24th January 2006

Dear Dr Walsh

re: **"How to put NICE guidelines into practice" (BMJ 2006:332:143)**

The article in this week's BMJ rightly states: "Providing guidelines can be a laborious job. They have to be evidence based, up to date, and reliable. To produce good ones you have to do a thorough literature search and get input from a range of interested parties, from patients to professors".

We entirely agree, especially about the need for comprehensive trident evidence to underpin the guidelines.

Some of your readers may not be aware that in one particular disorder (ME/CFS – myalgic encephalomyelitis / chronic fatigue syndrome) for which NICE is currently compiling guidelines that are due early in 2007, on the influence of its advisors NICE is restricting itself to RCTs.

Most of the very few RCTs available have been carried out in the UK by those same NICE advisors themselves. Despite the fact that ME has been classified as a neurological disorder in the ICD since 1969 – where it is also called CFS as well as PVFS (postviral fatigue syndrome) – the NICE advisors believe it to be a behavioural disorder. For almost two decades they have disregarded the significant body of international evidence of its organic pathoaetiology. The lead proponent of the psychosocial model is Professor Simon Wessely of GKT School of Medicine.

We maintain it is important that none of the NICE guidelines should over-ride the empirical evidence, but in the case of ME/CFS, this is what is happening.

Such is the tide of public and professional concern about the misinformation that currently surrounds ME/CFS – which includes the Systematic Review carried out in October 2005 by Bagnall et al from the Centre for Reviews and Dissemination at York specifically to support the forthcoming NICE guidelines -- that a Parliamentary Inquiry chaired by Dr Ian Gibson MP has been established. Over 100 people, including patients and professionals, have already submitted evidence. Should you wish to access some of these submissions, they are available at http://www.25megroup.org

One of the matters it is anticipated will be addressed by the Parliamentary Inquiry is the data contained in the October 2005 Systematic Review concerning the diagnosis, treatment and management of CFS/ME in adults and children, which is manifestly not comprehensive and without doubt is heavily biased toward a psychosocial model. It clearly lacks a balanced consideration of the available peer-reviewed literature.

Our concern is fully referenced in two documents: firstly in a 39 page analysis of the relevant section of the CRD Review by Hooper and Reid entitled Inadequacies of the York (2005) Systematic Review of the CFS/ME Medical Evidence Base available online at http://www.meactionuk.org.uk/FINAL_on_NICE_for_Gibson.html and secondly in an article

entitled “Pinching’s Perception?” available at
http://www.meactionuk.org.uk/Pinchings_Perception.html .

Mindful of some of the demonstrably erroneous conclusions of the CRD 2005 Systematic Review about the efficacy of cognitive behavioural management regimes, it is notable that Wessely himself is on record in this week’s BMJ as stating:

“Epidemiological research requires representative samples and high response rates. Response rates matter for two reasons. Firstly, if the sample size is reduced, the study loses statistical power and, therefore, may not be able to identify (and quantify) any true effects. Secondly, a low response rate means that participation bias is almost inevitable” (ref: Consent, confidentiality, and the Data Protection Act. Amy Iverson, Matthew Hotopf, Simon Wessely et al. BMJ 2006: 21 January: 332:165-169).

Even more pertinently, Wessely is also on record as stating:

“Sound evidence for the treatment of (ME)CFS is still poor. For patients seeking active treatment, cognitive-behavioural therapy (CBT) and graded exercise therapy (GET) are currently the best available options. However, it should be kept in mind that evidence from randomised trials bears no guarantee for treatment success in routine practice. In fact, many (ME)CFS patients, in specialised treatment centres and the wider world, do not benefit from these interventions” (ref: The act of diagnosis: pros and cons of labelling chronic fatigue syndrome. Marcus JH Huibers and Simon Wessely. Psychological Medicine 2006 [pre-publication]).

It is surely regrettable that Wessely persistently fails to apply his own criteria when he is addressing the issue of ME/CFS, his studies of which having been criticised in the literature for lacking the necessary rigorous scientific scrutiny.

Unless corrective measures are taken by NICE to ensure that their final guidelines for ME/CFS are unbiased and are based on sound and reliable evidence, they will not be effective.

Your article says that in November 2005 NICE commissioned BMJ Learning to produce a series of learning modules based on its guidance. If the future module for ME/CFS were to rely solely upon the intended NICE guidelines, it will not exemplify the standards you endorse in your article.

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competing interests: members and supporters of the ME community