NICE National Institute for Health and Care Excellence

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	Local ME
Disclosure Please disclose whether the organisation has any past or current, direct or indirect links to, or receives funding from, the tobacco industry.	No, none
Name of commentator:	Jill Cooper *et al.*

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	Concerns about the quality of CG53 and its impact in practice are longstanding, and a matter of record. For example, in June 2014 Professor Mark Baker, then Director of the Centre for Clinical Practice at NICE, met with the Forward-ME Group of ME organisations, convened by the Countess of Mar. The minutes of this meeting indicate that a range of concerns were presented: www.forward-me.org.uk/25th%20June%202014.htm
			In March 2007, at which point a draft of CG53 had been circulated for comment but the final version as yet unpublished, the LocalME list-owner contributed to a submission to a Health Select Committee Inquiry into aspects of the work on NICE. This submission addressed three of the Select Committee Inquiry's questions: • why NICE's decisions are increasingly being challenged; • whether public confidence in the Institute is waning, and if so why; • NICE's evaluation process, and whether any particular groups are disadvantaged by the process. The final version of the guidance emerged later that year. The concerns raised in the memorandum to the Health Select Committee remained pertinent. Points made to the Health Select Committee with reference to CG53 included: (1) DIAGNOSTIC GUIDANCE - The Institute's guidance conflates M.E. - a neurological illness with a unique and distinctive clinical presentation - with chronic fatigue due to mental health problems. Management approaches which may help the latter group of patients are contra-indicated in respect of those with M.E. This basic flaw renders the guidelines unsuitable for their purpose.

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			(2) COMPOSITION OF GUIDELINE DEVELOPMENT GROUP (GDG) - Few, if any, of the GDG had clinical experience of the illness they were advising upon. Authoritative medical professionals and researchers with in-depth experience and understanding of the neurological disorder M.E. were absent, while representatives with a belief in a 'biopsychosocial' model - which does not stand up to critical scrutiny - were many.
			(3) ELIGIBILITY AND ASSESSMENT OF EVIDENCE A narrow view is taken as to what constitutes admissible evidence, with the potential for a broad range of relevant information to be disregarded. This can lead, as with the guideline on 'CFS/ME', to false conclusions and inappropriate and dangerous guidance.
			GET and CBT as a management strategy for CFS and ME is presented by NICE on the basis of what is perceived as 'best evidence'. However, NICE is ignoring the fact that many scientists have questioned and demonstrated that, on closer inspection, the research is not as rigorous as is necessary and findings are not sufficient to support the original hypotheses. We feel this is a shoddy approach towards recommending a form of management or treatment in a clinical guideline.
			Graded Exercise 'Therapy' (GET) is still included as a management strategy when NICE has been made aware that patients report that it worsens their symptoms. http://www.meassociation.org.uk/2012/05/our-cbt-get-and-pacing-survey-what-led-us-to-run-the-survey-and-what-we-hope-and-expect-will-be-learnt-from-it/ We are appalled that NICE plans to continue to recommend GET despite overwhelming patient feedback including from our own members that Graded Exercise has caused serious harm to many ME patients. Patients need to be listened to, including those who have become severely affected after attempting graded exercise. Findings from a membership survey conducted by the 25% ME Group, which specifically supports those who are severely affected, show that the incidence of adverse impact was high, with 82% of those who had

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			undergone graded exercise reporting that it had made them worse. It was also noted that some patients were not severely affected before trying GET." REF: ***Severely Affected ME (Myalgic Encephalomyelitis) analysis report on questionnaire***; 25% ME Group 2004. NB: Their most recent published information is from summer 2016 and is in keeping with the prior survey, with 86% made worse (The Quarterly, Issue 41, p25: http://www.25megroup.org/Information/Newsletter/issue%2041/PDF%20ISSUE%2041.pdf)
			The Surveillance document cites a 2017 Cochrane review of 8 studies as a reason to continue to recommend Graded Exercise Therapy (GET). However, although Clinical Guideline 53 states that Post Exertional Malaise (PEM) is a key clinical feature required for diagnosis (page 165 section 1.2.1), NONE of the 8 studies reviewed by Cochrane made it a requirement that PEM should be present. 5 used the Oxford criteria, which do not require it at all: Sharpe MC *et al.* ***A report - Chronic Fatigue Syndrome: Guidelines for Research*** Journal of the Royal Society of Medicine, 1991, 84, pp118-121 and the remaining 3 the 1994 CDC criteria, for which PEM is only optional: Fukada *et al.* ***The Chronic Fatigue Syndrome: a comprehensive approach to its definition and study'*** Annals of Internal Medicine 1994; 121: pp953-959 These studies are all, therefore, on a heterogeneous group and to apply the findings in guidelines for patients with PEM is unsafe.
			Indeed, the Cochrane review itself concludes, under the Heading - ***What does the evidence from the review tell us?*** "limited information makes it difficult to draw firm conclusions about the safety of exercise therapy." It also advises, under the Heading - ***Quality of the Evidence*** "However, the number of potential heterogeneity factors is high and the number of available trials is low; therefore we were limited in our ability to explore heterogeneity in a sensible way at the aggregate level."

