

January 22, 2014

To: Institute of Medicine Committee on
Diagnostic Criteria for ME/CFS

Re: Important points to remember during the
study

PANDORAorg.net

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Critique of NICE Guidelines (2007)

A member of the Let's Get It Right group of patient advocates asked us to address the National Institute for Healthcare Excellence (NICE) guidelines for myalgic encephalomyelitis / chronic fatigue syndrome, created in England. These guidelines are mentioned in the Institute of Medicine statement of work for this committee as one of the multiple considerations in your study.

The Guideline Development Group (GDG) developed these guidelines with the aim of:

- Increasing the recognition of ME/CFS
- Clinicians to acknowledge the reality and impact of the condition and the symptoms
- Improving access to appropriate services
- Supporting consistent service provision
- Improving care for patients, particularly for those with severe CFS/ME

However, the NICE guidelines fail to meet these objectives and thus should be rejected by the Institute of Medicine's committee charged with determining an accurate and useful clinical diagnostic criteria for ME/CFS.

The reason these United Kingdom Health Service guidelines are flawed and harmful is because they are based on outdated and flawed research and flawed interpretation of research results.

NICE Guidelines Include Harmful Treatment Recommendations

NICE Guidelines 2007 states that cognitive behavioural therapy and/or graded exercise therapy should be offered to people with mild or moderate ME/CFS and provided to those who choose these approaches. It says these are the interventions for which there is the clearest research evidence of benefit.

This is an inaccurate statement as graded exercise, the type that includes pushing beyond fatigue, has been shown to not be beneficial. It is actually harmful. This is revealed in a report conducted by International Association of CFS/ME (IACFS/ME) where the reporting of harms associated with graded exercise therapy and cognitive behavioural therapy in these patients is found to be lacking in the research conducted and highlights that healthcare professionals, researchers and patients need high quality data on harms to appropriately assess the risks versus benefits of CBT and GET.¹

¹ <http://www.iacfsme.org/LinkClick.aspx?fileticket=Rd2tIJ0oHqk%3D&>

Additionally, the Centers for Disease Control and Prevention recommends pacing activity and cutting back on activity if the activity level exacerbates symptoms. In some cases, this might mean only stretching in a supine position and small increments of body weight (legs and arms) lifts for strength. Someone more able can do more activity. But pushing is discouraged as being harmful.

Moreover, the subjective research upon which NICE relies on to support the view of graded exercise does not take into account the most recent biological research findings that ME/CFS patients have:

- Oxidative stress²
- Muscle acidity
- Muscle fibre abnormalities and muscle damage³
- Oxygen transportation impairment⁴
- Circulatory and cardiac abnormalities⁵
- Mitochondrial dysfunction

Moreover, NICE guidelines continue to be predominantly influenced by subjective psychological research conducted by the same individuals who have a hand in developing the guidelines in the first place.

The 2011 Pacing, graded Activity and Cognitive behavior therapy: a randomized Evaluation (PACE) Trial in England, led by psychiatrists, that was a randomized controlled trial that compared cognitive behavior therapy (CBT), graded exercise therapy (GET), adaptive pacing therapy and specialized medical care. Its flawed results have been touted as confirming the NICE guidelines for this disease, whereas it does not. The PACE trial once again focused on subjective responses of patients and is heavily influenced by a behavior-focused erroneous paradigm.

The paper was found to omit the reporting of harms as identified by the IACFS/ME⁶. Furthermore, conflicting results by similar larger scale research conducted by the ME Association at the same time as the PACE Trial is not considered in the formation or modification of NICE guidelines. Pacing is rated very strongly as the most effective form of management and is consistent with several other surveys of patient opinion and a large amount of anecdotal reports, including an ME association 2010 survey.⁷

- Results for CBT: 25% improved; 55% reported no change; 20% made worse (sample size=2137)
- Results for GET : 22% improved; 21 reported no change; 57% made worse (sample size = 997)
- Results for pacing: 71% improved; 24% no change; 5% made worse (sample size=906)

