Comment on the P2P Draft Report regarding ME/CFS by Helle Rasmussen

Dear panellists,
The Draft Report adequately captures many important aspects of ME/CFS and the state of medical science and research into this disease. For this I would like to thank the authors.

However, some major points are missing from the report, and I would like to draw your attention to the most crucial of those, namely

- The lack of strong and specific recommendations for the NIH to bring the funding for biomedical ME/CFS research up to a level commensurate with the burden of the disease and on par with similar diseases

In this comment, I refer to:

[Lines 5-9] An estimated one million people, mostly women, are affected. ME/CFS is an unmet public health need with an economic burden estimated to be greater than $1 billion. ME/CFS results in major disability for a large proportion of the people affected. Limited knowledge and research funding creates an additional burden for patients and health care providers.

[Lines 213-221] Investing in bench-to-bedside to policy research for ME/CFS is recommended [...] The NIH Institutes and Centers [...] and other U.S. Department of Health and Human Services (HHS) agencies should coordinate research efforts to promote efficiency and effectiveness, while also using public/private partnerships to leverage and catalyze the use of existing NIH infrastructure and dollars.

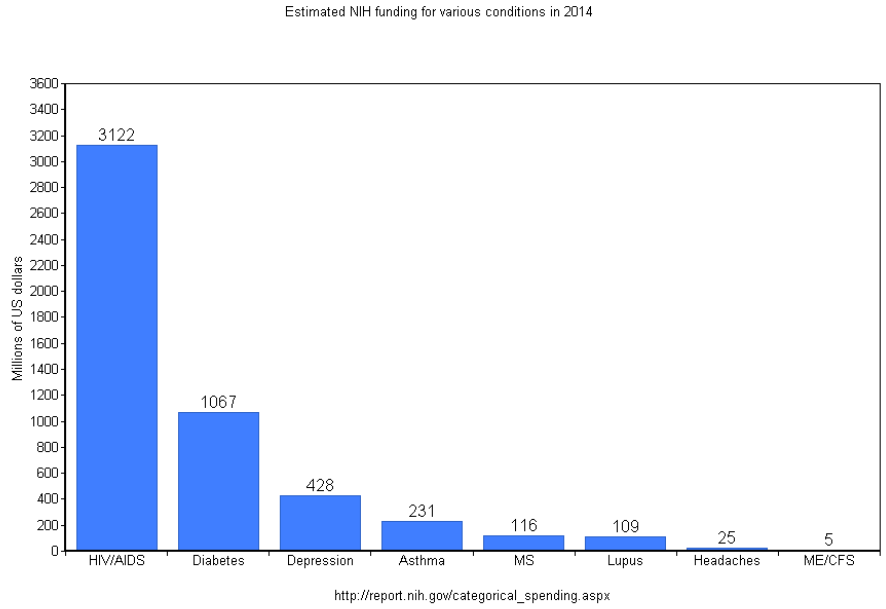
[Lines 390-391] There is a role for new and ongoing policies to spark innovation and fund new research. For instance, new avenues are needed to fund research, such as the Prescription Drug User Fee Act.

and I also refer to parts of the report where this recommendation should be mentioned, such as “Future Directions and Recommendations” [Lines 178-366] and “Conclusion” [Lines 367-403]

As the Draft Report states, ME/CFS is a disease affecting around 1 million Americans, and around 20 million people worldwide, with a very heavy disease burden both on a personal and a societal level. CDC studies show that ME/CFS can be as disabling as multiple sclerosis, lupus, rheumatoid arthritis, heart disease, end-stage renal disease, chronic obstructive pulmonary disease (COPD), and similar chronic conditions. Other research shows that ME/CFS patients have a similarly low quality of life as cancer patients undergoing chemotherapy. ME/CFS is an organic, multi-system disease, by many researchers termed neuroimmune, perhaps with an autoimmune component

(as recent research indicates). Progress in the ME/CFS field will only come through increased biomedical research into the etiology, disease mechanisms, biomarkers and subgroups of ME/CFS.

Considering these facts, ME/CFS should be allocated funding on par with other hard-hitting, chronic, organic diseases such as MS, RA, Parkinson's disease, lupus, etc. In the table on Categorical spending at NIH's website (http://report.nih.gov/categorical_spending.aspx) one can find out that MS is given approx. $115 million yearly, Parkinson's Disease approx. $130 million, lupus approx. $100 million. ME/CFS is awarded approx. $5 million per year.



As you can see, the available funding for research into ME/CFS is at least 20 times lower than that of comparable diseases. In the list of around 250 disorders into which research is funded by NIH, ME/CFS has always been situated in the bottom 10.

This, naturally, hinders many researchers from even entering the field. I would say the researchers we have today have fought an extreme uphill battle to even stay in the field – we owe them our thanks, they are trying to perform relevant and adequate research on less than a dime. Given these circumstances, many of the biomedical researchers are achieving remarkably good results, coming up with a number of very promising leads which could bring to light the disease mechanisms in ME/CFS. However, since NIH rejects the majority of applications regarding ME/CFS, these promising smaller studies are never followed up upon – the large-scale, high-quality studies called for in the AHRQ report can never be conducted.

We must assume that many of these rejected applications have been of high quality, since the same researchers easily receive funding when applying to study other diseases.

Hence, we do not yet know what we should have known long ago: How consistent is the finding of NK cell dysfunction in ME/CFS? Can it be used to identify subgroups? Could the identified protein profiles in spinal fluid which have been shown to differentiate ME/CFS from controls + Lyme be possible biomarkers? How do cytokine patterns differ before and after exercise? Can cytokine patterns be used as biomarkers? Do ME/CFS patients have abnormalities in the gut microbiome? Is there an autoimmune factor in ME/CFS, or in a subgroup of ME/CFS? How does the autonomic system dysfunction such as orthostatic intolerance relate to other disease mechanisms? Can orthostatic intolerance measures identify subgroups?

So the fundamental problem which has hampered progress in the ME/CFS field since the very beginning is grossly inadequate levels of public funding into the disease. This has to be addressed in the report. I would actually ask that this be made the main point of the report: NIH must take active measures to increase ME/CFS funding levels by 20x.

The Final Report needs to include very specific recommendations on what NIH can do to achieve this, such as:

- NIH must issue multiple RFAs for biomedical research into ME/CFS. This has been called for numerous times by the CFS Advisory Committee, the professional organization International Association for CFS/ME, and many others. Still, it has not been acted upon.

- NIH must make organizational changes so that ME/CFS belongs to a specific Institute within NIH. The Trans-NIH Working Group has not been successful in creating progress, probably due to its organizational form.

- NIH must bring back the biomedical Centres of Excellence that were closed down a number of years ago. New Centres of Excellence focused on biomedical research would be key to research progress. An excellent opportunity exists to make the clinics participating in the CDC multi-site study such COEs.

I hope recommendations such as these will be a prominent part of the Final Report. Long-awaited progress depends on this.

Thank you for accepting this submission.

Yours sincerely,
Helle Rasmussen
Denmark