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			We are sure that NICE will agree that the quality of the evidence and what the evidence tells us are both of relevance in the context of this surveillance review. However, by looking only at the abstracts of evidence published since CG53, it may be that this information has been missed. If this is at all indicative, we are of the view that this is a shoddy approach towards recommending a treatment in a clinical guideline. In any case, it is clear that the 2017 Cochrance review cannot be cited as providing straightforward and conclusive reinforcement of CG53's recommendations.
			The Surveillance document rightly refers to the PACE trial and notes that controversy surrounds this trial. However it fails to mention that it has been highly criticized by many scientists, both from the UK and abroad. Doctors and scientists who understand the illness need to be listened to. 101 international scientists and medics are here asking for retraction of a PACE trial paper that purports to refer to 'recovery': http://www.virology.ws/2017/03/13/an-open-letter-to-psychological-medicine-about-recovery-and-the-pace-trial/
			In our view, the PACE research publications have effectively been discredited. Even at best, the PACE trial shows that CBT and GET are not as efficacious as the researchers thought, so it does not support the promotion of those management strategies in a NICE guideline.
			Recent research backs our perspective, as it illustrates an illness that is not the same as the condition that PACE (and other behavioural research) authors are referring to, since it cannot be accounted for by imputed physiological effects of 'deconditioning' through inactivity. For example, research from Ronald Davis (Professor of Biochemistry and Genetics) and colleagues at Stanford University USA, including leading infectious disease

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			specialist Professor Jose Montoya, who was awarded a 2016 Top Doctor Award - dedicated to selecting and honoring those healthcare practitioners who have demonstrated clinical excellence while delivering the highest standards of patient care. Announcement at http://finance.minyanville.com/minyanville/news/read?GUID=32910992 Brief biography of Dr Montoya at : http://www.pamf.org/serology/montoya.html At the International Association for CFS/ME Conference in Fort Lauderdale last year, among more than 100 papers that further contribute to the evidence-base Dr Jose Montoya presented findings from a study involving 192 patients and 392 healthy but sedentary controls. He had found significant elevations for 17 specific cytokines, 13 of them pro-inflammatory, that correlated with symptom severity in the serum of ME/CFS patients compared with controls. Montoya said these findings "likely substantiate many of the symptoms experienced by patients and the immune nature of the disease". http://iacfsme.org/Conferences/2016-Fort-Lauderdale/Agenda An overview of Stanford's research work on immune system abnormalities (as of autumn 2014) can be found at: http://stanmed.stanford.edu/2014fall/immune-system-disruption.html http://stanmed.stanford.edu/2014fall/hacking-immune-system.html Other Stanford publications include this a small but robust study using different types of brain imaging, which found three distinct types of abnormality: ***Right Arcuate Fasciculus Abnormality in Chronic Fatigue Syndrome*** Michael M. Zeineh *et al.* Published online October 30 2014 Department of Radiology, Lucas Center for Imaging, Stanford University School of Medicine: http://bit.ly/1yLUTDA
			Even if NICE take the view that the above research is inconclusive, it is incumbent to advise our health professionals in line with a 'first, do no harm' approach. Asking a person to gradually increase exercise - or other form of activity - when the cause of

