

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

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	We would like to hear your views on these questions: 1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline? Developing NICE guidance: how to get involved has a list of possible areas for comment on the draft scope.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	The 25% ME Group (UK support organisation for people severely affected by the M.E.)
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	None
Name of person completing form:	Helen Brownlie

PLEASE NOTE:

It may look as though you have come to the end of the document when you have not.

This is because the pro forma provided by 'NICE' takes a new page at the start of a comment rather than split it with a page break.

There are a total of 28 comments here, and 11 pages in total.

Comment No.	Page number	Line number	Comments
1	General	General	<p>It is essential to learn from the experience of developing Clinical Guideline 53.</p> <p>The publication of this guideline did nothing to avoid promulgating the obfuscation of the neurological disorder M.E. as recognised by the World Health Organisation (ICD-10 G93.3). Time, money and effort was spent producing guidelines for a non-specific cohort of fatigued patients subsumed under the misnomer 'CFS/ME'. This tactic was doomed to lead to unsatisfactory results for people with M.E.</p> <p>The difficulties inherent in approaching a non specific cohort of patients were flagged up as long ago as January 2002, in <i>A Report of the CFS/ME Working Group: Report to the Chief Medical Officer of an Independent Working Group</i> (Department of Health publication):</p> <p>"The CMO assembled the Working Group to report on CFS/ME. Many correspondents with the Group noted that the term CFS/ME covered subgroups of patients who might have different aetiology, symptom complexes, or response to various treatments."</p> <p>"Some patients with CFS/ME might not respond, or might even respond adversely, to certain treatments found effective in other patients. ... In view of concerns raised over patients' experience, the question of whether differential treatment response represents some distinct difference in disease merits carefully planned research."</p> <p>The Report highlights the need for resolution of this issue as a "key message": <i>"One highly heterogeneous disease might exist that encompasses CFS/ME or several related pathophysiological entities may exist; these distinct hypotheses should be studied."</i></p> <p>The Report also acknowledges: <i>"These possibilities complicate the consideration of aetiology and pathogenesis, as they do other aspects of the condition."</i></p>
2	1	7-9 "The Department of Health and Social Care in England has asked NICE to develop guidance on diagnosing and managing myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS)."	<p>The most fundamental issue in terms of securing safe and relevant care for people with M.E. is that the forthcoming guideline is relevant to the diagnosis and management <u>of M.E. patients</u>.</p> <p>In almost any other area of healthcare this can be taken for granted: a guideline to inform the diagnosis, care and treatment of patients with Parkinson's disease will set out the results of deliberations relevant to Parkinson's disease; a guideline to be applied to patients with prostate cancer will set out the results of deliberations relevant to prostate cancer. Yet when it comes to the care and treatment of people with M.E. the fulfilment of this most basic of preconditions cannot be assumed.</p> <p>Notably, M.E. is routinely conflated with psychosocial / psychosomatic chronic fatigue - to the detriment of M.E. patients.</p> <p>It is therefore essential that the guideline equips professionals to identify M.E. patients, as a prerequisite to meaningful efforts to address M.E. patient need, while protecting from harm / inappropriate advice or intervention.</p>

