

Cecelia Blair,

As a 20-year patient with ME, I share and second the perspective which Jerrold Spinhirne has submitted to you here: <https://drive.google.com/file/d/0B4uD-VyWmlw2b1pXMzZOZWVUUE0/view?pli=1>

Using the 389 line document, my specific critique is as follows:

Line 2 and Line 199---ME and CFS have been differently defined so that combining them as ME/CFS causes confusion and inaccuracy.

Line 3---"fatigue" is too general a term. The fatigue in ME is a particular, unusual kind of fatigue which termed PEM or PENE and it can be established by a 2-day exercise test. Further, as "fatigue" is the single most common symptom across all illnesses as well as the ordinary experience of everyone short on rest, it is a singularly non-specific symptom upon to characterize any illness. For instance, it would be like calling another conditions Chronic Pain Syndrome or Weakness Syndrome, etc.

Line 3--"other symptoms". These have been described by the CCC and ICC. The foremost symptom in ME is neuro-cognitive--memory and cognitive difficulties. In addition to neurological abnormalities, there are commonly immune and endocrine abnormalities, generally of a hypo or under-functioning nature, digestive disturbances, etc. See CCC and ICC.

Lines 6-7---Not \$1 billion but \$20 to \$30 billion by Leonard Jason's studies and estimates. Wages lost and uncompensated medical expenses, the need for paid help, etc., amount to an undetermined but very high burden on patients and their families.

Line 10--Instead of "the research and medical community has frustrated its constituents", it is the NIH, the CDC and other federal agencies designated to protect public health and foster research, which have frustrated these constituents.

Line 33 and 94--"It overlaps with many diseases e.g. fibromyalgia, chronic pain.." Omit major depressive disorder as this has been shown to be biologically different in terms of brain scans, spinal fluid proteins and cortisol levels as well as in terms of response to exercise and CBT. Those with ME, or ME/CFS if you will, have not been shown to have any higher than average psychiatric disorders, and our depression is in relation to the consequences of our illness rather than its precursor. The conflation of our illness with Depression has done more harm than any other error so far.

Line 34-35--"There is no agreement from the research community on what needs to be studied" is only true at the level of the NIH and CDC so far. Our international expert doctors and researchers, though few and underfunded, have made many inroads into understanding this illness and seeing what further research is needed. Inquiring of them and supporting their work would be the quickest possible way to understand and define this illness as well as to establish diagnostic tests and treatments.

Line 113--"CBT and GET demonstrate measurable improvement". This was of the order of 10%, but since the patients were selected on the basis of the Oxford criteria which even this committee sees fit to

retire, as this definition includes patients with Depression, which is a far larger group and as a result, the outcomes of these studies may only apply to them.

Line 116 and Line 371--"multi-modal therapy" is not what our patient group seeks, but rather the expert care of physicians including specialists such as Neurologists with expertise in Autonomic Disorders, Immunologists, Endocrinologists, Cardiologists, etc. who are informed in the features and treatments for ME.

Line 130-138--"Self management". While it is true that patients need to progress in the area of self management to deal with a chronic illness, advice on this subject is abundantly available online once a patient has been diagnosed.

The first needs are the establishment of an accurate clinical and research definition (CCC or ICC are the best models so far), next biological research directed by our experts and third, the establishment of centers of excellence for further research and patient care.

Line 172-175--All the research done so far does not identify any single agent as cause. Instead the research indicates that it is the severity of the precipitating illness, whether from a virus, bacteria or parasite, etc. Research on genetic precursors and transmission has also been a fruitless pursuit for the purpose of identifying a simple cause and simple avenue of treatment. This type of approach has been tried unsuccessfully for years. The causes of many diseases are unknown, but yet research on treatment of them has still progressed.

Line 178 "Future Directions and Recommendations". My main suggestion is that the priority for funding and selection of research projects should first be in follow up studies of sufficient size and correct design to confirm or test the results from well designed initial studies which are prolific in this field. One such suggestion is the 2-day exercise test developed and first tested by Allan and Kathy Light.

