 & 2.)</p> <p>In light of this concerning lack of evidence, we recommend adding a research recommendation considering access to care and outcomes for people with ME in groups with potential equality issues.</p>
284	Equality Impact Assessment	1	Question 3.1	We suggest that there is evidence that black and minority ethnic people have specific issues relating to accessing information and support (e.g. Evidence Review C p17 and p22 and from feedback from our community) and would like to see this impact acknowledged in the Assessment. We have also noted this in our comments on the Guideline on p15 line 6.
285	Equality Impact Assessment	1	Question 3.2	The committee did not cite any additional potential equality issues to those identified during the scoping process. We are concerned that in its discussions the committee does not appear to have acknowledged one of the most obvious inequalities, which may be impacting access to healthcare for a large proportion of people with ME/CFS. The Guideline should recognise that substantively more women than men are thought to have ME/CFS, possibly by as much as a ratio of 4:1. ¹ Evidence indicates that women are often not taken seriously when reporting their symptoms and the severity of those symptoms, and that women’s symptoms are frequently psychologised. ^{2,3,4,5} This is particularly concerning in relation to ME because the disease has a history of being put down to “unhelpful illness beliefs” and “avoidance of activities”, ⁶ for which patients have been referred to cognitive behavioural therapy as a treatment or cure for ME (an approach the committee now rejects in the draft Guideline). We urge the committee to acknowledge that the disproportionate prevalence of ME in women; the

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				<p>difficulties faced by women in having their symptoms taken seriously; and that these may create gender-based inequalities that should be recognised in the Guideline in order to help healthcare professionals provide tailored and equitable healthcare services.</p> <p>We suggest that the Guideline recommends that healthcare professionals should “Be aware that ME is more common in women than men and the negative impacts of gender-based assumptions.”</p> <ol style="list-style-type: none"> 1. ME/CFS in women and men, ME Research UK, (2015) https://www.meresearch.org.uk/sex-differences-in-mecfs/ 2. Mirin, A. A. (2020). Gender Disparity in the Funding of Diseases by the US National Institutes of Health. <i>Journal of Women's Health</i>. doi: 10.1089/jwh.2020.8682. 3. Chen, E. H., Shofer, F. S., Dean, A. J., Hollander, J. E., Baxt, W. G., Robey, J. L., ... & Mills, A. M. (2008). Gender disparity in analgesic treatment of emergency department patients with acute abdominal pain. <i>Academic Emergency Medicine</i>, 15(5), 414-418. https://pubmed.ncbi.nlm.nih.gov/18439195/ 4. Hamberg, K. (2008). Gender bias in medicine. <i>Women's Health</i>, 4(3), 237-243. doi:10.2217/17455057.4.3.237 5. Hoffmann, D. E., & Tarzian, A. J. (2001). The girl who cried pain: a bias against women in the treatment of pain. <i>The Journal of Law, Medicine & Ethics</i>, 28, 13-27. http://dx.doi.org/10.2139/ssrn.383803; 6. Burgess, M., Chalder, T. (2004) PACE Manual for therapists - Cognitive behavioural therapy. https://me-pedia.org/images/b/b4/PACE-cbt-therapist-manual.pdf
286	Equality Impact Assessment	2	Question 3.4	<p>We welcome the committee making specific recommendations in relation to severe and very severe ME, including the recognition that some of these recommendations may require additional resources.</p>
287	Equality Impact Assessment	2	Question 3.5	<p>The answer here is incorrect. The committee has acknowledged that physical activity can have an adverse effect on people with ME. The recommendation of physical activity programmes, with the included proviso that for some people with ME this can worsen their symptoms due to their illness, is the definition of a recommendation leading to an adverse impact due to the person's disability.</p> <p>The answer can only be no if the committee removes the recommendation for physical activity programmes and replaces it with access to safer advice around physical activity that is not premised upon incremental increases.</p>

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288	Equality Impact Assessment	2	Question 3.6	We very much welcome the committee's identification of children and young people with ME, and people with severe or very severe ME, as groups for special consideration requiring separate recommendations.
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Insert extra rows as needed

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