P2P Comments from Johan Edsberg

Dear Sir/Madam

As a general practitioner and specialist in internal medicine as well as the husband of a person with severe ME/CFS, I would like to submit the following comments to the P2P draft report (the 389 line version).

Severity

I would like to express my gratitude to the authors for describing the severity of ME/CFS and the massive impact it has on many patients and their families.

Not a psychological disorder

Thank you for establishing that this is not a psychological disorder (lines 92-93). If possible, I think this would be worth repeating in the Conclusion (lines 353-389). The false assumption that ME/CFS is a psychiatric condition has caused enormous damage to the patient group and has severely hampered research. It would be most important if the final report states clearly in its conclusion that ME/CFS is an organic multi-system disease (evidence for this has long been in the literature).

Biomedical research urgently needed – NIH *must* allocate funds for biomedical ME/CFS research

Thank you for stating that biomedical research is urgently needed (lines 186-187). In the past, NIH and other public research funders have spent only a minimal amount on research into ME/CFS. For decades ME/CFS has been among the bottom five disorders on the list of circa 280 disorders into which NIH funds research. It is really no wonder that so little progress has been made. Furthermore, on a global scale, a large portion of what little money has been allocated for ME/CFS research has been spent on psycho-social studies which have failed to contribute to any advancements in the field.

I follow the literature closely and there is certainly no lack of promising leads in biomedical ME/CFS research. Immune system abnormalities; brain imaging studies showing abnormalities; protein profiles in CSF differentiating ME/CFS from controls as well as Lyme patients; signs of inflammation; a possible autoimmune factor (B-cell inhibitator Rituxan has been shown to be effective in 2/3 of patients in small studies); and the repeated findings of abnormalities in 2-day CPET tests showing metabolic dysfunction which probably explains the cardinal symptom of post-exertional crash.

However nearly all of these leads have been left without follow-up due to the extremely limited public funding available for ME/CFS research. I personally am familiar with several cases where highly-qualified researchers with cutting-edge technology have had grant applications rejected for follow-up ME/CFS studies. When they apply the same

technology to other diseases, they receive significant funds. This, of course, has led to many researchers leaving the field; to a lack of new researchers wanting to enter the field; and to stagnation of progress in the ME/CFS field.

The only way to change this is by NIH setting aside funds for biomedical research into ME/CFS, for example via multiple RFAs in the coming 10-year period. ME/CFS funds need to be brought up to the same level as, for example, MS funds. (As it is, MS receives 20 times as much NIH funding as ME/CFS.)

I strongly urge you to include in your recommendations, for example under the heading of 'Create new knowledge', line 212, that NIH must issue multiple RFAs for biomedical ME/CFS research over a 10-year period, with the aim of bringing their spending on biomedical ME/CFS research to levels compatible with the disease burden and needs of the ME/CFS patient group.

This should also be stated in the Conclusion (lines 353-389).

Multimodal therapy not the way to go – Biomedical Centres of Excellence needed

'Multimodal therapy' can have different meanings, but as I understand the draft report, it stands here for a treatment program consisting of different modalities, which can include CBT and exercise (GET), and is carried out by a 'multidisciplinary care team (e.g., physicians, nurses, case managers, social workers, psychologists)'.

I would like to inform you that this very approach to ME/CFS treatment has been tried in several locations in Scandinavia. Units have been created with teams consisting of nurse, doctor, psychologist, physiotherapist, counsellor, offering multimodal therapy for ME/CFS patients.

The results have been very discouraging. It has become evident that this treatment model does not meet the needs of ME/CFS patients as things stand today.

We know multidisciplinary teams can be beneficial in chronic diseases where the biomedical etiology has been firmly established, such as MS or RA. With these diseases, the primary requirement: specialist care where biomedical treatments are trialled, is satisfied. As such, in these cases, multimodal therapy can be useful in secondary rehabilitation. However, with ME/CFS, the primary need has not yet been satisfied. First and foremost this patient group needs biomedical care by a specialist medical practitioner with expertise in ME/CFS. The main focus needs to be on trialling biomedical treatments for the patient, just as is done in MS or RA.

For this basic care to become available to ME/CFS patients, Centres of Excellence where patients can be referred and biomedical research organized are necessary. A multidisciplinary approach is advisable, but in a different form. Given that ME/CFS is such a pronounced multi-system disease, ME/CFS patients need a team of physicians from different specialities: immunology, neurology, rheumatology, general medicine, etc.

A team or network of medical specialists is much more effective for ME/CFS patients and a better use of resources.

Health care boards in Scandinavia have recognized this and are now steering away from the multimodal therapy model. The main need for ME/CFS patients has been identified as continuous contact with a knowledgeable physician who approaches their disease from a biomedical viewpoint and can help with symptomatic treatment (such as pain relief and sleep), sound advice on illness management (such as pacing/envelope theory), further investigations when necessary and management of new or flaring symptoms. This physician needs to be able to make home-visits, since a substantial percentage of the patient group are house-bound.

I hope you will remove the recommendations on multimodal treatment and the multidisciplinary team in its current form from the final report (lines 115-116; 303-306; 350; 370-371), and instead include a recommendation that biomedically oriented COEs be established.

ME/CFS cannot be managed by GPs

As a general practitioner, I would like to emphasize that ME cannot be managed by GPs. It is far too complex a disease and it is not realistic for each GP to build the expertise needed to adequately treat ME patients. Instead, we GPs need to know where to refer these patients. Again, I urge you to recommend that Centres of Excellence be established, so that ME can develop into an integrated part of specialist care.

Again, my sincere thanks for highlighting many of the crucial issues in the ME field. I hope my comments can be used for a final report which is even more attuned to the needs of ME patients and their carers.

Kind regards,

Johan Edsberg, MD