

January 16, 2015

Below are my comments in response to the 389-line version of the Draft executive summary of the Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome December 9-10, 2014
<https://prevention.nih.gov/docs/programs/mecfs/ODP-MECFS-DraftReport.pdf>

Line 14 Specifically, the workshop sought to clarify the following key issues:

Line 18 ...How the measurement outcomes (tools and measures) currently used by ME/CFS researchers are able to distinguish among those patients diagnosed with ME/CFS, including the sensitivity of tools and measures to identify subsets of patients according to the duration, **severity**, nature, onset characteristics and other categorizations of the illness

My comment:

How can the illness be characterized with consistency when the research cohorts cannot be reproduced? Broad and sloppy case definitions produce broad and sloppy cohorts.

Line 143 There is little understanding of the inciting

Line 144 event or the cellular and molecular mechanisms that underlie ME/CFS, preventing quantitative

Line 145 assessments of disease **severity** or prognosis.

My comment:

How could there be understanding of disease severity when most studies are designed to exclude severely ill people? The people who are chosen for studies are usually ambulatory. These study cohorts often consist of people who can drive, work, go to school, and raise children. Some of them can ride horses, surf, compete in sports and take exercise classes.

Line 145 *There is a failure to give adequate attention to the*
Line 146 **severity** *of the physical, social, and emotional implications*
of ME/CFS.

My comment:

I disagree. The social and emotional severity of the disease is well studied. It's the physical severity of the disease that is not studied— unless it's a way to blame the disease on exercise deficiency, incorrect thoughts and emotions. Has anyone, for example, ever studied CFS patients who must live in nursing homes at a young age?

Line 223 *Gene expression, protein, or metabolite signatures*
Line 224 *that can correctly diagnose patients with ME/CFS*
and distinguish them from patients
Line 225 *with other chronic conditions, while predicting disease*
severity *and clinical outcomes, are needed.*

My comment:

You can't predict disease severity if severe patients are not studied. Below is part of a letter signed and posted today by some severe patients who are in the subset that is not studied. The letter ends with a plea to be included in research studies.

“We are nine patients from three countries who have severe or very severe myalgic encephalomyelitis (ME). The world doesn't hear from us very often because our extreme disabilities make it difficult for us to communicate. All of us are homebound, bedbound, or largely bedbound and need help with basic activities of daily living (ADLs) such as bathing, dressing, and feeding ourselves.

“We live in nursing homes, our childhood bedrooms, and subsidized housing. At least two of us can't walk at all. Some of us have not been able to leave our homes for many years. Most of us can almost never leave our beds. We all score 10 or below on the Bell Disability Scale.”

The entire letter is at this link:

<https://www.dropbox.com/s/qqdmemsa5e3bu75/Severe%20Patients'%20Letter%20to%20IOM.pdf?dl=0-->