3	1	<p>10-11</p> <p>“The guideline will be developed using the methods and processes outlined in ‘developing NICE guidelines: the manual’</p> <p>https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview “</p>	<p>In view of the outcome of the previous process of guideline development, we must emphasise that adherence to ‘NICE’ methods and processes is not a sufficient condition to ensure that the final product is fit for purpose in application to M.E. patients.</p> <p>For explication on this point we would direct ‘NICE’ to relevant written submissions to the Health Select Committee Enquiry relating to aspects of the operation of ‘NICE’ (2007). The Select Committee sought views on several issues, including: why NICE’s decisions are increasingly being challenged; whether public confidence in the Institute is waning, and if so why; NICE’s evaluation process. The 25% ME Group made a submission to this enquiry. Pertinent submissions were also lodged by ScotME and by the ME Association. All can be read in the published report of written evidence: s https://publications.parliament.uk/pa/cm200607/cmselect/cmhealth/503/503ii.pdf</p> <p>See also submissions to NICE from 2017 consultation on CG53 replacement.</p> <p>To elucidate the validity of broadening the evidence base, see the 2008 Harvean oration by Sir Michael Rawlins, then chair of NICE. An article based on this speech was published as: Rawlins M. <i>De Testimonio: on the evidence for decisions about the use of therapeutic interventions</i>. Clinical Medicine (the Journal of the Royal College of Physicians) 2008; 8: 579-88. Quote: “The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an uncomfortable pedestal for while the technique has advantages it also has disadvantages. Observational studies have defects but they also have merit. Decision makers need to assess and appraise all the available evidence irrespective as to whether it has been derived from RCTs or observational studies; and the strengths and weaknesses of each need to be understood if reasonable and reliable conclusions are to be drawn. Nor, in reaching these conclusions, is there any shame in accepting that judgements are required about the ‘fitness for purpose’ of the components of the evidence base. On the contrary, judgements are an essential ingredient of most aspects of the decision-making process.”</p> <p>Suggest taking in evidence cases of M.E. patients where the response of NHS and/or social services (or the lack of it), has been problematic, with serious adverse outcomes. This would serve to (i) ground the guideline in how and why existing practice needs to change and (ii) help gauge the utility of fresh guidance in terms of pointing towards securing an appropriate - and not harmful - service response.</p> <p>We have become acutely aware that professional mindset is a huge problem - tends to remain firmly set in the face of observed patient response to present NHS approach (variously - lack of improvement, deterioration, continued very low plateau for those patients who can’t attempt what is being advised); no cognisance of harm; outcome is more of the same, no matter how much the patient is struggling / being set back; blame the patient. This does underline the clear need for makes robust guidance, that is congruent with M.E. patient reality.</p>
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4	1	14 onwards Section 1 "Why this guideline is needed"	This is a rather bland and 'bloodless' rationale for change. In view of the lives - and deaths - of people with severe M.E. occurring over the last 11 years (<i>i.e.</i> since CG53 was published), with many truly unacceptable encounters with health and care services, a much more urgently worded section might be expected.
5	1	16-18 "It is recognised that there are people who need care but who may not meet existing clinical or research criteria."	Far from being overly exclusive, existing criteria tend to be broadly inclusive of a heterogeneous group. Warnings about the dangers flowing from this have been sounded for many years. See, for example, ScotME submission to the Gibson Parliamentary Enquiry - ' <i>Heterogeneity of CFS/ME - the dangers of failure to sub group</i> ' (2005): citing the 2002 CMO's working group report (see comment 1), this flags up the difficulties inherent in a situation whereby "varied needs, degrees of disability and confounding conditions [are] subsumed under the broad diagnostic banner of CFS as currently defined in the UK, yet a 'one size fits all' approach to treatment has been adopted". It is vital that robust guidance is provided to practitioners to facilitate a positive diagnosis of M.E. (<u>not</u> a 'dustbin' diagnosis - <i>i.e.</i> a diagnosis of exclusion) and to distinguish patients with M.E. from patients with other physical disorders, and also from patients with a mental or behavioural disorder. This is essential because of the specific care needs of people with M.E.
6	1	20-21 "Clinically, ME/CFS is heterogeneous and multifactorial and people experience the illness differently."	Delete this sentence. It is essential instead to recognise core features that delineate the unique clinical profile of M.E. It should be noted that this does not hinge on 'fatigue' as such but does entail the cardinal feature of Post Exertional Malaise (PEM). This can be done while acknowledging that some variation can and does occur. However, simply emphasising 'heterogeneous', 'multifactorial' and 'different illness experience' in isolation from the core features is a recipe for continued diagnostic mess and iatrogenic harm to M.E. patients.

