

In 2015, the Institute of Medicine declared what patients and their doctors have known for years: ME is not a psychological disease or deconditioning but a neuroimmune disease characterized by a systemic intolerance to even trivial cognitive or physical exertion. The IOM definitely stated that because the CFS definitions do not require this hallmark symptom, “a diagnosis of CFS is not equivalent to a diagnosis of ME.”¹

A 2015 report from HHS’s Agency for Healthcare Research and Quality (AHRQ) stated that one of these CFS definitions, the Oxford criteria, was so broad that it could include patients with other fatiguing conditions.² A 2015 report from NIH said that Oxford could cause harm and explicitly called for it to be retired.³ The IOM report dismissed a childhood trauma study done with the Reeves CFS definition because it included an overrepresentation of patients with other conditions.

And while AHRQ reported that CBT and GET were effective, the review was explicit in saying that these treatments had only been studied in CFS studies, not in studies requiring the hallmark post-exertional malaise. In fact, in published comments, the authors acknowledged that the CBT improvement on one measure was seen only in the Oxford studies.

Finally, blistering criticisms of the design, conduct, and conclusions of the PACE trial have been leveled by journalist David Tuller and numerous scientists, including those new to the field.⁴ PACE is one of those Oxford studies and the flagship of the flawed psychogenic theory that this disease is perpetuated by patients’ fear of activity and subsequent deconditioning that can be cured with CBT and GET.

And yet in spite of all this, “evidence-based” clinical guidelines and medical education information—even those issued since the IOM report and even those issued by the CDC—continue to use these studies as the basis of treatment recommendations and of statements about the nature of the disease.

One example is UpToDate, widely used by the medical community. UpToDate recommends the IOM criteria for diagnosis but recommends PACE style CBT and GET for treatment. It does not describe what systemic intolerance to exertion is, discourages rest, and states that a poor prognosis may be caused by a “patient’s belief that the illness is due to a physical cause.”

A second example is a list of references provided by CDC on its Science Clips site as part of its March 2016 Grand Rounds.⁵ Those references said that the disease was perpetuated by “patients’ perceptions, attributions, and coping skills,” suggested that lack of exercise capacity was due to lack of effort linked to perceptual issues, cited childhood trauma as a risk factor, and recommended CBT and GET.

These statements were based on Oxford studies and/or studies based on a psychogenic view of this disease, a case definition and disease theory in direct conflict with the disease as described by the IOM or the Canadian Consensus Criteria.

This is so wrong. The most fundamental rule of evidence-based medicine is that the statements and treatment recommendations made about a disease ***MUST*** be based on studies in patients that actually had the disease. Using evidence that is so obviously inappropriate is medically unethical and puts these patients at great risk of harm. This would never be tolerated in any other disease.

CDC must use its leadership position fix this mess so that patients can stop being harmed and start getting the clinical care that they need. CDC must stop using evidence from these studies as the basis of clinical guidelines. And CDC must explicitly separate the disease described by the IOM and the Canadian Consensus Criteria from the non-specific conditions of medically unexplained fatigue described by Oxford, Fukuda and Reeves.

Anything less will only perpetuate the medical confusion about this disease and cause harm to patients.

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- ¹ Institute of Medicine of the National Academies. "Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness." Final report May 2015. <http://www.iom.edu/Reports/2015/ME-CFS.aspx>
 - ² U.S. Agency for Healthcare Quality and Research. "Evidence Report/Technology Assessment Disposition of Comments Report. Research Review. Diagnosis and Treatment of Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome." April 16, 2015. <http://effectivehealthcare.ahrq.gov/ehc/products/586/2064/chronic-fatigue-disposition-150416.pdf>
 - ³ Green C, Cowan P, Elk R, O'Neil K, Rasmussen A. "National Institutes of Health Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome." *Ann Intern Med.* 2015; 162(12): 860-865. Doi:10.7326/M15-0338 <http://annals.org/article.aspx?articleid=2322804>
 - ⁴ David Tuller. Reexamining Chronic Fatigue Syndrome Research And Treatment Policy. *Health Affairs Blog.* February 4, 2016. <http://healthaffairs.org/blog/2016/02/04/reexamining-chronic-fatigue-syndrome-research-and-treatment-policy/>
Butterworth, T. "On PACE." Sense About Statistics. March 21, 2016. <http://www.stats.org/editorial-on-pace/> Also see the analysis by Goldin, R. "PACE: The research that sparked a patient rebellion and challenged medicine." Sense About Statistics. March 21, 2016. <http://www.stats.org/pace-research-sparked-patient-rebellion-challenged-medicine/>
 - ⁵ Centers for Disease Control and Prevention. "Chronic Diseases and Conditions - Chronic Fatigue Syndrome." Centers for Disease Control and Prevention *Science Clips:* February 16, 2016. Volume 8, Issue 7. <http://www.cdc.gov/library/sciclips/issues/v8issue7.html> Besides for Oxford studies, some of the references in this list used studies in just chronic fatigue. One example is the Avon Longitudinal Study of Parents and Children (ALSPAC) that was cited by the Crawley paper as the basis of prevalence and impact of family adversity in pregnancy.