Line 179--It is a "condition of unknown cause". It is a condition of many causes and no known cure.

Line 192--"focus on primary care providers". These ought to be informed about ME, able to diagnose and to refer, but do not have the time or expertise to treat the many abnormalities in this illness.

Line 193-194--One "conflict of interest" has been demonstrated in the coverup of years of mismanagement and neglect by the powers that be including the CDC and NIH. Another potential conflict of interest would be funding any of the Get Well Quick hucksters and snake oil salesman always ready to exploit any ill defined condition with no proven cure. Everyone ought to expose and drop these harmful agendas--including dropping any blame or guilt from failures of the past--and get busy right now on the needed research.

Lines 205-208 and Lines 246-248--"Commonalities and differences with other conditions"--These have been studied and can be studied further, but quick answers for treatments will probably not be found in this way. For instance, the anti-depressants which help those with fibromyalgia typically do not work for those with ME. We do not need further years wasted through further conflations with other conditions. We have had 20 or 30 years conflating ME with Depression. We do not want to see further years wasted

in conflating and confusing our illness with fibromyalgia, Lyme Disease and the like. Specificity should be the goal in studying the particular parameters and features of ME, as it has been so far, so lacking.

Lines 286-289--the CESD should not be “encouraged”, nor should “exploring psychiatric comorbidities”. The priorities for limited funding for research, for defining and studying the illness, and for diagnosing and treating the patients must be focussed on biological measures. The irony is that much of the depression, fear and anxiety patients have felt over the years has come from the stigma and lack of understanding or effective treatment due to ME being regarded as a psychosomatic illness. This was never proven and treatment based on this supposition never succeeded. That is why we say that we do not need any more attention paid to our supposed depression, fear or anxiety. We need scientific attention paid to our physical illness.

Lines 273-276--No funding should be assigned to “alternative and complementary” treatments such as homeopathy, etc. None of these has been shown to be effective and no more time and money should be invested in them. It is essential to have priorities in order for research needs.

Lines 303-305 “ ME/CFS is a distinct disease that requires” experts in ME, first of all. It requires centers of excellence or specialized clinics and providers in the major cities and areas of the country. In addition to these, protocol can include referrals to other medical specialists such as Immunologists, Neurologists, Endocrinologists and the like. Not “nurses, case managers, social workers, psychologists”. The diffusion of care across too many providers can lead to dangerous gaps and omissions, inefficiencies as well as much added expense, and finally, exhaustion on the part of patients going from one provider to the next for every aspect of care.

Lines 344-350 Patients not only should “be active participants in care and decision making”, we have had to be. In fact we have had to be our own researchers and doctors over the years, which is why you are finding us an informed and assertive group. It is true we need to work on self management strategies for the best quality of life, but we have been doing so and find much needed help and support through online groups. I believe that it should not be a priority in terms of spending and projects to focus on support and life skills, but rather on biological research as I continue to emphasize.

Lines 363-368 We affirm and celebrate the proposal to retire the Oxford definition and think that retiring Fukuda would also be sound, given that a person could qualify under Fukuda without having the major symptoms of ME, as Leonard Jason has so aptly and repeatedly pointed out. Relying on our experts in the field of our particular illness for clinical and research definitions, whether the same or somewhat different due to their different applications, is what patients want and what the professionals working in this field want. The CCC or ICC Definitions are the best of the pack so far, and should clearly be accepted as the starting point for any future refinements. CFSAC has been recommending them for years.

Thanks to the P2P group for your efforts at understanding and advocating for the research and clinical needs of those of us with ME, or ME/CFS. The priorities for research and funding still need to be established. Your draft report lists everything-but-the-kitchen sink. Definition, types of research, use of experts in the field to guide the whole show, and adequate funding all seem of major importance.

Lastly, while your report suggests that the field of ME could be benefited by findings and treatments for other illnesses, I would suggest the other way around too--the learning from studying ME will greatly benefit the understanding of other multi-systemic illnesses.