Anonymous #9

Comments on the "Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome Draft Executive Summary"

– Using the 389 line version of the Draft Report –

Dear Members of the Panel,

I must commend you on having done a remarkable job, given the rather difficult circumstances with the limited time-frame for your work and the shortcomings of the AHRQ review–many of which stem from the charge and scope of the report, which for example was not designed to include studies on etiology (even though in an immature research field, etiology is just where the science is at!)

There are many parts of this P2P Draft Executive Summary which I welcome and endorse, such as the recognition of the urgent need for innovative biomedical research (lines 186-187), the areas of biomedical research needed as specified in the lines 221-269, the statement that the scientific community has a need to address issues that are meaningful to patients (lines 80-81), the statement that the Oxford criteria should be retired and the description of ME/CFS as a disabling disease which is not psychological.

I thank you for having pin-pointed these and many more important aspects of the disease and the needs of the research field.

However, I believe a few parts of the report need to be changed in the Final version. These are my suggestions:

1. I suggest that you give more emphasis in the report to the plight of the severely affected ME/CFS patients. This is a part of the patient population which is generally very overlooked and invisible in the medical system, and in urgent need of support. They are too ill to manage to travel to a clinic, so they do not see any doctors. Many are even too fragile to seek emergency care, since EC units and hospitals are poorly adapted to the needs of the severely ill ME/CFS patients and any visit there often causes deterioration. This is a patient group with virtually no medical services at all available to them.

I would suggest that you expand on the situation for the severely affected in the report, thereby raising awareness of the massive suffering of these patients. Perhaps as high a percentage as 25% of ME/CFS patients, when ME/CFS is defined by

narrow criteria such as the Canadian Consensus Criteria, CCC), are severely affected: housebound, bedridden, many unable to perform activities of daily living and in need of 24 hour care. The disease burden for these patients and their families is huge.

I am glad to see that in line 52, you list the lack of inclusion of the homebound as one of the problems of the to-date research studies. This is a very important factor for relevant future research, since physical abnormalities can be expected to exist in higher, more easily detectable levels in the severely affected. They should, in fact, constitute the basis for further research. I would ask you to include this in your recommendations and conclusions as well, for example under the heading "Create new knowledge", line 212 et seq, and in the section "Conclusions", line 352 et seq.

2. I think it very important that the Final Report clearly states that all future treatment research needs to include objective outcome measures which measure activity levels over time, as well as long-term follow-ups including relevant parameters such as return to work/studies and use of disability benefits. Please clearly state this as a recommendation.

The lack of objective measures and long-term follow-ups of generally accepted parameters of improvement/recovery is the core problem of clinical ME/CFS trials to date. The exclusion of these measures, combined with the use of broad criteria such as Oxford, Reeves or Fukuda, which do not require the cardinal symptom PEM, has allowed psychosocial treatment options to be proclaimed effective, when in fact they are often very harmful to ME/CFS patients and show no objectively measurable improvement. This has caused enormous problems to the ME/CFS patient community, at great personal loss to thousands of patients and their families.

I suggest you remove the phrase "Existing treatment studies (cognitive behavioral therapy [CBT] and graded exercise therapy [GET]) demonstrate measurable improvement" (lines 113-114), since these studies in fact have not shown any objectively measurable improvement and the very modest subjectively reported improvements are likely to represent a placebo-effect.

I urge you to include a recommendation in the section "Future Directions and Recommendations" (lines 187 et seq) that all future treatment research must include objective outcome measures monitoring activity levels over time, as well as long-term follow-ups including relevant parameters such as return to work/studies and use of disability benefits.

3. Referring to lines 105-106 and 202-204:
"A clear case definition with validated diagnostic tools is required before studies can be conducted."
"Define disease parameters. Assemble a team of stakeholders (e.g., patients, clinicians,

researchers, federal agencies) to reach consensus on the definition and parameters of ME/CFS"

I find it worrying that the Draft Report states that a clear case definition is required before studies can be conducted. This can put a halt to research progress, quite unnecessarily. There is a wide consensus among ME/CFS researchers and clinicians that the Canadian Consensus Criteria is fit for use both clinically and scientifically. (I am sure you are aware of the letter sent by 50 leading researchers to the Secretary of Health, urging HHS to adopt the CCC for both clinical diagnostics and research.)

What is really needed is a surge in ME/CFS research, and this can be done using the existing CCC. While not perfect, they are functional.

I am quite convinced that new efforts and meetings to establish criteria should not be a priority at this point. Functional consensus criteria already exist, in the form of CCC.

It will be easier to create case definitions when more research is done on disease mechanisms.

Please remove lines 105-106 and 202-204 from the Final Report.

4. And finally: the most crucial need for the ME/CFS field is increased public funding. None of your recommendations will ever come to fruition if the NIH does not increase funding for biomedical ME/CFS research from the current level of $5 million yearly to a level on par with comparable diseases, which would mean a range between $100 million and $275 million yearly.

We are all aware of current budget restraints, but ME/CFS has been overlooked and stuck in the bottom 5% of ailments funded by NIH for three decades, which in fact is the fundamental cause of most of the problems of the field which you list in your report. In fairness, money must now finally be relocated so that ME/CFS, too, is allowed funding levels proportionate to disease burden, prevalence and societal cost.

It has been repeatedly recommended (by CFSAC, Members of Congress, IACFS/ME and others) that NIH issue grant opportunities with set-aside funds for biomedical ME/CFS research. This is an absolute necessity. NIH issued an RFA for ME/CFS in 2005, so clearly this can be done.

I very strongly urge you to:

rephrase line 219: "leverage and catalyze the use of existing NIH infrastructure and dollars" – and state that new money is fundamental for progress

include a recommendation that NIH must issue multiple RFAs for ME/CFS, prioritize

this recommendation as the No 1 recommendation of the Final Report, and state a clear time-table for this.

If the above mentioned suggestions are incorporated into the Final Report, there would–finally–be reason for hope among ME/CFS patients, clinicians and researchers.

Thank you for your work.

Yours sincerely,