P2P Draft Comments
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I endorse the CFSAC recommendations which I read at Jennie Spotila's blog, OccupyCFS. Like many of my fellow patients, I am cautiously pleased that you arrived at a decent initial draft given the parameters of the literature review and workshop which, like so many fellow patients and the leading ME advocates and researchers, I objected to. It is commendable that through this truncated approach you arrived at so many conclusions we reached some time ago. If my tone is a bit defensive, you will remember that we've had a long and difficult history as a patient community and our resentment precedes your involvement. However, I do believe you could turn around this terrible history substantially with your final draft, and I hope you will take bold steps to do so.

I will not so much re-state the points made so well by CFSAC and others, but will focus on additional comments as well as underscore a few points with perhaps different language, utilizing your 389-line draft report. I will also use personal experience to illustrate some points.

Lines 10-11: "Unfortunately, ME/CFS is an area where the research and medical community has frustrated its constituents." The research community that has developed around ME does not frustrate the constituents, it's the lack of funding and support for their work by the federal government that frustrates us. It is the federal government's decades-long pushing of psychological and psychosocial causes of the illness which has created the narrow parameters by which the medical community can treat us that frustrates us.

The patient community knows and respects those researching the illness that we actually have, ME. Psychiatric and psychological studies have burgeoned, well-fed by federal funds, in the decades that federal funding for the bio-medical science for our illness languished. To the patient community, the rise of "body-mind" medicine has felt more like a scuffle between the psychiatric and bio-medical fields over which one gets to be the head that tells the others what the patients' bodies are doing. Meanwhile, our ranks have grown and we remain sick.

Line 11: "…failing to address and treat the disease and by allowing patients to be stigmatized." Failing to address the disease as a biomedical one is what created the stigma of psycho-somatic illness that has dogged this patient population. Stop that stigma now. Do so by not only retiring the Oxford Case Definition, as you have suggested, but also withdrawing endorsement of it from the medical literature. Suggest that studies using the Oxford be redacted by medical journals. Be bold in standing with patients on this.

Stop giving pride of place to studies of psychological causes or treatments, "multi-modal therapy," "biopsychosocial parameters," "psychiatric comorbidities" for ME. ALL serious and chronic illness may give rise to secondary conditions that may be aided by those approaches. No one would suggest that bio-medical research into the causes of heart disease or psoriasis stop—nor that no other treatments are offered--because Mindfulness Based Stress Reduction training has been helpful for people who suffer from those conditions, but they have done exactly that with ME. Inclusion and the preponderance of these approaches in the ME case definitions, studies, or treatment plans fosters the misapprehension that this is a psychological, psycho-social, or somatoform illness. It perpetuates the stigma you

acknowledge has hurt the patient population and derailed science and treatment for decades. Stop trumpeting these studies and treatment approaches. Stop funding them.

113-14: "Existing treatment studies (cognitive behavioral therapy [CBT] and graded exercise therapy [GET]) demonstrate measurable improvement, but this has not translated to improvements in quality of life. Thus they are not a primary treatment strategy and should be used as a component of multimodal therapy." Echoing fellow patients for emphasis: Those studies demonstrate improvement for people who are fatigued for reasons other than ME. If the same studies had been applied to a patient population with the hallmark symptom of post exertional malaise the results would have been much different.

161-62: "Patient-centered tools that use simple statements need to be developed to ensure that the patients understand the questions. Overall, there is a need to simplify measures while prioritizing face-to-face interactions." The amount of medical knowledge ME patients have had to attain to help ourselves is quite astounding. Many of us have heard from our doctors and specialists "you know more about this than most doctors." From our experience it's more that "simple statements need to be developed to ensure that the *doctors* understand the questions." You might rephrase this in such a way that commends what so many patients have had to achieve in the face of so little support from the health agencies of the federal government and the medical community.

And the related:
Line 315-16: "… in addition to the medical therapies they are receiving, patients must become active participants in their overall treatment." That's all we have! We read all of the literature, bring studies related to our presentation to our GPs and specialists—if we are lucky enough to find some who will "entertain" this—and see if they can try to work the existing system to get us tests or treatments that may be helpful.

178 and following: "Future Directions and Recommendations"
Your writing these recommendations is both validating and frustrating because a case definition has already been agreed upon by the experts in the field, the IACSFMS; all of your recommendations are things we've been talking about in the patient, advocate, and ME research communities and trying to get funded for years. Putting money into the current field of researchers who have dedicated their professional lives to our cause is what will attract new scientists and doctors to the field. If you fund it, they will come.

