

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

(Oct 2020)

**NICE** National Institute for  
Health and Care Excellence

Consultation on draft scope – deadline for comments by 5pm on 26 July 2018

email: CFSME@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 or arrive after the deadline.</p> <p>We would like to hear your views on these questions:</p> <ol style="list-style-type: none"><li>1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?</li></ol> <p><a href="#">Developing NICE guidance: how to get involved</a> has a list of possible areas for comment on the draft scope.</p>
<b>Organisation name – Stakeholder or respondent</b> (if you are responding as an individual rather than a registered stakeholder please leave blank):	<b>Action for M.E.</b>
<b>Disclosure</b> Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	<b>Not applicable</b>
<b>Name of person completing form:</b>	<b>Katie McMahon, Policy Officer</b>
<b>Type</b>	[for office use only]

Comment No.	Page number or ' <b>general</b> ' for comments on the whole document	Line number or ' <b>general</b> ' for comments on the whole document	<p align="center"><b>Comments</b></p> <p align="center">Insert each comment in a new row.</p> <p align="center">Do not paste other tables into this table, as your comments could get lost – type directly into this table.</p>
1	General	General	<p>Action for M.E. surveyed people with M.E. and people who care for a person with M.E., asking for their opinions on each section of this scope, to help ensure that we were accurately representing the views of people affected by M.E. when responding to this consultation. We received responses from over 260 people, and any quotes included in this submission are taken from this survey. Our answers are informed by the opinions and experiences shared by this group of people, as well as our wider interactions with people with M.E. through our Information and Support Services and social media.</p> <p>Considering the whole scope, 74% of patients who responded to our survey felt that at least some changes were needed. Of these, 50% felt the scope was mostly fit for purpose but felt some changes were needed; 20% felt that some parts of the scope were fit for purpose but that a lot of changes were needed; 4% felt that the scope was not at all fit for purpose. We have outlined the key themes that patients highlighted to us in the following comments.</p>

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2	1-2	Page 1 line 14 – page 2 line 28	<p>In Action for M.E.'s survey, 47% of respondents felt that improvements needed to be made to the section 'Why the guideline is needed'.</p> <p>While this section does describe some of the ways in which people can be affected, patients felt that it does not adequately address the serious nature of M.E. People with M.E. commented:</p> <p><i>"Life with M.E. is not just severely disrupted, normal life as previously known is completely impossible. You are unable to do everyday things that most people take for granted i.e. having a bath when you want to, washing your hair, taking a walk, go shopping, enjoying cooking and many, many more things".</i></p> <p><i>"This disease is utterly disabling, the effect on quality of life is devastating, I feel this section downplays the severity of symptoms and how completely life-changing they are".</i></p> <p>Patients commonly suggested three key ways to ensure that this is addressed. Therefore, Action for M.E. recommends:</p> <ul style="list-style-type: none"> <li>- More detail is included on the variation in M.E., particularly symptom severity</li> <li>- The fluctuating nature of the condition is described</li> <li>- Post-exertional malaise is listed as the hallmark symptom of M.E.</li> </ul> <p>We have included more detail on each of these points in the following three comments (numbers 3-5).</p>
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3	1	19-25	<p>It would be a more accurate depiction of the impact of the condition if this section included more detail on the varied experiences that patients have, namely in symptom severity. By highlighting those who are severely affected, and detailing the ways in which the condition impacts on them, it would accurately describe the need for the guideline.</p> <p>A person who is currently experiencing moderate M.E. symptoms and has had the condition for over 5 years said he didn't think "<i>it highlights how severe M.E. can be for some people</i>". Other symptoms experienced by people with M.E. that are not included in this section include severe headaches, nerve pain, orthostatic intolerance, and sensitivity to light, touch and sound. Patients with severe M.E. are frequently either house-bound or bed-bound.</p> <p>It is particularly important to recognise the experiences of those with very severe M.E. who experience symptoms severely and on a continual basis. People who are very severely affected are often unable to live independently, and can require full-time care and support with all aspects of their personal care. They can also require tube-feeding. By including a description of this full spectrum of severity, it will ensure that the scope has accurately and clearly specified the considerable need for this guideline.</p>
4	1	19-25	<p>Additionally, professionals frequently do not understand the fluctuating nature of M.E., which can prohibit the provision of appropriate care and support. Therefore, it is important that this section accurately describes the ways in which M.E. symptoms can change over time. One person said:</p> <p><i>"The fluctuating severity of the condition is not recognised here. Over 20+ years I have had several extended periods of 'severe' (housebound/bedbound) but also some periods of 'mild'. Even when overall 'moderate' due to careful management, severity can fluctuate significantly over the course of a week/month"</i>.</p> <p>It is necessary to accurately capture the nature of M.E. in this scope, as the basis for the overall NICE guideline. To do so, the fluctuating nature of the condition must be included. It is vital that health professionals, and others involved in the care of people with M.E., are equipped to recognise and respond to the varying symptoms, as this can make a huge difference in the support that the patient receives. For example, a well-informed health care professional can respond flexibly, by recognising a flare-up in symptoms and taking steps to prevent any additional exertion.</p>

