

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



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"> 1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline? <p>Developing NICE guidance: how to get involved has a list of possible areas for comment on the draft scope.</p>
<p>Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):</p>	<p>FORWARD-ME</p>
<p>Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.</p>	<p>None</p>

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Type		[for office use only]	
Comment No.	Page number or 'general' for comments on the whole document	Line number or 'general' for comments on the whole document	Comments
Example	3	55	<p>Insert each comment in a new row.</p> <p>Do not paste other tables into this table, as your comments could get lost – type directly into this table.</p> <p>The draft scope currently excludes people who have already been diagnosed. We feel this group should be included because....</p>
1	General	General	<p>The use of the term 'chronic fatigue syndrome', whilst used historically in research documents, fails to convey the multi-systemic nature of the illness and should be made redundant. The Myalgic Encephalomyelitis: International Consensus Criteria. [Carruthers <i>et al</i> July 2011] explains that "it is more appropriate and correct to use the term 'myalgic encephalomyelitis' (ME) because it indicates underlying pathophysiology". Patients refer to themselves as 'having ME'. In contrast, the term 'chronic fatigue syndrome' has fuelled the conflation of ME with fatigue syndrome (chronic fatigue rooted in psychosocial factors). This has historically bedevilled understanding, care and progress- particularly in the UK – with catastrophic consequences for ME patients.</p> <p>This confusion has been further fostered by the overly broad 'CFS' criteria, particularly the 'Oxford' research definition, which the US National Institute for Health has called to be retired as it could "impair progress and cause harm". (Green 2015).</p> <p>For these reasons we are strongly of the view that:</p> <ul style="list-style-type: none"> ∞ The term 'Chronic Fatigue Syndrome' should be made redundant, with the guideline in development focussing specifically on the needs of people with ME. ∞ The reported findings of research studies recruiting based on the 'Oxford' criteria (or similar) should not be considered relevant to this patient group.

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2	1	19 - 23	<p>There is a need for a clear and robust description of the unique clinical profile that ME presents – if not here in the scope, then certainly in the final version of the guideline. It should be noted that this does not hinge on 'fatigue' as such but does entail the cardinal feature of Post Exertional Malaise (PEM). PEM is unique to ME and prevents confusion with other causes of chronic fatigue. The latest update of the CDC website (12.7.19) advises: "Post exertional malaise (PEM) is the worsening of symptom following even minor exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or even weeks." However, Post Exertional deterioration can be even more long-lasting, as the Institute of Medicine Report acknowledges: "PEM is unpredictable in duration, potentially lasting hours, days, weeks or even months." https://www.ncbi.nlm.nih.gov/books/NBK284902/ (under heading 'PEM', references provided)</p>
3	1	23-25	<p>This is a most severe illness in terms of impact on the patient, as indicated by multiple quality of life/sickness impact studies. For example, US infectious diseases specialist Philip Peterson and team employed the 'Medical Outcome Study' to measure physical suffering, with a maximum score of 100 representing best health. 'CFS' patients in Peterson's clinic scored, on average, 16. Presenting findings, Peterson said "<i>We really haven't seen anything like it with respect to the other medical illnesses</i>" adding that he needed to engage an artist to redesign the morbidity graph for the slide presented, since no other category of patients scored so low. SOURCE: Hillary Johnson; Osler's Web 1996; Peterson published as Peterson PK, Schenck CH, Sherman R. <i>Chronic fatigue Syndrome in Minnesota. Minnesota Med 1991; 74: 21-26.</i> A Danish study found that ME patients on average had a lower quality of life than patients with multiple sclerosis, diabetes, stroke and multiple forms of cancer. SOURCE: http://journals.plos.org/plosone/article?id=10.1371/journal.pone0132421. it should be noted that the most severely affected patients are bedbound, tube-fed because they are very weak or have severe gastrointestinal problems and are unable to swallow, unable to speak or to tolerate light, sound or touch. Regarding prognosis, there is no age group for whom 'complete recovery' is the norm. Indeed, we are not aware of a single documented case of recovery to the point where life is not at all restricted by this illness. To cite published findings, a systematic review of 14 studies found: ∞ A median full recovery rate during follow-up periods of 7% ∞ That only a minority of participants had improved at all over the study period – the median proportion of patients who improved during follow-up being 39.5% SOURCE: Carruthers. B et al <i>Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols</i> Journal of Chronic Fatigue Syndrome, Vol 11(1) 2003, pp7 – 115.</p>

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4	2	3-4	<p>It is quite correct to say that, at present, patients are identified based on the clinical picture presented – and that this applies to both research and clinical care settings. However, this is rooted in the insistence on locating a single, unique biological identifier (not found to date and may not be findable, given the various stages through which this illness progresses) rather than in “lack of understanding” of aetiology.</p> <p>The fact that diagnosis is made clinically makes it even more important to ground the NHS in a recognition of the unique clinical profile that an ME patient presents. See the seminal work of A Melvin Ramsay, for example. More recently, the International Consensus Criteria, the Canadian Consensus Criteria the US IOM criteria are accepted by the ME community; these definitions are well grounded in empirical studies.</p> <p>Delete from ‘a primary’ to end of sentence.</p>
5	2	15-16	Delete from ‘a primary’ to end of sentence.
6	2	20	After ‘added’ insert ‘safeguarding’.
7	2	22	These can create an unnecessary burden on those involved in safeguarding procedures and the unwarranted stress can exacerbate the illness of the child or young person.
8	2	23 - 28	Delete this section. It is important to note that the primary reason for the requests for review of the current guideline was because of the evidence of harm caused by GET and the lack of effectiveness of CBT. Note the recent update (12.7.18) of the CDC website: “Any activity plan for people with ME/CFS needs to be carefully designed based on individual presentation with input from each patient. If possible, evaluation by a rehabilitation specialist may be beneficial. For some patients, even daily chores and activities such as cleaning, preparing a meal, or taking a shower can be difficult and may need to be broken down into shorter, less strenuous pieces. While vigorous aerobic exercise can be beneficial for many chronic illnesses, patients with ME/CFS do not tolerate such exercise routines. Standard exercise recommendations for healthy people can be harmful for patients with ME/CFS.” (Their bold). The evidence for CBT is weak.
9	3	6	Delete ‘may’, insert ‘will’