7	1	<p>22-23 “Common symptoms include chronic pain, disordered sleep, digestive problems and cognitive difficulties.”</p>	<p>Listing symptoms which commonly occur is no substitute for recognising that a distinctive clinical profile exists (see comment above).</p> <p>The presentation of symptoms in abstraction from identified areas of pathogenesis is also problematic. This was recognised as long ago as 2003, with the publication of Carruthers, B <i>et al. Myalgic Encephalomyelitis / Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols</i> in the Journal of Chronic Fatigue Syndrome, Vol. 11 (1) 2003, pp7-115; and the accompanying editorial (pp 1-6), which advise:</p> <ul style="list-style-type: none"> • the clinician should not be confused that fatigue (or myalgia or the other symptoms that occur with increased frequency with fatigue) is an entity in its own right but is a common symptom of underlying disease [p2-3] • We present a systematic clinical working case definition that encourages a diagnosis based on characteristic patterns of symptom clusters, which reflect specific areas of pathogenesis. [p7-8] • We hope that the clinical working case definition will encourage a consideration of the ongoing interrelationships of each patient's symptoms and their coherence into a syndrome of related symptoms sharing a complex pathogenesis rather than presenting a 'laundry list' of seemingly unrelated symptoms. [p10] • We believe this will sharpen the distinction between ME/CFS and other medical conditions that may be confused with it in the absence of a definite laboratory test for ME/CFS. [p10]
8	1	<p>19-25 “ME/CFS is a disabling and distressing illness characterised by extreme and debilitating fatigue, particularly after exertion. ... [continues as per lines 20-23, above] ... For most people with ME/CFS, everyday life is severely disrupted and a complete recovery is unusual, although this can vary depending on the age of onset.”</p>	<p>This section does not do justice to the severity of this illness.</p> <p>It should be noted that the most severely affected patients are bedbound, tube-fed because they are very weak or have severe gastrointestinal problems and are unable to swallow, and may be unable to speak or to tolerate light, sound or touch.</p>

9	2	13 “... research has highlighted that many GPs lack the confidence and knowledge to diagnose and manage ME/CFS. However, a review of diagnoses at a referral centre found that 40% of people referred did not have CFS ...”	The study cited bears out that lack of confidence among GPs in making a diagnosis is well grounded. Therefore suggest delete “However” and replace with “This is borne out by”.
10	2	13-17	Insert after “ <i>found that 40% did not have CFS</i> ” the clarification “ <i>according to the 1994 US CDC CFS criteria</i> ”
11	2	23-28 “The previous NICE guideline (CG53) made recommendations on the use of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The evidence supporting these interventions has been challenged and some people with ME/CFS report being pressured to participate in exercise programmes, leading to a worsening of symptoms. There is therefore a need to review the evidence for these and other interventions.”	We welcome the acknowledgement that such approaches need to be looked at again. Concerns are (i) what is - and is not - considered admissible evidence and (ii) the method whereby this ‘evidence’ is scrutinised. Parameters set on both when CG53 developed are exactly what got us into the present mess in the first place. We would welcome the opportunity to elaborate on this point and to feed into guideline development process accordingly.
12	3	2 and 8	Occupational health services appear twice: listed at “Who the guideline is for” and “It may also be relevant for”