² <http://www.cfs-ireland.com/scientific/31.htm>

³ <http://www.cfs-ireland.com/scientific/17.htm>

⁴ <http://www.cfs-ireland.com/scientific/15.htm>

⁵ <http://www.cfs-ireland.com/scientific/14.htm>

⁶ <http://www.iacfsme.org/LinkClick.aspx?fileticket=Rd2tIJ0oHqk%3D&>

⁷ http://www.meassociation.org.uk/?page_id=1345

A similar study to the PACE trial, which was carried out in Spain and published in January 2011, found no benefits from CBT and GET when compared to standard medical care.⁸

Contrary to the assumptions of many, physical deconditioning does not seem to be a perpetuating factor in CFS.⁹

The NICE guidelines fails to take into considering the conflicting research findings on GET and CBT and pacing, as well as biological research findings into the benefit and harms of exercise. Guidelines should not be based on just subjective research alone conducted by the same individuals that have a hand in creating the guidelines.

Lastly, the ME Association identifies that the form of adaptive pacing used in the PACE trial is not the same as the model they recommend and which is favoured by the overwhelming majority of people with ME/CFS.¹⁰ Clarification of what pacing, gradual activity and, graded exercise actually specifies to needs clarification for both research and clinical recommendation.

NICE Guidelines Harm

Because its foundation is outdated, flawed and limited research, the NICE guidelines on ME/CFS fail to educate physicians on the true nature of the disease. It fails to confirm the multi-system dysfunctions and the appropriate World Health Organization classification of the disease as neurological, which is supported by preponderance of research evidence.¹¹

By not addressing what the disease is biologically, the NICE guidelines perpetuate the erroneous idea that the disease is a group of “medically unexplained symptoms,” which clinicians assume means it is psychological. Of course, this is contrary to the ample biological research in the last 20years.

Patients are time and time again not treated with respect and understanding of the biology, severity and impact of their symptoms by neurologists and general practitioners who operate within the NICE guidelines.

Additionally, the guidelines aim of “influencing practice in the real world” is discredited by their failure to acknowledge the physiological abnormalities identified by the available research. The gap between research and practice remains vast. Further investigation into patients symptoms are prevented from being investigated by NICE guidelines. In practice patients are receiving no investigation into symptoms or testing as used in research which finds abnormalities, and therefore receiving no assistants in better managing the symptoms that arise.

Nice guidelines 2007 states that referral to specialist CFS/ME care should be offered:

⁸ <http://www.ncbi.nlm.nih.gov/pubmed/21234629>

⁹ <http://www.ncbi.nlm.nih.gov/pubmed/11200949>

¹⁰ <http://www.meassociation.org.uk/2011/02/me-association-press-statement-on-the-pace-trial-results/>

¹¹ Categorized available research by abnormality. <http://www.cfs-ireland.com/listing.htm>

- Within 6 months of presentation to people with mild CFS/ME
- Within 3–4 months of presentation to people with moderate CFS/ME symptoms
- Immediately to people with severe CFS/ME symptoms.

This does not happen in a large majority of cases, as identified by Action for ME investigation into England's National Health Services specialist services.¹² Similarly, the Aviva Health of the Nation Study in 2011 cited M.E/CFS as the most difficult condition for GPs to refer; exactly the same as it did in a similar report in 2003. This is hardly surprising given the admission by most PCTs that they have not complied with either the National Service Framework (NSF) for Long Term Conditions or the NICE Guidelines for ME/ CFS.

While such an outline for referral to an ME/CFS specialist is good, in the U.S., no specialty has embraced the diseases leaving patients lacking expert knowledgeable care.

Sincerely,

A handwritten signature in cursive script that reads "Lori Chapo Kroger".

Lori Chapo-Kroger, RN
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¹² <http://www.actionforme.org.uk/Resources/Action%20for%20ME/Documents/get-informed/NHS%20report%20Ignorance%20injustice%20and%20neglect.pdf>