National Institute for Health and Care Excellence

Proposed Static List Clinical Guidelines

Stakeholder Comments

Please enter the name of your registered stakeholder organisation below. **NICE is unable to accept comments from non-registered organisation or individuals. If you wish your comments to be considered please register via the NICE website or contact the registered stakeholder organisation (links to stakeholder lists are at the bottom of this document) that most closely represents your interests and pass your comments to them.**	
Stakeholder organisation:	**INVEST in ME (UK Charity Number 1114035)**
Name of commentator:	Kathleen McCall (Chairman)

Comment No.	Guideline title and number comment relates to, e.g. CG29 dental recall	Agree / Disagree with proposal to put on the static list	**Comments** Please insert each new comment in a new row. Please do not paste other tables into this table, as your comments could get lost – type directly into this table
1	CFS/ME (CG53)	**DISAGREE**	In order to comment on the recommendation by NICE not to perform a review of the guidelines it is not sufficient merely to look for new evidence which has come about in recent years - one necessarily needs to look back on the original guidelines to understand what a failing they were and what they missed. We use the comments from our original submission in this document. To comment on why a review of the guidelines is required it is necessary to repeat that the original guidelines were at fault and they were rejected almost unanimously by the patient community. This left the NICE guidelines in a state where they became, and have become, of little use to anybody – neither to patients nor to healthcare staff. NICE state – "Putting patients and the public at the heart of NICE's work NICE is committed to involving patients, carers and the public in the development of its guidance and other products. By involving the very people for whom the guidance will be relevant, we put the needs and preferences of patients and the public at the heart of our work." [**1**] It was no small matter that the very population for whom the NICE guidelines were supposedly intended to benefit were instead forced to take NICE to a Judicial Review, such was the dissatisfaction with the guidelines and it was plain for all to see that patients were not listened to. Over twenty internationally renowned ME/CFS experts provided Statements in support of the Claimants" case for the Judicial Review of the National Institute for Health and Clinical Excellence (NICE) Clinical Guideline on "CFS/ME" that was brought by ME/CFS sufferers **[2]** IiME concluded that the basis of the NICE Guidelines was in viewing as broad a section of fatigue states as possible, where high quality biomedical research into ME was ignored. Essential research showing the multi-system nature of ME was not considered or discussed. There was little in the guidelines that would persuade a GP to conduct a proper and full medical examination before diagnosis. This was a major failing. There was almost universal condemnation of the guidelines by patients, patient support groups, most ME charities and even healthcare providers. The only organisations who agreed with the guidelines were those who had accepted government money in the past to support government policies on ME or those who had vested interests and gained from promoting ME as a behavioural illness. **1]** http://www.nice.org.uk/getinvolved/patientsandpublic/patientandpublichome.jsp **2]** Statements of Concern about CBT/GET provided for the High Court Judicial Review of February 2009 http://www.investinme.org/Article-361%20Statements%20of%20Concern%20-%20CBT-GET%20JR%20Feb09.htm