Recommendations I'd like to see addressed or added:

Line 36: "…and there are not primary prevention strategies." I have had eleven years of being disabled to contemplate how and why I got sick, and how to help others avoid what I have. It is hard to prevent an illness for which a singular cause has not been determined, but so many of us became ill and disabled after a viral illness that addressing the contraction and spread of viruses would have a positive impact in preventing ME. Developing more anti-viral drugs would be wise and helpful.

But long before that is accomplished—and long after—it would be prudent to promote some cultural shifts about illness in public life through public awareness campaigns reinforced during visits with primary care physicians, much like questions about alcohol use and depression that were added for annual physicals through a policy mandate in recent years.

Right now our culture not only condones but glorifies people who "tough it out" and come to work while sick. Others have no choice but to come to work sick because they have no sick leave. Fund and create broad public health campaigns to make it socially unacceptable to come to work sick but socially acceptable to stay home while symptomatic.

People often say that they have "just a little bug" or "a 48-hour flu" but there are no such pathogens, only people fortunate to have a big enough immune system capable of dealing with them quickly and completely. Others encounter the same pathogen and suffer life-long consequences. This is something a public awareness campaign can address. A community's immune system may only be as strong as its weakest members. We are inter-connected. We must love our neighbor's immune system as our own.

Support and create employment policies that include paid sick days and universal insurance to foster a society where the sick can get the help they need and take the time they need to heal.

Public health campaigns could also help make it socially acceptable to wear face masks in public places and while using mass transportation, especially during peak germ seasons.

Beginning these practices now would make our society more prepared to respond in the face of a pandemic.

Some with ME have reported that they no longer seem to catch those "bugs" going around, while others like me are more susceptible, and when we do we stay sick for weeks and months. Understanding this difference could be addressed by your recommendation in line 164 and a few other places for studies of how ME develops and changes "across the lifespan."

In addition to studies "across the lifespan," it is important to study causes of death in our population. One of the small studies that was not included for your review was one about this published by Jason et al in 2006[1]. Heart failure, cancer, and suicide were the leading causes, and surprisingly not encephalitis or other serious complications of viruses. Working backwards from those who have died (and those who will die) while having ME may reveal as much or more about the illness path than studying onset (though I am in no way suggesting to not study onset as well).

The first two of those—heart failure (at a median age of 58.5 compared to 83 in the general public) and cancer—may be linked to ideas in other studies that you could not review. It is well known that some viruses are pre-cursors to cancers, and cancer pathology often involves bone marrow. Bone marrow also is involved in creating blood, and another small study that you could not review was Bell's in 1998[2] that found remarkably lower blood volume (20 to 40+% less ) in people with CFS (albeit a name we now all agree is inadequate) than in healthy controls. Low blood volume in turn could create the varieties of orthostatic intolerance so common among those of us with ME, as well as heart failure, and even the unusual symptom common to so many of us of having serious side effects to all variety of drugs. Why has no one looked at bone marrow as a common point of what may kill us? Why has no one followed up on blood volume in these as well as studies like Peckerman's "Abnormal Impedance Cardiography Predicts Symptom Severity in Chronic Fatigue Syndrome"[3] , a study that made a huge splash in mainstream media, a study then considered a turning point for the field.

Building on small "poor quality" studies like these, the work that has given many of us real hope and some improvement are the studies into VO2-max and aerobic/anaerobic threshold. Many of us have not been able to afford, physically and financially, to travel to have these tests, but we have been able to

read the scientific papers and patient blogs about their experience, approximate our AT and attempt safe exercises within it as well as managing our activities of daily living to maximize energy reserves and minimize depletion. Many of us have experienced incremental improvement by doing so.

Exploring these cardiac issues further, patients have found a connection between orthostatic intolerance and AT as well as observing the symptoms of low blood volume. Many of us have been able to convince our doctors to try treating low blood volume with IV-saline infusions—a tricky prescription to secure in many provider groups and under insurance because it is not an FDA-approved treatment for ME. I have been greatly helped by IV-saline, but my provider group is balking at further treatment—despite the facts, which I can demonstrate in daily graphs created from print-outs of data captured by my heart rate monitor and smart phone app—that IV-saline has improved the length of time and frequency I can perform my exercise routine safely within my AT, my tolerance for heat shown in significantly less and lower tachycardia in general and particularly in hot weather or following a hot shower, and diminished the frequency of heart arrhythmias--which are thought to be "safe" but are quite improved by this simple treatment nonetheless. My heart palpitations have disappeared, and the infusions have helped my cognitive difficulties while also abating typical signs of low blood volume such as swollen hands and feet. I have felt so much better with this treatment that I have considered trying to take a university class to test my stamina (in hopes of someday being healthy enough to go off disability), something I have not been well enough to attempt since 2008. My husband comments on reading this draft that my ability to organize my thoughts in writing with few drafts is dramatically better since beginning saline treatment. But this fabulous treatment may soon go away for me because of my provider group and insurance. Saline is very safe and easy to administer, with simple follow up blood tests for monitoring; FDA approval for this treatment would not require lengthy and expensive studies.

