Public Comment
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Thank you for this opportunity to address CFSAC.

First, I would like to comment on the short time – less than a week and right before the Thanksgiving holiday weekend – that the public was permitted to submit testimony. This is the shortest time ever that the public was given notification in the history of CFSAC. Given people's busy lives (even perfectly healthy people) and the severe disability of many patients, this is an added hardship that does not at all honor the spirit of obtaining public input nor accommodating those affected by ME/CFS or their caregivers and interested clinicians/ researchers. I myself am completing this letter the night right before the deadline. Actions like these do not build trust nor good faith with the ME/CFS community.

CENTERS OF EXCELLENCE (COE)

This has been a top and repeated recommendation of CFSAC members since 2004 yet no real action has been taken on it. There were 3 active COEs for ME/CFS back in the early 2000s – at the University of Washington, University of Miami, and the University of Medicine/ Dentistry New Jersey; they served patients and conducted research, publishing multiple articles in various journals, yet all three were cancelled for unclear/ unknown reasons. Since then, there have been no federal efforts to fill their void.

Earlier in my career, I trained at an equivalent of a COE for geriatric medicine. It was a wonderful experience for me and a valuable resource for the local community and region. The center had a three-prong mission: take care of patients, conduct research, and educate both existing and future healthcare providers.

These three areas are sorely needed for ME/CFS. There are only a handful of providers nationally and they are concentrated in a few geographic areas. Even those patients fortunate enough to have the physical, financial, logistical means to reach those providers often face a waiting list of several months to several years. A ME/CFS COE(s) may not be able to care for every patient but it would be a start and could serve as a resource for especially complex cases. Educational efforts could make local healthcare providers more comfortable with diagnosing/ managing basic aspects of ME/CFS and construct a pipeline of future ME/CFS experts. In his rejection of CFSAC's Spring 2014 recommendations this June, Dr. Collins noted that career development grants are one source of funding for ME/CFS research yet without an adequate supply or easy identification of mentors and infrastructure to support them, what young promising clinician or investigator would enter this field? I was partly attracted to geriatric medicine because of the number of active/ influential mentors at the COE I trained at as well as the faculty development grant I was awarded targeted specifically towards geriatric medicine. Finally, we still do not have a single diagnostic test, biomarker, or disease-modifying treatment for ME/CFS. A major bottleneck in clinical research is subject recruitment. Current studies suggest that up to 90% of patients with ME/CFS have not yet been appropriately diagnosed. COEs could help overcome this obstacle by providing a ready source of subjects.

If a brick-and-mortar COEs are not able to be created, I hope that DHHS will at least consider creating a virtual COE where several groups, universities, etc. are networked together to serve the functions outlined above.

PATIENT REGISTRY

Currently, there are a number of different efforts spread across the country attempting to gather data on ME/CFS subjects. However, most of these efforts are not integrated so that different variables are collected by different groups, variables are defined in diverse ways, numbers of subjects per effort may not be enough to define subgroups, and hypotheses/ theories advanced by one group cannot be verified or replicated easily.

Registries have long been in use and have been of benefit in answering questions and spurring research into cystic fibrosis, COPD, cancer, and a host of other illnesses. Recently, the NY Times published an article concerning how careful analysis of patient databases can provide information to clinicians and researchers when studies have not been performed.

http://www.nytimes.com/2014/10/05/magazine/can-big-data-tell-us-what-clinical-trials-dont.html?_r=0

Similarly, for ME/CFS, there are lots of questions but very little answers. A registry would be one way to begin to answer some of these questions.

Here in the US, because of a fragmented healthcare system and patient privacy laws, we have not been able to answer questions that other countries with a national healthcare system are able to do. For example, in Taiwan and Norway respectively, the risk of developing CFS post-infection with HSV-1 and Girardia was able to be captured because of their databases:

http://www.ncbi.nlm.nih.gov/pubmed/24715153

Other than treatment efficacy, natural history, and epidemiology, registries can also illuminate practice patterns/ variations, assess harm/ safety of treatments, explore health-related quality of life/ patient-reported outcomes, assess economic impact, and inform policymaking.

In terms of patient privacy, while that is a concern that needs to be taken into account, best practices that have been used in other registries can also be employed here and patients have already shown a willingness to share the data via the other efforts mentioned previously as well as through Internet sites like Patients Like Me.

ME/CFS RESEARCH FUNDING:

Considering the millions that DHHS has put into exploring the research background, gaps, and opportunities in ME/CFS via the 2011 NIH State of the Knowledge Conference, NIH P2P, and IOM efforts, I hope DHHS will also provide targeted funding for research. Otherwise, these efforts will not yield the advances we hope to accomplish.

Thanks,

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