2	CFS/ME (CG53)	**DISAGREE**	NICE state in the original guidelines – “There is a lack of epidemiological data for the UK, so population estimates are based on extrapolations from other countries. Overall, evidence suggests a population prevalence of at least **0.2–0.4%.** This means that a general practice with 10,000 patients is likely to include up to 40 people with CFS/ME; half of these people will need input from specialist services.” **[3]** This would place the number of patients to be approximately 240,000 – if the higher estimate were taken. This figure is what the NICE guidelines was based on. Recently (a month ago) the National Institute of Health Research (NIHR) awarded £1.2 million to Bristol University, including Dr Esther Crawley for research into CFS/ME. On their web site they state that – “Two new research projects that aim to advance treatment for people with Chronic Fatigue Syndrome [CFS] or Myalgic Encephalopathy [ME], which affects an estimated 600,000 adults and children in the UK, have been awarded funding totalling nearly £1.2 million from the National Institute for Health Research [NIHR].” **[4]** There is, therefore, a difference between the original NICE guidelines prevalence figure of 240,000 and the recent NIHR-awarded Bristol University projects’ figure of 600,000 – a difference of over 350,000. This must mean either that – - an epidemic is occurring to explain the 100% + increase in patients in seven years; - or that Bristol University/Dr Esther Crawley’s figures are wrong (in which case the NIHR may like to revisit their grant award); - or the original NICE figures are wrong. As the newly formed Science Media Centre/ Medical Research Council CFS Collaborative (formed in April 2013) has already stated that the prevalence is 600,000 then we must assume that the original NICE figures were incorrect or that we have an epidemic occurring. Either of these facts means new guidelines are necessary. Certainly these figures demand that the original NICE guidelines premise of one size fits all management strategies cannot be beneficial for such a range of patients. One needs to separate different conditions currently under the CFS umbrella and not lump them all together. A new review is necessary now. **3]** http://www.nice.org.uk/nicemedia/live/11824/36193/36193.pdf **4]** http://www.bris.ac.uk/news/2013/9741.html
3	CFS/ME (CG53)	**DISAGREE**	At a recent meeting organised by Invest in ME with Dr Martin McShane, Director of Domain Two, NHS Commissioning Board **[5]**, was presented with evidence of families of ME patients being prosecuted due to their children having ME and the healthcare staff dealing with the cases not understanding the disease process sufficiently. This is far from uncommon. Dr McShane stated that he understood the family’s anger and said he would feel exactly the same if he was in their situation. He expressed his apologies and acknowledged the need to balance the system to ensure that situations such as this would not occur and that a major task was to alleviate stress for patient and carer. He said he heard what the parents were saying This means that the NICE guidelines have failed as the guidelines still allow this intolerable situation to occur. We need to address the major flaw in the NICE guidelines – namely its bias toward promoting a predetermined one-size fits all approach to ME by continually highlighting CBT and GET therapies despite widespread derision from ME patients. **5]** http://www.investinme.org/IIME-Newslet-1303-04.htm

4	CFS/ME (CG53)	**DISAGREE**	In stating that the guidelines for ME will be placed on a static list NICE state – The following criteria have been applied to identify suitable guidelines to be placed on the static list: · No quality standard commissioned or · A previous full review which yielded a 'no update' decision and at that time no major ongoing studies/research was identified as due to be published in the near future (that is within the next 3-5 years) When that decision regarding a “no update” was made then NICE failed (again) to recognise biomedical research into ME. New research has and is being carried out with conclusions to be reached. Yet new research has been performed since **[6]** and is scheduled to begin again with a multi-centre clinical trial **[7]**. This research will be completed well within the next 3-5 years. Also research being funded by Invest in ME has and is being started and the results will be available well within the next 3-5 years – IiME/UCL Rituximab clinical trial **[8]** and IiME/UEA gut microbiome study **[9]**. This therefore is another reason for a review and nullifies the NICE statement that “no major ongoing studies/research was identified as due to be published in the near future (that is within the next 3-5 years)”; **6]** http://www.plosone.org/article/info:doi/10.1371/journal.pone.0026358 **7]** B-lymphocyte depletion with rituximab induction and maintenance in CFS / ME. A multicenter, randomized, double-blind, placebo-controlled study. Project: flug, Oystein Project coordinator: Haukeland University Hospital, Helse Bergen http://bit.ly/111BQ6D **8]** A UK Rituximab Clinical Trial for ME http://bit.ly/HeOfRu **9]** A role for a leaky gut and the intestinal microbiota in the pathophysiology of myalgic encephalomyelitis http://bit.ly/11etHil
5	CFS/ME (CG53)	**DISAGREE**	NICE state – “Clinical guidelines placed on the static list will be reviewed every 5 years to determine if they should remain on the static list. Routine surveillance every 2 years (as per the process for active guidelines) would not be carried out on guidelines transferred to the static list. ” This is negligence by a body that refers to its own “excellence” Dr Clare Gerada (chair of Royal College of GPs) stated that GPs know very little about ME [**10**]. Therefore to leave the current outdated and unusable NICE guidelines for ME for another 5 years, just sitting on the shelf with no updates reflecting the current poor education regarding ME and without any knowledge of the biomedical research performed/about to be performed, would effectively mean that no clinical guidelines for ME will have been reviewed for 12 years. That is unacceptable. This would show not only contempt for the patients and families suffering from the effects of this disease – it would also show gross incompetence and negligence by NICE. Patients are currently being misdiagnosed, mis-treated and healthcare staff are being mis-informed and the current unsatisfactory status cannot be left for another generation. GPs are left in a situation where their patients have rejected NICE, they do not understand enough about the disease, they are not familiar with the real effects and consequences of ME or of the possible research producing data. The chair of the GPs organisation admits that GPs do not know enough about ME – seven years after the NICE guidelines were published! **10]** Invest in ME International ME Conference (IIMEC8) London May 2013 http://bit.ly/10VfRhu

