To Dr. David Coombs

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26/11/18

Email complaints@nice.org.uk
From: LocalME, NICE Guideline Stakeholders

Dear Dr. Coombes,

We are writing in response to the publication of the ME/CFS NICE guideline committee member list. Please take this letter as a formal complaint about the composition of the committee.

We, LocalME, NICE Guideline Stakeholders[1], have previously pointed out[2] the harm of the psychiatric biopsychosocial model which has led to the neglect of patients (particularly those with severe ME), the promotion of harmful exercise therapy, and impeded clinical assessment and research into ME. The harm has not been properly evaluated, partly because of the lack of a “yellow card” system for non-pharmacological therapies. Nevertheless, the biopsychosocial model and these therapies have been heavily criticised by a large number of scientists as well as patients, and is countered by extensive evidence of pathophysiology in ME patients.

In reviewing the NICE guidelines, it is important to move forward constructively to ensure that no more harm is done by healthcare professionals to patients with ME. The committee should therefore be heavily weighted towards those with biomedical expertise, not, as so far announced, towards those who favour graded exercise therapy and cognitive behaviour therapy, many having a recent, clearly stated clinical approach supporting GET and CBT. If they were all to remain on the committee, the committee would be biased and there will be an issue of "predetermination"; there is a real risk that the new guidelines will do harm to patients.

The new guideline must be based on objective review of research worldwide and the committee should include those with clinical experience of ME, but in addition, the committee should include members outside of the field of ME to ensure the necessary spread of expertise and objectivity.

We consider that expertise in three fields are paramount:

· Firstly, expertise in cardiology is needed to review evidence for testing and treatment for abnormalities in cardiovascular function in ME patients, for which there is now an abundance of evidence that they are highly prevalent, yet for which clinical assessment is proscribed by the current guidelines. These abnormalities include low cardiac output, reduced cardiac mass, reduced blood pool volumes, small left ventricular size, abnormal left ventricular myocardial dynamics, neurocardiogenic syncope, increase in low-frequency heart rate variability, shorter-than-usual QT interval, abnormal Holter readings, preload failure, orthostatic intolerance, and postural tachycardia. Note that these abnormalities are not due to de-conditioning.

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1 LocalME is a long standing and respected organisation of 196 ME local group leaders who work along side all the major ME charities to represent the patient care voice.

2 Stakeholder Comments Table 21 June 2018 to 26 July 2018 Local ME 44-48. https://www.nice.org.uk/guidance/gid-ng10091/documents/consultation-comments-and-responses-2

· Secondly, expertise in special educational needs and disabilities, since all children and young people with ME need additional support with their education, and many cannot attend school or college at all. Most will therefore need an Education, Health and Care Plan which takes into account the fluctuating nature of ME, its effects on cognitive function, and the need to protect children from over-exertion (the most common cause of relapse) in the face of pressure to attend school.

· Thirdly, there should be at least one member of the committee with extensive, direct experience of home-visiting and treating patients with severe ME who are bedbound or need stretcher ambulance to attend hospital, and specialist expertise in preventing malnutrition in patients with feeding problems.

Expertise is also needed to assess the evidence for testing for physiological response to exercise, testing for mitochondrial dysfunction and other abnormalities in energy metabolism, oxidative stress, immune abnormalities, gastrointestinal abnormalities, imaging for cerebral blood flow deficits and intracranial hypertension, small fibre neuropathy, abnormalities in visual processing, abnormal gait pattern and so on. We believe that only a multidisciplinary composition will provide the expertise necessary to ensure that appropriate clinical assessment and treatment for ME, based on evidence from robust clinical and scientific research, are included in the guidelines.

Wilshire et al[3] pointed out that graded exercise therapy in the PACE trial yielded worse results than those obtained in patients with chronic heart failure despite ME patients being primed to expect improvement. Each and every member of the committee should understand and accept that there exists in ME an underlying pathophysiology that can lead patients to have worse outcomes than those with chronic heart failure. We believe that the composition of the committee membership should be revised and remedied as soon as possible.

Yours sincerely

Barbara Robinson, LocalME Representative

On behalf of LocalME, NICE Guideline Stakeholder

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3 Wilshire CE, Kindlon T, Courtney R, Matthees A, Tuller D, Geraghty K, Levin B. Rethinking the treatment of chronic fatigue syndrome—a reanalysis and evaluation of findings from a recent major trial of graded exercise and CBT. BMC Psychol. 2018 Mar 22;6(1):6