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5	1	19-20	<p>As well as highlighting severe M.E. and the fluctuating symptoms of the condition, another way to improve this section would be naming post-exertional malaise (PEM) as the hallmark symptom of M.E., and describe the impact of PEM. 'Post-exertional malaise' means that the body does not recover normally after expending energy, and can have an impact on many or all of the symptoms that a person with M.E. has. The International Consensus Criteria for M.E. uses the term 'post-exertional neuroimmune exhaustion' to refer to PEM and says "<i>this cardinal feature is a pathological inability to produce sufficient energy on demand with prominent symptoms primarily in the neuroimmune regions</i>" [Carruthers et al. (2011), <a href="#">Myalgic Encephalomyelitis: International Consensus Criteria</a>, p. 329]. Recognising this feature ensures an accurate portrayal of what living with M.E. is like for those with the condition.</p> <p>Someone with M.E. commented that the description included in the scope needed to focus on PEM rather than fatigue because while "<i>fatigue occurs in many illnesses [PEM] is what makes M.E. unique</i>". It would be beneficial to demonstrate how this particular feature affects people with the condition, as this provides clarity as to how additional activities, physical or cognitive, can worsen symptom severity and even cause a long-term deterioration in their condition. One person with M.E. told us they felt the "<i>impact of post-exertional malaise isn't sufficiently addressed. The effect on daily living and quality of life should be stressed further</i>".</p>
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6	2	23-28	<p>Patients have clearly stated that they do not wish CBT and GET to be included in the final guideline, for example:</p> <p><i>“That GET CBT are removed because they do more harm than good and doctors have no accurate way of assessing the very small group who may be helped. Risks massively outweigh the benefits”</i></p> <p><i>“The current CBT and GET treatments are inappropriate”</i></p> <p>Action for M.E. supports NICE’s decision to review the evidence relating to M.E. diagnosis and management, particularly given the need to consider the evidence base for CBT/GET that is being increasingly challenged [Wilshere et al. (2018) <a href="#">Rethinking the treatment of chronic fatigue syndrome</a>, Twisk (2017) <a href="#">Dangerous exercise: the detrimental effects of exertion and orthostatic stress in M.E. and chronic fatigue syndrome</a>]. Graded Exercise Therapy in particular has been shown to cause harm to M.E. patients, with 47% of Action for M.E. survey respondents saying that it made their condition worse [Action for M.E. 2014, <a href="#">Time to deliver</a>]. Therefore, we would only want CBT and GET included in the scope in the circumstances that these treatments are reviewed in light of this research and patient evidence.</p> <p>CBT and GET constitute a significant component of M.E. treatment in the UK as it stands, and it is reasonable that they are included in the considerations of the NICE guideline committee. In reviewing the evidence on these treatments it is vital that NICE listen to patient voice and experience. A number of trials have taken place relating to these treatments, and the methodology and findings of these trials have been challenged and rejected [Wilshere et al. <i>op. cit.</i>]. To provide a true and accurate picture of how people with M.E. have been impacted by these treatments, the NICE guideline scope must enable the guideline committee to review all relevant evidence including the experience of patients. Furthermore, given the harms reported by patients, NICE has an ethical obligation to safeguard patients and ensure that no harms are incurred as a result of their recommendations.</p>
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7	3	6-9	<p>Under 'Who the guideline is for', the majority of patients (52%) felt that this section was appropriate. However, a significant minority (31%) felt that more groups needed to be included. Their comments consistently highlighted that a wider pool of professionals could make use of this guideline, namely those involved with benefit provision, employers and educators.</p> <p>Additionally, many children with M.E. who are unable to attend school have then been referred to social services. Action for M.E.'s 2017 survey found that 20% of respondents had a safeguarding referral had been made against them, commonly for fabricated/induced illness. 70% of cases were dropped within a year, and Action for M.E. is not aware of any of these referrals being upheld [Action for M.E. (2017), <a href="#">Families facing false accusations</a>]. This further underlines the need for professionals outside of the health and care sector to make use of this guideline, to understand the condition and the impact it has on capability, to prevent such referrals. Therefore, this guideline would also be relevant for professionals working in social services.</p> <p>Action for M.E. recommends the addition of the below professionals, who are frequently involved with patients with M.E., to the list of those who this guideline may be relevant for:</p> <ul style="list-style-type: none"> <li>- Department for Work and Pensions benefits assessors and providers (including Capita, Maximus and Independent Assessment Services employees who are commissioned on behalf of the DWP)</li> <li>- Employers</li> <li>- Department of Education and individual schools</li> <li>- Social services</li> </ul> <p>A lack of understanding of the nature of M.E., and how it can be best managed, among these groups has caused additional hardship for those with the condition. The information in this guideline could improve their understanding of the condition and the support they offer. Naming them in this scope shows that it contains information that would enable them to better support people with M.E. in their professional capacities.</p>
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8	3	24	<p>As well as specifically considering children and young people in the guideline, the scope also ought to give the NICE guideline committee the remit to consider the transition from paediatric services to adult services. Action for M.E. often hears from children who either do not receive care when they reach adult age, or who find themselves routed to inappropriate support for their life stage. For example, one young person in an adult service kept on receiving advice on how to manage employment, despite continuing to point out that they were still attending school. Therefore, they missed out on the support that could have targeted their specific educational needs.</p>
9	3	25	<p>54% of survey respondents felt the section on groups and settings was appropriate, while 28% felt that changes were needed (18% did not have a strong opinion).</p> <p>While patients welcome the need to address severe M.E., the NICE committee developing this guideline need to be aware that the different groups of severity are not discrete. As one patient explains:</p> <p><i>“All those who have the illness should be treated with the same degree of care. Without that those in the moderate to severe range could become or are becoming worse through lack of care. The distinction between moderate and severe was not an accurate representation of what the illness is like. Some of us go between moderate and severe verging more to the severe end depending on the time of year of other health issues on top”.</i></p> <p>Severe patients do need particular consideration, given the extra burden the disease places on them and the acute lack of research and understanding of severe and very severe M.E. The scope ought to additionally recognise that the severity of a person’s condition is on a spectrum and that the guideline’s recommendations for each level of severity cannot be treated as completely distinct.</p>