6	CFS/ME (CG53)	**DISAGREE**	NICE state – “Consideration to transfer a clinical guideline back to the active surveillance list may occur in the following circumstances: · The high level review at 5 years yields new evidence which may impact on the guidance · Stakeholders notify NICE of relevant new evidence which may impact on guidance at any time point, for example safety data. · A quality standard is commissioned that relates to a guideline on the static list ” We submit that – New evidence is available for ME A quality standard needs to be commissioned urgently The PACE trial **[11]** demonstrably proved that CBT and GET (the primary treatment recommendations of the NICE guidelines) do not work. Many articles have proven the PACE Trial to show that CBT and GET do not benefit ME patients and do not back up the original NICE guidelines’ recommendations **[12]**, **[13]**. NICE guidelines should be updated to reflect recent evidence that the recommended therapies in the existing guidelines (CBT and GET) do not lead to objective improvements in physical activity (6min walking test in PACE), increased employment rates or reduce service costs. [PACE] References: **11]** Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60096-2/fulltext **12]** The PACE Trial - Recovery Rates Published Observations from the PACE recovery study http://www.investinme.org/IIME-Newslet-1302-02.htm **13]** The PACE Trial: An Expression Of Concern -A Summary http://www.investinme.org/Article430%20The%20PACE%20Trial-Expression%20Of%20Concern%20A%20Summary.htm

Please add extra rows as needed
Please email this form to: staticlist@nice.org.uk

Closing date: 5pm on 23rd October

PLEASE NOTE: The Institute reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion or the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

Registered Stakeholder Lists:

1. A model of service provision for pregnant women with complex social factors (CG110)
2. Acutely ill patients in hospital (CG50)
3. Antenatal care (CG62)
4. Antisocial personality disorder (CG77)
5. Barrett’s oesophagus – ablative therapy (CG106)
6. CFS/ME (CG53)
7. Colonoscopic surveillance (CG118)
8. Common mental health disorders (CG123)
9. Critical illness rehabilitation (CG83)
10. Dental recall (CG19)
11. Diarrhoea & vomiting in children under 5 (CG84)
12. Donor breast milk (CG93)
13. Drug misuse – opioid detoxification (CG52)
14. Faecal incontinence (CG49)
15. Food allergy (CG116)
16. Metastatic malignant disease of unknown origin (CG104)
17. Metastatic spinal cord compression (CG75)
18. Neutropenic sepsis: prevention and management in cancer patients (CG151)
19. OCD & BDD (CG31)
20. Prophylaxis against infective endocarditis (CG64)
21. PTSD (CG26)
22. Respiratory tract infections (CG69)
23. Sedation in children (CG112)
24. Self-harm (CG16)
25. Surgical management of OME (CG60)
26. Urinary incontinence in neurological disease: management of lower urinary tract dysfunction in neurological disease (CG148)
27. When to suspect child maltreatment (CG89)