

10 year surveillance (2017) – [Chronic fatigue syndrome/myalgic encephalomyelitis \(or encephalopathy\) \(2007\) NICE guideline CG53](#)

Stakeholder consultation comments form - proposal for 'no update'

Consultation on the proposal for 'no update' opens on: 9am Monday, 10 July 2017

Comments on proposal to be submitted: no later than 9am Monday, 24 July 2017

Please enter the name of your registered stakeholder or respondent organisation below.

Please use this form for submitting your comments to NICE.

1. Please put each new comment in a new row.
2. Please note – we cannot accept comments forms with attachments such as research articles, letters or leaflets. If we receive forms with attachments we will return them without reading the comments. If you resubmit the comments on a form without attachments, this must be by the consultation deadline.
3. If you wish to draw our attention to published studies, please supply the full reference.
4. NICE is unable to accept comments from non-registered organisations. If you wish your comments to be considered please register via the NICE website or contact the [registered stakeholder organisation](#) that most closely represents your interests and pass your comments to them.

Organisation name – Stakeholder or respondent	The ME Association
Disclosure Please disclose whether the organisation has any past or current, direct or indirect links to, or receives funding from, the tobacco industry.	No current or previous links to the tobacco industry
Name of commentator:	Dr Charles Shepherd

[Developing NICE guidelines: the manual](#) gives an overview of the processes used in surveillance reviews of NICE clinical guidelines.

ID	Questions	Overall response yes / no	Comments Please insert each new comment in a new row
1	Do you agree with the proposal not to update the guideline?	NO	<p>The ME Association is shocked and surprised to learn that the expert group appointed by NICE to review all new relevant research evidence on clinical assessment, diagnosis and management of ME/CFS has concluded that there is no need to review or update the 2007 NICE guideline (CG 53) on ME/CFS.</p> <p>The MEA consistently takes the position that key parts of the 2007 NICE guideline on ME/CFS are unfit for purpose. In particular, recommendations relating to the use of cognitive behavior therapy (CBT) and graded exercise therapy (GET) for everyone with mild or moderate ME/CFS are inappropriate and need to be revised.</p> <p>We believe this is also the position taken by the vast majority of people with ME/CFS. We therefore published an online petition supporting our position and are carrying out an MEA website survey that gives people an opportunity to support the NICE guideline on ME/CFS if they wish to do so.</p> <p>The MEA petition, calling for a review of the guideline, opened on Monday 10th July. This has attracted over 14,000 signatures in less than two weeks. The petition can be viewed here:</p> <p>https://www.change.org/p/petition-the-nice-guideline-for-cfs-me-is-unfit-for-purpose-and-needs-a-complete-revision?recruiter=744708136&utm_source=share_petition&utm_medium=copylink&utm_campaign=share_petition</p> <p>The wording and current results from the MEA website survey, which opened on Tuesday 11July, are as follows:</p> <p style="text-align: center;">Do you think the NICE guideline for CFS/ME is working for you?</p> <p style="text-align: center;">Yes - I think it is (0%, 2 Votes) Yes - but it could be better (1%, 3 Votes) No - I think it needs a minor review (1%, 7 Votes) No - I think it needs a major review (95%, 565 Votes) I am not sure (1%, 4 Votes)</p>

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			<p style="text-align: center;">What's the NICE guideline? (3%, 16 Votes) Total Voters: 597 (at 4pm on Friday 20 July)</p> <p>MEA website link: www.meassociation.org.uk</p> <p>The principle reason we believe the NICE guideline must be reviewed is because it is no longer ethical to produce a 'one size fits all' guideline to the management of ME/CFS. The current guideline basically consists of recommending CBT and/or GET for everyone with mild or moderate ME/CFS. However, it fails to acknowledge differing views on both the value and potential harm that can occur when these two treatments are used as primary interventions for the majority of people with ME/CFS.</p> <p>We also have a number of other reasons, especially in relation to assessment and management of people with severe ME/CFS. These are set out in our response to question 2.</p> <p>Ethically speaking, we believe the only way forward is for NICE to revise the 2007 guideline on ME/CFS to ensure that:</p> <ul style="list-style-type: none"> (a) physicians and patients are fully informed about the reality of the international debate on the acceptability, effectiveness and safety of CBT and GET (b) people with ME/CFS are provided with information and guidance on approaches to management that they consistently report as being helpful and (c) there is meaningful information and guidance on the assessment and management of people with severe ME/CFS. <p>The current UK guidance from NICE on the management of ME/CFS is 'stuck in the past', is unethical, and is not acceptable to the patient community.</p> <p>If this unethical position continues following the stakeholder consultation process, The MEA will be left with no option but to continue to campaign for the NICE guideline to be reviewed.</p>

