Comments on THE NATIONAL INSTITUTES OF HEALTH

Pathways to Prevention Workshop:

Advancing the Research on Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome

"DRAFT EXECUTIVE SUMMARY"

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I will preface my comments by saying that, like so many other patients who have observed the P2P process unfold, I have been very concerned at the lack of M.E. specific expertise represented on the panel. In my opinion this has resulted in a somewhat ill-informed report and one which reflects the naivety of the panel. It could certainly be argued that, given the way that the P2P process works, it was a fundamentally inappropriate way of looking at the problem.
On a positive note, there is much to welcome in the report, such as the recognition of the seriousness of the plight of M.E. patients, the lack of help, recognition and respect that they get for their suffering and the absence of any meaningful treatments. But this must not be allowed to simply translate into yet another long-winded discussion exercise. There are many very experienced M.E. researchers out there who know what needs to done and how to do it. They don't need NIH to reinvent the wheel, which this report appears to be trying to do.

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1. Use of the vague term "fatigue" has been made far too often in connection with this illness and yet despite acknowledging this fact, it still features too prominently throughout the draft P2P document. M.E. Is not "characterised by extreme fatigue" as is stated on line 3. This statement should be replaced with an emphasis on "Post exertional malaise" or "Post exertional worsening of symptoms" – a phenomenon which is uniquely experienced by M.E. patients and which is therefore a much more useful feature of the illness upon which to focus.

2. With the exception of those who's vested interests are served by them, it is widely accepted that the "Oxford Criteria" need to be retired. The statement to that effect on lines 38 & 39 are therefore most welcome.
   Having acknowledged that research conducted using the "Oxford Criteria" has inevitably included subjects who don't have M.E., the report ought to go further and say that all such research should therefore be considered to be invalid and therefore be excluded from consideration in the future.

3. The "Canadian Consensus Criteria" (CCC) have the widespread support of M.E. experts and patients alike. They should be adopted as the case definition for M.E. forthwith and this should be stated in the P2P report.
   Support for adopting the CCC was demonstrated by a large number of M.E. experts from around the world, who signed the letter (addressed to NIH Secretary Sebelius last year) which opposed the NIH's decision to contract the Institute of Medicine to redefine M.E/ Chronic Fatigue Syndrome. In the light of that letter and the outcry from patients, it is extraordinary that the NIH still decided to go ahead with that unnecessary expenditure.

4. Given that it was carried out using the "Oxford criteria" to select participants, the "PACE trial" has no relevance to people who actually suffer with M.E.
   It has been roundly condemned (by the patient community and M.E. experts alike) as a highly dubious piece of work and yet it's unconvincing findings have been used as the justification for

over-blown claims about the effectiveness of Cognitive Behavioural Therapy and Graded Exercise Therapy programmes as treatments for M.E. sufferers.
Despite acknowledging that M.E. is a physical (not mental) illness, CBT and GET still get to enjoy far too much attention in the draft P2P report. They should rightly be presented as adjunct therapies and not "front line" treatments for M.E. patients. The statement on line 114, that *"Existing treatment studies (cognitive behavioral therapy [CBT] and graded exercise therapy [GET]) demonstrate measurable improvement"* is worded in a way which overstates the case.

5. Whilst the draft P2P report highlights the fact that making progress in understanding this illness has been so slow, it fails to acknowledge the part that NIH have played in that failure, insofar as they haven't provided proper funding for the right kinds of research to be conducted. Furthermore, by historically preferencing their support towards studies which promoted a "psychosomatic" theme, they have been instrumental in taking the research effort in an unhelpful direction.

6. Research into the biological mechanisms of and new pharmacological treatments for M.E. needs to be funded properly. This need is not currently reflected adequately in the draft P2P report. NIH's past claims that they haven't received the requisite high quality research grant applications worthy of their support, is patently not true.
There are many good researchers out there who have already demonstrated that they have some very good ideas on this subject and who are ready and willing to turn their attention to the cause. Given the progress that has been made recently in M.E. research (particularly in the fields of immunology and neurology), with the benefit of only relatively tiny budgets, it is clear that, if properly resourced, a significant breakthrough in understanding this disease, is not far away. Therefore, if NIH are serious about wanting to improve the currently lamentable situation for M.E. patients, then the one really useful contribution that they could make would be to allocate a significant sum of money to fund that work. The P2P report ought to recommend what that sum of money should be and set out a plan for how it will be made available to researchers.

7. When talking about the difficulties in diagnosing the illness (lines 48 – 53) no mention has been made of the repeat cardio-pulmonary exercise testing (CPET) protocol, pioneered by Snell & colleagues at Pacific Fatigue Labs / Work well Foundation. This repeat test regime has been demonstrated to be very effective in identifying patients who suffer from M.E. It's omission from mention is a serious oversight.

8. I believe that the statement on lines 108 – 110 is misleading:
"However, the few cross-sectional studies with limited applicability have provided few insights to the disease or its treatment"
In my opinion, this is an example of how the inexperience of the P2P panel (in M.E. terms) has had a negative influence on this report. Whilst in factual terms, what they say may be correct, had they attended any of the Invest in ME conferences in London over the past few years, their perspective would undoubtedly have been different.

9. To anyone remotely experienced in coping with this illness, the statement on lines 135 – 137 is laughable:
"lack of instructions or guidance for including graded exercise therapy often causes additional suffering, creating fear of harm from a comprehensive self-management program that may include some physical activity."
It is not a fear of physical activity that is the problem. It is the inappropriateness of Graded Exercise regimes being applied to people with this illness that is the problem. It would have been far better to have pointed out the efficacy of self-adapted "Pacing" as being the more effective strategy.

10. Lines 142 - 143 state: *"Many patients with ME/CFS are misdiagnosed and treated erroneously with potentially toxic therapies that may cause harm and diminish hope."*
    What is the evidence for stating this ? To what do they refer ? It seems to me that this is a somewhat casual and unjustified statement to make.

11. There is a huge contradiction between what is said (lines 151 – 158) about the need for defining clear endpoints, measuring statistical and clinical significance etc. in M.E. research and the apparent faith which the authors of the report have in the results of the "PACE" trial – one of the least trustworthy studies in medical history.

12. I welcome the range of questions posed on lines 172 – 177, but would add that they still seem to me to be a bit limited. For example, the potential for a number of pathogens acting in combination hasn't been mentioned, nor has the role of the microbiome in the gut been considered. The growing body of evidence that patients accumulate food and environmental sensitivities over time as their illness progresses isn't mentioned, nor is there any comment about the suggestion that M.E. could potentially be an autoimmune disease.

13. Much of what is proposed in lines 200 - 316 appears to be trying to reinvent the wheel. It isn't necessary. Just provide the funding to build on what is being done already, but please don't try to send the whole thing back to square one.