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10	4	22-25	<p>When asked about the section 'Activities, services or aspects of care', 40% of patients surveyed felt that changes were needed. In their comments, people raised two common concerns. We have addressed the first concern here, with the second concern addressed in comment 11.</p> <p>Firstly, patients highlighted that the information included in the related guidelines may not be appropriate for a person with M.E. For example, one person said "<i>when prescribing medication, [health professionals] need to think about the fact that people with M.E. are often highly sensitive to drugs and will need to be prescribed a lower dose</i>". Another said "<i>pain may need to be managed differently with M.E. than other illnesses</i>".</p> <p>While the related guidelines do address some of the symptoms of M.E., there is a need for some information in the M.E. guideline to highlight the ways in which patients may require adjustments to the general care and support on offer. This ought to be included clearly so that practitioners know that they cannot use the related NICE guidance wholesale and must consider the individual needs of their patient.</p>
11	5	5-6, and 23-24	<p>The second common concern expressed by patients was the inclusion of two guidelines relating to mental health, under 'Related NICE guidance' (<i>Common mental health problems: identification and pathways to care</i> and <i>Service user experience in adult mental health</i>).</p> <p>M.E. is a neurological condition, with the evidence base continuing to find ways in which the condition has a physiological impact on patients. While patients can experience co-morbid mental health problems, this is frequently due to the isolation and lack of understanding they face from peers and professionals. The scope states that the list of related guidelines are for the "<i>specific management of symptoms where NICE guidance already exists</i>". Mental health issues are not a symptom of M.E. If these guidelines are to be included in this list, the scope should explicitly state that the related guidance applies to co-morbid conditions (rather than exclusively symptoms of M.E.)</p> <p>One patient explained:</p> <p><i>"As no mention of mental health was made in the symptoms section, the rationale for [the inclusion of mental health guidelines] could be made clearer. This is particularly important as the focus of previous guidelines on GET and CBT have treated M.E. as a primarily psychological condition. If the purpose of this guidelines is to rethink this approach then reference to mental health needs to be justified"</i>.</p>