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2	Do you agree with the proposal to remove the guideline from the static list?	YES	<p>There are serious omissions and lack of detail in numerous parts of the current NICE guideline covering clinical assessment, diagnosis and management. Our recommendations for improvement were made in the comprehensive submission that we submitted in 2013 when we opposed the proposal to place the NICE guideline in the NICE static list.</p> <p>Website link to MEA recommendations re NICE static list consultation:</p> <p>http://www.meassociation.org.uk/2013/10/mea-opposes-plan-to-put-review-of-nice-mecfs-guideline-on-hold-23-october-2013/</p> <p>Having attended a meeting with Professor Mark Baker from NICE at the House of Lords on 25th June 2014, we were left with the clear impression that Professor Baker understood and accepted the concerns of the ME patient community about defects in the guideline. Consequently, we find it very difficult to understand why NICE decided to reinforce their inactivity over the guideline by placing it on the static list only a few months earlier in September 2013</p> <p>These are two relevant extracts from the Minutes for this meeting:</p> <p>2.2 Turning to the ME/CFS Guideline specifically, the Professor said that it did not meet our needs and it did not meet theirs (NICE's) either. The pressure for guidance started in about 2002 when the then CMO, Sir Liam Donaldson, wanted the subject "put to bed" in the form of advice to doctors that ME/CFS was a real illness and what they should do about it. It did serve a purpose because it was the only bit of guidance in the NHS on ME/CFS, but it was limited in its scope. It was designed to get patients seen and helped, but it assumed there were specialists who knew what to do – and there were not.</p> <p>2.4 In summary, Professor Baker said:</p> <ul style="list-style-type: none"> · He sympathised with the position we were in with the Guideline · The Guideline failed to address the real issues in ME/CFS

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			<ul style="list-style-type: none"> · It does not promote innovation · It had a disappointing impact on specialist care and commissioning issues. <p>Complete Minutes for this meeting can be found here: http://www.forward-me.org.uk/25th%20June%202014.htm</p> <p>We must, however, return to two key issues that are of major concern to the ME/CFS patient community. These relate to:</p> <p>(a) guidance on clinical assessment and diagnosis of ME/CFS and</p> <p>(b) the failure of NICE to provide any meaningful guidance on management of people with severe ME/CFS.</p> <p>Both issues were recently raised at a meeting at the House of Lords between members of the Forward ME Group of ME/CFS charities and two senior representatives from the Royal College of General Practitioners.</p> <p>Minutes for this meeting can be found on the Forward ME Group website: http://www.forward-me.org.uk</p> <p>Delays in diagnosis, resulting in no clear guidance, or even harmful guidance on management, creates a very distressing and unsatisfactory situation for patients.</p> <p>Both NICE and the Chief Medical Officer's Working Group report on ME/CFS have issued clear guidance on the timeline for making a diagnosis. The NICE guideline states:</p> <p><i>A diagnosis should be made after other possible diagnoses have been excluded and the symptoms have persisted for 4 months in an adult or 3 months in a child or young person and that this should be made or confirmed by a paediatrician.</i></p>

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			<p>Despite the NICE guidance being in place for almost 10 years, recent patient evidence collected by the ME Association indicates that less than 20% of people are diagnosed within 6 months of symptoms occurring. Over 60% are waiting a year or more.</p> <p>At the other end of the spectrum, a GP with special interest in ME/CFS sent in written evidence to the RCGP meeting relating to a GP trainee who had been chastised by her trainer for even making a diagnosis of ME/CFS.</p> <p>In addition, what has become known as the NICE guideline diagnostic criteria for ME/CFS is far too broad. This is in direct contrast to the much more selective criteria that has been proposed by the Institute of Medicine in America. Use of the NICE diagnostic criteria increases the possibility that people who do not meet one of the stricter research or clinical diagnostic criteria for ME or CFS can be diagnosed as having ME/CFS without proper consideration being given to other possible explanations for having ME/CFS like symptoms.</p> <p>Misdiagnosis is therefore another significant concern to The MEA. In support of this position, one research study reported that around 40% of people referred to a specialist ME/CFS service in Newcastle did not even have a diagnosis of ME/CFS on further assessment.</p> <p>Reference:</p> <p>Newton JL et al. (2010) The Newcastle NHS Chronic Fatigue Syndrome Service: not all fatigue is the same. <i>The Journal of the Royal College of Physician of Edinburgh</i> 40 (4): 304 - 307.</p> <p>Around 25% of people with ME/CFS are severely affected – being wheelchair, house, or bed-bound. This group faces a number of serious problems that are not being addressed in the current guideline.</p> <p>First is the lack of any meaningful guidance on clinical assessment of people with severe ME/CFS.</p> <p>Second is the failure to refer to serious neurological symptoms such as diplopia, blackouts, atypical</p>