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10	3	16	<p>The Equality Impact Assessment is perfunctory, being confined to identification of certain groups in respect of whom “there are challenges for these groups to be identified and diagnosed with ME/CFS” followed by a glib assurance that “these groups are not excluded from the scope”. If equality is truly to be achieved, the guideline will require to think through a suitable NHS approach to people with ME in these groups <i>with regard to other health issues</i>. For example, the need for pregnant women with ME to have due cognisance taken of their ME in terms of pre- and neo- natal health care, as well as at the time of delivery, similarly, for transgender ME patients, presence of ME has to be factored in – the person cannot tolerate hormone treatment as a person without ME would.</p> <p>There are Equality Issues which apply to all: the core issue of having ME <i>is in itself a potential barrier</i> to the achievement of Equality.</p> <p>Most fundamentally, there are the challenges for any ME patient to be diagnosed with ME. There are also ‘challenges’ for the health and social care needs of any person with ME to be factored in when providing for the other health needs, and the home care needs. People with ME lack access to suitably delivered healthcare, and many live in dread of requiring hospital treatment, for example, due to the impact of the hospital environment (light, noise and other stimuli) on their ME. Similarly, some very sick people do without home care and suffer neglect of most basic care needs in consequence of failure of home care providers to deliver care in a manner that does not exacerbate ME. The current vogue for ‘reablement’ as a first line/default response to expressed need for care, including as a means of ‘assessment’ is of huge concern. Despite raising such concerns with NICE when developing ‘reablement’ guidance (NG74 Intermediate care including reablement) the resulting advice signally fails to provide any protection for people with ME.</p> <p>The equality issues failed to identify the fact that the severely affected, wherever they are located, do have difficulty with access to paramedical services such as dentists, opticians and podiatrists, for example. Such services are required on a domiciliary basis for all but the least severely affected or those in remission.</p> <p>In respect of hospital outpatient appointments, social care has a role in assisting. This is a significant unmet need for people with ME who lack family or other informal support. In this, as in other respects we would wish to see joined-up thinking on NHS and social care roles when the guideline is developed.</p>
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11	3	22	<p>People with ME may have co-morbid conditions that will not respond to recommendations for in the same way as patients who have those conditions for which NICE guidance is already available because of the unique way in which their bodies respond to medications. Co-morbid conditions in these patients need to be dealt with within this guideline if the intention is to reduce harm.</p>
12	6	8	<p>Patients with post viral fatigue syndrome (PVS) should be considered as possible candidates for ME. Although most patients with PVFS recover spontaneously, there may be some for whom standard recovery procedures – e.g. – reducing rest time and increasing activity, may not be suitable. Proceed with caution!</p>
13	6	11	<p>Disability or assessment scales tend to be based on subjective outcomes. The fluctuating nature of the condition would be unlikely to give accurate information.</p>
14	6	13	<p>Preconceived views by professionals are potential barriers to identification. Listening to the patient and taking a full history are facilitators.</p>
15	6	14	<p>Advise patients to listen to their bodies and to stop activities before they exceed their tolerance threshold. Involve family who will be better able to observe when limits are being reached.</p>
16	6	19	<p>CDC, IOM or International Consensus Criteria</p>
17	7	15	<p>The main outcomes listed are nearly all subjective judgements. Why not measure return to work/education on a full or part-time basis or joining civil society for example? Adverse effects and the impact of treatment or management strategy should be added to the main outcomes to be assessed.</p>
18	4	11	<p>Whilst recognising that most of the management for patients with ME will be in the Primary Care sector, there is a need for all patients to have access to consultant-led, multi-disciplinary services with early referral, accurate diagnosis and expert care and advice</p>
19	1	26 - 27	<p>This statement is far too vague and negative – plausible hypotheses as to the underlying cause have emerged through decades of biomedical research and a wide range of physical abnormalities have been documented. Granted, this information has not been drawn together to produce an incisive and conclusive picture of the reasons behind the onset and persistence of ME in each and every case. However, it would be misleading to imply that we do not have, at a minimum, some very strong clues as to the cause.</p>

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20	4	17 - 19	<p>This may be the 'normal scenario but such strictures are highly problematic in the present context. Because of the absence of much research evidence of the use of drugs for symptom relief in ME, a pragmatic approach using drugs that may not be licensed for this condition is justifiable, based on pharmacological principles and the judicious use of therapeutic trials. We ask that this context is reflected in the process of guideline development.</p> <p>It is important to note that, because people with ME may not respond to prescribed medications in the same way as people who do not have the illness, it may be advisable for prescriptions for medications for people with ME to start at a very low dose and, if no adverse reaction occurs, to build up the dose gradually.</p>
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Checklist for submitting comments

- Use this form and submit it as a Word document (not a PDF).
- 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.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Underline and highlight any confidential information or other material that you do not wish to be made public.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
- For copyright reasons, do not include attachments such as research articles, letters or leaflets. We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments.

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