**10 year surveillance (2017) –** [**Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (2007) NICE guideline CG53**](https://www.nice.org.uk/guidance/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

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| **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](https://www.nice.org.uk/guidance/cg53/documents/stakeholder-list-2) that most closely represents your interests and pass your comments to them. | |
| Organisation name – Stakeholder or respondent | Welsh Association of ME & CFS Support |
| Disclosure  Please disclose whether the organisation has any past or current, direct or indirect links to, or receives funding from, the tobacco industry. | There are no links to the tobacco industry |
| Name of commentator: | Mrs S C Penny |

[Developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/1-introduction-and-overview) 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 |
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| 1 | Do you agree with the proposal not to update the guideline? | No | Thank you for the opportunity to comment on this surveillance consultation.  We do not agree with the proposal not to update the guidance in CG53 on CFS/ ME.  We believe the NICE Guidance CG53 on CFS/ ME omits guidelines on key issues, includes guidance that is potentially harmful and is misleading to both patients and clinicians. It is in need of urgent revision.  The decision not to review the guidelines has been taken on the basis that evidence in other trials supports the original PACE trial results. No consideration has been given to the flaws that are common to all these trials:  **i)**             broad patient selection criteria, ignoring the possibility of subgroups requiring different management approaches and ignoring the wide range of severity experienced by patients, or the possible differences between children and adults or men and women – research has repeatedly been shown that different criteria identifies different groups of patients and reduces the usefulness of research results e.g. Baraniuk <http://www.tandfonline.com/doi/abs/10.1080/21641846.2017.1353578?journalCode=rftg20> Johnston <http://hqlo.biomedcentral.com/track/pdf/10.1186/1477-7525-12-64?site=hqlo.biomedcentral.com> Nacul <http://www.tandfonline.com/doi/full/10.1080/21641846.2017.1273863>, & Jason <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3658447/>  ;  **ii)**            measuring only subjective outcomes;  **iii)**           the lack of double-blind, randomised, placebo-controlled trials, especially as some trials have actively sought to influence the results by promoting their approach as ‘the most effective therapies’;  **iv)**           assumptions about the nature of the illness, the factors that sustain it and the suitability of exercise therapy which are contradicted by scientific research into the illness.  The PACE trial was set up to validate the evidence base for GET & CBT, which was recommended for mild to moderately affected people with CFS/ME. <https://www.nice.org.uk/guidance/cg53/chapter/4-Research-recommendations>. Its failure to replicate those results, without the goalposts being moved, should not be ignored, in spite of the authors’ continuing support of and justifications for it. It is not good research practice to change the way outcomes are measured part way through a trial, even if 2 oversight committees were involved, or for smaller earlier trials to over-ride the results of the later larger one. Rather the failure of the PACE trial should raise questions about the earlier studies.  A new Cochrane review will only be of value if a stricter assessment of the quality of research is carried out.  A recent study by the FITNET researcher Dr Crawley concluded that only 30% derived some benefit from specialist treatment in England for CFS (largely CBT and GET based) and only 5.7% considered themselves recovered. They concluded that ‘CFS/ME is a long term condition that persists for the majority of adult patients even after receiving specialist treatment’. This is an important comment by a CBT researcher and should influence considerations of how cost effective CBT and GET are when applied to all patients, without any attempt to assess whether it might be beneficial.  The guideline contains little to help healthcare and social care professionals to give ongoing care and management advice to patients who do not improve, who remain ill over a long period and who are severely affected. The guidelines do not recommend CBT or GET for the severely affected, but fails to provide adequate alternative guidance. The assumption that patients must be encouraged to do more and more regardless of how ill they are is rife within the NHS and Social services. Support can be withdrawn because there is no understanding that ME is a long term condition, that refusing support has a negative physical and mental effect, or that some people do not improve and need continuing palliative care. The guideline should include such information and direct professionals to appropriate guidance to caring for the severely ill.  The guideline should be clear that there is a difference between CBT that aims to change negative illness beliefs about ME and CFS, and CBT that aims to help you adapt and cope better with the limitations of the illness. The latter may have value as it provides support and better understanding but does not mitigate against some degree of improvement or recovery, where the former is simply offensive.  A number of other issues also need to be updated e.g. Pharmacological interventions (1.6.3.2).  NICE recommend amitriptyline for pain but there is recent research which links this drug directly with an increase in developing dementia.  This recommendation should be withdrawn immediately <http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2091745>  A failure to update the guideline will simply drive a bigger wedge between the medical and the patient communities.  Many already go without medical help due to the pressure they experience to receive inappropriate psychological therapy and/or physiotherapy.  A failure to acknowledge patient experience and the flaws in research trials (PACE, FUTNET, GETSET, MAGENTA etc. have been ridiculed all over the world), places the NICE guidelines in the same category. They will continue to fail to be a valuable and believable resource. |
| 2 | Do you agree with the proposal to remove the guideline from the static list? | Yes | If the reason for being removed from the static list is because there is ‘important ongoing research in this area’, then we agree. The trials into rituximab (<https://clinicaltrials.gov/ct2/show/NCT02229942>) and cyclophosphamide (**EudraCT Number:** 2014-004029-41) are important examples of trials which could make a life changing difference to many of the people with ME in the UK.  We do not consider the trial mentioned - ’UK trial of internet-based cognitive behavioural therapy in children and young adults’ – as important research into CFS or ME. On the contrary the FITNET-NHS trial is a waste of time and money as it shares many of the same flaws as the PACE trial, including lack of objective measures. The leaflet accompanying the trial claims that CBT will aim to ‘change negative thinking’. There is no evidence that negative thinking causes or perpetuates ME or CFS in any of the subgroups of patients. No attempt will be made to identify individuals with this specific problem it is simply assumed that all subgroups of people falling under the broad heading of CFS suffer from negative thinking.  This trial appears to be attempting to replicate results from a similar FTNET trial in the Netherlands where no difference was found between the active and control groups at long-term follow-up (<http://pediatrics.aappublications.org/content/early/2013/05/08/peds.2012-2007>),which is consistent with every other trial of CBT. The trial has been criticised by many professional researchers around the world e.g. ‘the height of clinical trial amateurism’ by Dr Bruce Levin of Columbia University and It’s ‘more meaningless research based on flawed assumptions and bad studies’ by Prof David Tuller of University of California, Berkeley.  WAMES wishes to see the research into dysfunction in the body’s systems (neuro, immune, endocrine etc.) play a more important role in determining the NICE guidelines. We do not believe it makes sense to promote a management approach, simply because it has been more widely researched than others, when i) there is research about the role of exercise in the dysfunctional ME body that contradicts the assumptions of such a management approach; ii) the research does not use objective measures. |
| 3 | Do you have any comments on areas excluded from the scope of the guideline? | Yes | When research into an illness is in the early stages and there is so little good quality research currently available into drugs and therapies for ME and CFS, it does not make sense to ignore the evidence of patients or the clues to pathogenesis being uncovered by scientific researchers.  More effort should be given to assessing the research into management approaches **in the context** of what scientists are uncovering about the multisystem dysfunction in the body, the role of exercise in altering the way body systems function and the importance of the post exertional response affecting symptoms.  The lack of benefit and experience of harm that patients report should also be given greater weight. |
| 4 | Do you have any comments on equalities issues? | No |  |

**Please email this form to:** [**surveillance@nice.org.uk**](mailto: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.