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			<p>convulsions, loss of speech, and loss of swallowing necessitating nasogastric feeding – all of which are referred to in section 4.2.1.1 of the 2002 Chief Medical Officer's Working Group report on ME/CFS. The only reference to management of severe ME/CFS in the CG53 Quick Reference guidance is on page 17 where it recommends the use of telephone or email based management based on the principles of CBT and GET. This recommendation has not been welcomed or used by people with severe ME/CFS.</p> <p>Third is the almost complete lack of any form of domiciliary care or assessment being provided by hospital-based referral services for people with severe ME/CFS. When added to the fact that it has become increasingly difficult for people with severe ME/CFS to obtain a home visit from a GP, many are left with no form of on-going medical care at all.</p> <p>McDermott et al surveyed all of the 49 English NHS specialist CFS/ME adult services in England, in 2013. This involved a cross-sectional survey conducted by email questionnaire</p> <p>All 49 services replied (100%). 33% (16/49) of specialist CFS/ME services provided no service for housebound patients. 55% (27/49) services did treat patients with severe CFS/ME and their interventions followed the NICE guidelines. The remaining services (12%, 6/49) offered occasional or minimal support where funding allowed. There was only one NHS unit providing specialist inpatient CFS/ME provision in England.</p> <p>Reference:</p> <p>McDermott C, Al Haddabi A, Akagi H, <i>et al</i> (2014) What is the current NHS service provision for patients severely affected by chronic fatigue syndrome/myalgic encephalomyelitis? A national scoping exercise <i>BMJ Open</i> 2014;4:e005083. doi: 10.1136/bmjopen-2014-005083</p> <p>Fourth is the way in which lack of proper medical care results in people with severe ME/CFS having great difficulty in accessing social care. This situation resulted in an Inquiry by the All Party</p>

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			<p>Parliamentary Group on ME.</p> <p>Reference: Social care and ME/CFS – interim report prepared for the APPG on ME: https://www.actionforme.org.uk/uploads/pdfs/close-to-collapse-report-UPDATED.pdf</p> <p>Problems relating to late diagnosis and misdiagnosis, along with the difficulties in accessing both medical and social care are two key issues that must be re-visited by NICE. The only way to do so is through a proper review and update of the 2007 guideline.</p>
3	Do you have any comments on areas excluded from the scope of the guideline?	YES	<p>a) The NICE expert group appears to have ignored or dismissed the fact that outside the UK, especially in America, there has been a very significant shift in official guidance on management of ME/CFS away from the use of CBT and GET.</p> <p>In America, guidance on management issued by the highly respected Centres for Disease Control (CDC) has now dropped all reference to their previous recommendations relating to CBT and GET. As a result, the CDC is now producing a far more balanced, comprehensive and pragmatic overview of management of ME/CFS. This approach is welcomed by the US patient community, whereas the 'one size fits all' approach involving CBT and GET in guidance produced by NICE, is opposed by the UK patient community.</p> <p>Link to new CDC guidance: https://www.cdc.gov/me-cfs/treatment/index.html</p> <p>In a letter dated May 2017, sent to 85,000 doctors by Dr Howard Zucker, Commissioner at the New York Health Department, revised guidance relating to the use CBT and GET in ME/CFS is summarised as follows:</p> <p><i>In the past, cognitive behavior therapy (CBT) and a graded exercise therapy (GET) were recommended as treatments. However, these recommendations were based on studies that included patients with other fatiguing conditions. Because of the hallmark intolerance to exertion of ME/CFS, exercise may actually worsen the health of those living with this disease. Currently, there are no FDA approved treatments for ME/CFS.</i></p>