While cardiac anomalies are shown to be common in ME (again, in small studies that you could not review), and so many of us suffer from Postural Orthostatic Tachycardia Syndrome and Neurally-Mediated Hypotension, it is a shameful state of science and medicine that the American Heart Association, as recently as last summer when I was about to visit a new cardiologist, listed the causes of POTS on their website as being caused by a heart two sizes too small; there was no mention of ME or CFS when quite likely many with a POTS diagnosis have concomitant or primary ME. What might have been different with the AHA by now had studies like Peckerman's led to larger studies? Peckerman went on to study other conditions, where there was funding. The new cardiologist I saw could not be bothered to look at the studies of cardiac anomalies in ME, and suggested that anti-depressants are usually prescribed for what I have.

Meanwhile, I must hope and pray that my saline treatments will continue. Additionally, my GP was able to secure the prescription for IV-saline because I had fainted in a tilt-table test in 2007, though the attending cardiologist said then and maintains that he does "not believe in ME/CFS." He further counseled my GP that she need not send other patients for a tilt-table, that she could diagnose based on symptoms, yet doing so may preclude these patients from helpful treatment. This dis-connect with the AHA must be addressed. IV-saline is among possible treatments for POTS and NMH; cardiologists could play a large role in securing this helpful treatment for patients now, before FDA approval as a treatment for ME.

125-29: "Small [studies]…. High dropout rates." Preclude funding studies by the NIH with a mandate for including detailed reasons for drop outs in all studies funded by NIH.

175: "…Is there a genetic-environment interaction?" I would also ask if there is simply environmental interaction. Define and name environmental triggers. Are they chemical? Radiologic? Both? Do these environmental factors lead to one wallop of a break down, or accumulate over time? Some have wondered if those of us with ME are the "canaries in the cave," the first to respond to and warn of a world that is increasingly polluted. Developing food allergies, and other immunologic conditions commonly concomitant to ME, may suggest so.

180: "…but nothing has improved the lives of patients." This is not quite true. You probably intended that to mean that no singular treatment has improved the lives of all or most patients. Different subsets of patients have benefitted from some treatments, some incrementally, some greatly. The IV-saline infusions, acupuncture, and supplements, studied in peer-reviewed scientific journals and chosen together with my health care providers, have helped me to move from bed-ridden to mostly home-bound. I am still disabled, but I am fortunate to not be as severely ill as many. Certainly I'd like a cure, but I am grateful to no longer be as sick as I was in the first months of illness. Ampligen helped many, though reading about their presentation I doubt that I would be a candidate. It may be a matter of wise policy to abandon the idea that singular cause and singular treatment will be found, and to publicize that philosophy so as not to further stigmatize those among us who are not helped by something that serves others very well.

1. Causes of Death Among Patients With Chronic Fatigue Syndrome. LEONARD A. JASON, KARINA CORRADI, SARA GRESS, SARAH WILLIAMS, and SUSAN TORRES-HARDING. DePaul University, Chicago, Illinois. Health Care for Women International, 27:615–626, 2006.

2. Circulating Blood Volume in Chronic Fatigue Syndrome. David H. P. Streeten, MB, DPhil, FRCP, FACP David S. Be11, MD, FAAP Journal of Chronic Fatigue Syndrome, Vol. 4(1) 1998 .

3. Abnormal Impedance Cardiography Predicts Symptom Severity in Chronic FatigueSyndrome ARNOLD PECKERMAN, PHD; JOHN J. LAMANCA, PHD; KRISTINA A. DAHL, MD; RAHUL CHEMITIGANTI, MD; BUSHRA QUREISHI, MD; BENJAMIN H. NATELSON, MD. THE AMERICAN JOURNAL OF THE MEDICAL SCIENCES, August 2003 Volume 326 Number 2.