13	3	13 Equality Considerations	<p>We endorse the submission of the Forward-ME group in this regard: http://www.forward-me.org.uk/Reports/NICE-comments-form-2.pdf [comment number 10]</p> <p>We would add that access to 'wait and return' stretcher service for out patient appointments can be vital for people with severe M.E. This is a further example of the type of practical issue that requires to be robustly addressed in the forthcoming guideline if equal access to health and social care is to be achieved for people with M.E., particularly those who are most severely affected.</p> <p>Lack of reasonable adjustments to facilitate access to services can result in patients not attending hospital and other healthcare appointments, not seeking investigation for red flags, not participating in screening programmes with all the potential adverse consequences this entails.</p> <p>The current vogue for 'reablement' as a first line/default response to expressed need for care, including as a means of 'assessment' is of huge concern. Despite raising such concerns with NICE when developing relevant guidance the resulting guideline - NG74 Intermediate care including reablement - signally fails to provide any protection for people with ME.</p> <p>The consequences of the above can be dire. As submitted to the consultation on NG74: "Viewing 'reablement' calls as part of an assessment creates a paradox whereby people are having workers in to 'assess' whether or not they require care support, with a starting point being that this requires to be demonstrated in this way, and only in this way. This is both flawed in principle and can be highly dangerous in practice. Case example from M.E. support: 'We were called for by a woman with ME and other conditions. She was sound and light sensitive and had lost several stones in weight and was not coping with eating. Had fridge and freezer stocked but too weak to eat. We asked for an assessment of her condition and she was allocated two Carers to see her for 6 weeks reablement. The only way to get her any kind of help. They encouraged her to engage with them in the kitchen to prepare food despite her extreme weakness and grossly swollen legs. The reablement had to run for 6 weeks before future help would be decided so Social Services would not discuss her needs further. She regularly called out the ambulance for severe breathing condition CPOD but would not go into hospital with them because of previous experience of A&E's noise and bright lights. We prepared her for admission to hospital. Only way was through A&E, so called GP. GP would not have her admitted even though we could see she was dying (weighed less than 5 stones). Finally Carers visited and found her unconscious, admitted straight to Ward and medical staff asked where she had been and why she was not admitted earlier. Fought to save her for a week and she then died." See https://www.nice.org.uk/guidance/ng74/documents/consultation-comments-and-responses comments number 317-358, starting on page 51, for comments from The 25% ME Group & responses. The comment cited here is number 354.</p>
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14	3	22 “Groups that will be covered • People with suspected or diagnosed ME/CFS”	We would prefer to see a guideline that delineates M.E., facilitating specificity of diagnosis and congruent care recommendations - guidance on both being urgently required. This implies that the guideline should not set the bar at relating to “people with suspected ME/CFS”. It should strive to permit, through it’s application, the relevant diagnosis to be confidently confirmed, or not.
15	3	25 “Specific consideration will be given to... people with severe symptoms”	A specific focus on severely affected M.E. patients will be welcome. However, please reword this proposal. <u>All</u> people with M.E. experience “severe symptoms”. The requirement is to produce a guideline that adequately covers the care needs of the most severely affected patients, whose suffering is extreme. We would argue that the primary focus should be on the most severely affected patients, on the basis that if the guideline gets it right for the most severe then the needs of less severely affected patients will de facto be covered.
16	3	25 “Specific consideration will be given to... people with severe symptoms”	The emphasis on “symptoms” here - as in other parts of the draft scope - tends to the ‘reification’ of symptomatic manifestation. In other words, viewing symptoms as entities in themselves, rather than rooted in underlying disease. We suggest that “people who are most severely affected by this illness” would be appropriate
17	3	25 “Specific consideration will be given to ...people with severe symptoms”	It is essential that guidance on appropriate care for severely affected patients has a high profile, including when presented on the NICE website. At present, when health professionals consult the ‘NICE’ website for guidance on this condition the on line presentation omits crucial awareness raising guidance on severely affected patients. For example, in the full version of CG53 the chapter specifically titled ‘People with Severe CFS/ME’ contains this guidance “People with severe CFS/ME may face many difficulties in achieving adequate and balanced dietary intake including ... <i>[list follows]</i> . The healthcare professional should work with the patient and carers to address these problems. In some extreme cases, this may include the use of tube feeding, if appropriate.” However this Chapter begins over 300 pages into the document, which is now construed as ‘evidence’ (https://www.nice.org.uk/guidance/cg53/evidence) It is very difficult to find, unless you first know what you are looking for (and even then not too easy). Few if any professionals are aware of it, in our experience.