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			<p>Link https://drive.google.com/file/d/0B37JHmPXER6JZkZRd0hIalA2bUE/view</p> <p>With regard to the ethical position of the situation facing NICE, we cannot stress too highly that the significant change in direction taking place in America regarding the use of CBT and GET does necessitate a revision of the NICE guideline. This should reflect the fact that there is now a serious debate surrounding the use of these two treatments taking place amongst both patients and health professionals. This is the case regardless of whether the UK medical establishment agrees or disagrees with the US position.</p> <p>As organisations responsible for the nation’s health care, NICE and the Department of Health have a duty to protect every patients right to receive safe and appropriate care. They should therefore be producing recommendations on treatments that are acceptable, effective and safe – as well as providing up to date information that can be presented and discussed with patients as part of the long established principle of informed consent.</p> <p>The new position taken in the US establishes that there is growing and convincing evidence to support the view that people with ME/CFS have a serious and debilitating biomedical condition involving neurological, immunological and energy producing impairments. This is a condition that does therefore require a biomedical approach management. The change in position in America has profound ramifications in relation to a revision of the NICE guideline and cannot be ignored.</p> <p>b) Patient evidence on the acceptability, efficacy and safety of CBT, GET and Pacing appears to have either been dismissed or ignored by the expert group. This is in sharp contrast to the Chief Medical Officer’s Working Group Report on ME/CFS. The CMO report recognized the importance of taking patient evidence into equal account where there are strong and differing opinions on the value of CBT, GET and Pacing.</p> <p>Extensive patient led research carried by The MEA, and other ME/CFS charities, has consistently found that the majority of people find CBT to be of no value. Over 50% report that GET has made their condition worse.</p> <p>The MEA carried out the largest ever survey of patient reports on the use of CBT, GET and Pacing. This</p>

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			<p>was followed up with a detailed report containing qualitative and quantitative patient evidence. A paper carrying these results, which has been subjected to peer review, has been accepted for publication in the <i>Journal of Health Psychology</i>. A summary of the MEA report, along with a link to the full report, can be found here:</p> <p>http://www.meassociation.org.uk/2015/05/23959/</p> <p>c) The expert group has not given proper attention to the widespread and serious criticisms of the methodology and presentation of results from the PACE trial from academics, clinicians and patients.</p> <p>This criticism includes a letter to the editor of <i>Psychological Medicine</i> from over 100 clinicians, medical researchers, epidemiologists and statisticians, calling for the retraction of the PACE trial recovery paper and the re-analysis of the recovery data by Wilshire et al who concluded:</p> <p><i>The claim that patients can recover as a result of CBT and GET is not justified by the data, and is highly misleading to clinicians and patients considering these treatments.</i></p> <p>References:</p> <p>Letter to the editor of <i>Psychological Medicine</i>:</p> <p>http://www.meassociation.org.uk/2017/03/we-call-for-the-retraction-of-the-pace-trial-recovery-paper-open-letter-to-psychological-medicine-13-march-2017/</p> <p>Re-analysis of PACE trial recovery data: Wilshire C, Kindlon T, Matthees A (2017) Can patients with chronic fatigue syndrome really recover after graded exercise or cognitive behavioural therapy? A critical commentary and preliminary re-analysis of the PACE trial. <i>Fatigue: Biomedicine, Health & Behavior</i> 5: 43–56.</p> <p>http://www.tandfonline.com/doi/abs/10.1080/21641846.2017.1259724?journalCode=rftq20</p>
4	Do you have any	YES	The MEA Association is a member of the Forward ME Group of charities. We will repeat the position

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	comments on equalities issues?		<p>that was agreed by the whole group in relation to equality issues in the group response to NICE. This is as follows:</p> <p><i>In the context of well-understood conditions such as cancer, a significant possibility of need for biological medical care is immediately understood as sufficient to secure a right of access to that care. Based purely on the possibility of need, policy makers are clear that any patient or patient group who might well suffer from cancer has a right to access biological testing, treatment and support.</i></p> <p><i>Stigma about ME/CFS has made it difficult for policy makers to recognize the profound importance of their obligation to continue to protect that right in the context of this condition. Given the conclusion among US health authorities that ME/CFS is a biological condition for which patients do require biological testing, treatment and support, a significant possibility of biological need is a scientific fact for this patient group.</i></p> <p><i>Because the need for biological medical care is a possibility rather than a proven fact, it is unclear at this time whether policy makers have an obligation to proactively ensure that all patients in this group receive biological medical care. Still, the possibility of need is sufficient to establish that it is unethical for policy makers to knowingly obstruct access to biological testing, treatment and support for this patient group.</i></p> <p><i>Because the current guideline directs patient care squarely down the mental health track, it clearly does obstruct patients' access to biological testing, treatment and support. To avoid this ethical violation, we request that the guideline be revised to present a truthful, neutral picture of current debate about the nature and optimal management of ME/CFS.</i></p>

Please email this form to: surveillance@nice.org.uk

Closing date: 9am, 24 July 2017

PLEASE NOTE:

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, if NICE's reasonable opinion is that the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