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			their condition has not been conclusively established may hold the potential for harm. For example, a person with Polymyalgia Rheumatica needs steroid treatment before being advised to try GET. The potential exists that exercise is contra-indicated in people with an unknown physiological disease if the underlying mechanism of the disease is not corrected. GET is a dangerous treatment for a patient with unidentified autoimmune disease and NICE in view of a substantial body of biomedical evidence - including evidence that directly contraindicates exercise - is wrong to encourage the medical profession to recommend it in the case of 'CFS/ME'. (As far as we are aware, NICE has been made aware of the biomedical evidence we are alluding to. If not, please ask and we will furnish some details.)
			The WHO classify myalgic encephalomyelitis as a neurological disorder (code G93.3), and index 'the chronic fatigue syndrome' to this classification. A classification with which the Department of Health concurs. CBT/GET are therefore no more suited as a primary treatment for ME/CFS than they would be for cancer, multiple sclerosis etc. They may possibly have some value as coping aids but they are not a treatment. CBT as currently researched and administered for ME and CFS patients is based on deconditioning and fear of exercise and is designed to change patients' beliefs about their illness to encourage them to undertake graded exercise. See P White: http://www.sciencedirect.com/science/article/pii/S0140673611600962 It is not, therefore, used as in other chronic physical illnesses like Cancer, Multiple Sclerosis to help patients adjust and cope with their illness.
			The Quick Reference Guide is the resource used by GPs, and states that one of the key priorities is: The health care professional should provide information about the range of interventions and management strategies as detailed in this guidance (such as the

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			benefits, risks and likely side effects). [page 4] Most Health professionals will be unaware of the following 1. the controversy surrounding research into the use of CBT and GET for patients diagnosed with CFS/ME. 2. that while NICE carry out a detailed research review process, this is rigidly blinkered, and does not grapple with the questions being raised by concerned patients and scientists. 3. That research studies into CBT and GET have been criticized by large numbers of scientists. 4. That GET has been the cause of worsening symptoms according to a vast body of patient reports. We consider that health professionals and patients have the right to know of the reports of harm and any controversy regarding the management strategies being recommended by NICE. At present, they are unable to accurately provide information about the range of interventions and management strategies as detailed in this guidance, in terms of the benefits, risks and likely side effects.
			ME and CFS are seen by many NHS UK healthcare providers and commissioners as somatoform illness, despite the biomedical evidence to the contrary and the fact that the WHO classify myalgic encephalomyelitis as a neurological disorder under G93.3, a classification with which the Department of Health concurs. There is widespread confusion with 'fatigue syndrome' - a mental/behavioural disorder (WHO ICD code F48.0). The guideline does nothing to dispel this and it is time NICE took the time to consider why this is happening and who benefits from such a serious factual error.

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			In view of the above, Myalgic Encephalomyelitis becomes 'lost' in this Guideline, including in relation to those who are severely affected.
			The existence of people presenting with M.E. in its severest forms almost seems to muddy the waters. The section on severely affected patients can only be found towards the end of the full guideline (over 300 pages into the document), where it is advised: "this is not intended as a definitive guide to the specialist CFS/ME care needed for this patient group, and further reading is recommended. REF 50: Crowhurst G. ***Supporting people with severe myalgic encephalomyelitis.*** Nursing Standard 1921; (21).
			Many of us contributing to this response have first hand experience of severe ME and it is not something patients and carers can ignore. It is a form of living hell. These patients need more help from NICE and the NHS. The most severely affected ME patients are unable to attend GP surgery or hospital - even by ambulance. Many such patients are currently receiving no healthcare at all, not even a GP home visit for monitoring purposes. The guideline should recommend that patients with ME who are housebound be entitled to home visits by their general practitioner, and if necessary specialists in other areas of medicine, including for identification and treatment of concurrent illnesses.
			The core defining feature of this illness is adverse impact of activity. In terms of access to healthcare, GPs should therefore be made aware that patients may relapse and be too ill to attend in future, even if they managed to get to the surgery at some point previously. As a forum for Local Groups, we hear of too many local group members denied a home visit after relapsing, and of people relapsing as a direct result of the effort of getting themselves to the doctor's surgery, having been denied a home visit.

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2	Do you agree with the proposal to remove the guideline from the static list?	yes	
3	Do you have any comments on areas excluded from the scope of the guideline?		
4	Do you have any comments on equalities issues?		

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.