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12	6-7	Page 6 line 7 – page 7 line 14	<p>In our survey, a significant minority (36%) felt that changes were needed to the section ‘Key issues and draft questions’. The information people affected by M.E. felt was missing was varied, but commonly centred on aspects of treatment and management for which there is not yet a robust evidence base.</p> <p>Given the lack of treatment, people with M.E. frequently contribute to online forums and can provide management suggestions based on what has worked for them. This includes the use of medication that is not specifically licensed for M.E., but help with individual symptoms. While NICE will be considering robust research evidence on M.E. treatments, this condition is in a unique position in that there is no consensus on what can be beneficial to patients, and there has been no research investment to evidence the techniques commonly used by patients, such as pacing. To best serve people with M.E., there needs to be some mechanism in place by which patient evidence can inform the NICE guideline and be given significant weighting in relation to other forms of evidence.</p> <p>Therefore, one addition to this section should address the consideration of patient evidence on treatment and management methods. It may be that this cannot be used as the basis for formal NICE recommendations, but could enable healthcare professionals to recognise the variety of symptom management methods that could be utilised, and to therefore respond flexibly to the needs of a patient.</p> <p>One person with M.E. told us they “<i>have suffered for 30 years and have neither found an effective strategy or management technique that can indicate when I’m going to fall off a cliff edge</i>”.</p>
13	6	22-31	<p>Action for M.E. recommends the addition of the question ‘What is the clinical and cost-effectiveness of management within primary care for people with ME/CFS?’</p> <p>Patients with M.E. are commonly treated within the primary care system, given the lack of secondary specialist care for those with the condition [Action for M.E. (2017), <a href="#">Spotlight on specialist services</a>]. It is vital that management within primary care is considered by the NICE guideline committee, to ensure that any recommendations they make take account of this aspect of care. It is particularly important that primary care is made accessible to those with severe M.E. The services that do exist commonly focus on patients with mild or moderate symptoms, and people who are severely affected must receive some care and support, with provision available for domiciliary visits.</p>

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14	7	15-25	<p>For the section 'Main outcomes', 36% of our survey respondents felt that changes were needed. Frequently, patients commented that there was a need to include objective measures in addition to the subjective questionnaires that have been listed in this draft scope.</p> <p>For example, one person said “<i>where possible trying to restore some of the patient’s previous goals</i>” whereas others suggested that a person’s ability to participate in education or employment should be measured. Such measures would allow health professionals using the NICE guideline to consider the extent to which the condition was materially affecting a patient’s ability to participate in normal, daily life. Another objective measurement would be a change in the benefit status of the patient, where it is linked to a change in their condition. Reliance on subjective questionnaires such as SF-36 means that patient ability may not be accurately measured.</p> <p>We wish to emphasise that employment or education must not be considered as the sole measure for a person’s capability. Work or school attendance can be used as an outcome, but should not be an objective for a patient whose symptoms are preventing participation, as the exertion of attempting to attend could worsen their symptoms and the long-term severity of their condition.</p> <p>However, by including these as an outcome health professionals can capture one aspect of the patient’s capability. Where a patient can sustain the levels of activity required to participate (even part-time), they are demonstrating a particular level of capability.</p>
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- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include page and line number (not section number) of the text each comment is about.
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