18	4	10 `"Key areas that will be covered 2 Diagnosis of ME/CFS"	<p>Poor medical education on this topic has been a barrier to diagnosis and appropriate care.</p> <p>The dearth of suitable medical education makes the provision of robust guidance on M.E. diagnosis in the guideline all the more important. A confident and early diagnosis based on medical history and clinical presentation would facilitate the identification, diagnosis and care of M.E. patients. Major costs are implicated in multiple 'second opinions', delayed diagnosis and/or irrelevant investigations - while relevant investigations may be overlooked.</p> <p>The process of guideline development could coherently go hand in hand with a focus on addressing and responding to shortcomings on medical education, with expertise enlisted on the Guideline Development Committee to identify areas of shortfall in education on M.E. and to champion new guidelines and communicate them as part of continued professional development for practitioners and to introduce this topic to the medical school curriculum.</p> <p>cost saving recommendation would be to appoint a professional committee member with</p>
19	4	11 `"Key areas that will be covered 3 Management of ME/CFS"	<p>Avoiding the conflation of M.E. with disorders with quite different care needs is of paramount importance if harm is to be avoided.</p>
20	4	11 `"Key areas that will be covered 3 Management of ME/CFS"	<p>Addressing M.E. patient need implies:</p> <ul style="list-style-type: none"> • ameliorating symptom impact (given that there are few established treatments aimed at addressing underlying cause); in other words, a form of palliative care; • appropriate management advice for those patients who haven't already figured out how best to manage activity within the strictures of their illness; • an end to the tendency to fail to treat co-morbid conditions. <p>Suggest tap into existing expertise in the field of palliative care, as M.E. patients may benefit from expertise developed in this field. Rebut the present tendency of professionals mindset to shy away from the relevance of palliative care simply on the basis that the patient is not in an end of life situation, even though such expertise may hold key to best quality of life.</p> <p>Aim to provide robust guidance as to how people with M.E. are treated across the spectrum of provision, including: within 'specialist' clinics; hospital outpatients; hospital inpatients; community services (e.g. tube feeding specialist nurse); GPs.</p>
21	4	11 `"Key areas that will be covered 3 Management of ME/CFS"	<p>In keeping with the 2015 supreme court judgement on patient consent, the guideline must equip staff to explain to patients the prospective benefits and potential harms of any intervention(s) they are suggesting / advising:</p> <p>https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf</p> <p>http://www.medicalprotection.org/uk/for-members/news/news/2015/03/20/new-judgment-on-patient-consent</p>

22	4	17-21 “Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine’s summary of product characteristics to inform decisions made with individual patients..”	Because of the absence of much research evidence of the use of drugs for symptom relief in M.E., a pragmatic approach using drugs that may not be licensed for this condition is justifiable, based on pharmacological principles and the judicious use of therapeutic trials. To do otherwise is to condemn patients to what may be quite unnecessary suffering. Medications may have a logic as to why they may help certain symptoms, on the basis of the pharmacology of the drug and with an understanding of what underlying pathophysiology may be contributing/causing the symptoms that the physician is attempting to treat. Clearly this would imply that medication introduced on a 'trial' basis for a period in respect of the patient concerned, so that the patient is not left on the medication if it proves ineffective.
23	4	22 “Areas that will not be covered”	We welcome the qualification of the exclusion of “ <i>Specific management of symptoms where NICE guidance already exists</i> ” with “ <i>and management is not expected to be different in ME/CFS</i> ”. However this matter needs careful attention when developing the guideline. Notably, co-morbid conditions in people with M.E. may not respond to recommendations for these conditions in the same way as other patients - this may be because of the unique way in which their bodies respond to medications, another reason why this may occur is the M.E. patient’s adverse response to exercise / activity. Some consideration must be given to such issues when addressing co-morbid conditions in these patients within this guideline, if the intention is to reduce harm.
24	4	26 / 27 “Related NICE guidance, published”	Include on the list: <ul style="list-style-type: none"> • Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition NICE clinical guideline 32 (2006). • Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005) Please be aware that both are listed as ‘related NICE guidance’ on webpage for CG53 www.nice.org.uk/guidance/cg53/chapter/6-Related-NICE-guidance
25	5	5-6 “Related NICE guidance, published”	The guideline on: <ul style="list-style-type: none"> • “Common mental health problems: identification and pathways to care (2011) NICE guideline CG123” is not related to the care of people with M.E. and should not be listed as such.

26	5	9 “Related NICE guidance, in development”	The guideline in development on: <ul style="list-style-type: none"> • Suspected Neurological Conditions (GID-CGWAVE0800 https://www.nice.org.uk/guidance/indevelopment/gid-cgwave0800) should be included.
27	5	17 “NICE guidance about the experience of people using NHS services”	The Guideline on: <ul style="list-style-type: none"> • “Service user experience in adult mental health (2011) NICE Guideline CG136 is not related to the care of people with M.E. and should not be listed as such.
28	7	15 “Main outcomes”	Adverse effects / impact of treatment intervention or management strategy should be added to the main outcomes to be assessed.

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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