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Trans-NIH ME/CFS Research Working Group
Office for Research on Women's Health (ORWH)
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Summary

On December 9–10, 2014, the National Institutes of Health (NIH) held [illegible] Pathways to Prevention Workshop [illegible]

agencies, patient advocacy groups, and patients and their families, have a shared responsibility for meeting the needs described herein, and thereby improving the lives of people living with ME/CFS.

Background

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a chronic, complex, and multifaceted disease characterized by substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities; post-exertional malaise; unrefreshing sleep; and at least one of the

diagnostic test. The absence of a standard case definition and lack of consensus in the community about which one to use for clinical studies of ME/CFS leads to confusion and the inability to draw correlations across studies that use different definitions. It is agreed that such features as the heterogeneity of symptoms and the specific quality of the fatigue (i.e., post-exertional malaise) need to be taken into account in all studies of ME/CFS. Clinical criteria outlined in the Institute of Medicine's recent report on ME/CFS should inform these efforts. Discussants acknowledged that more research is needed before a case definition can be established. Involvement of individuals with ME/CFS and health care providers in defining both disease parameters and outcome measures will lead to optimal results.

- The information contained in the FDA guidance for industry on developing drugs for ME/CFS (April 2013) was developed to advance the regulatory science to support clinical outcome assessment for ME/CFS, and can help to guide future ME/CFS research efforts.

Opportunities for Collaboration Among Federal Agencies, Resource Development, and Next Steps:

Several opportunities for federal partner collaboration in supporting activities and research that may lead to an improved definition of ME/CFS were identified:

- Develop Common Data Elements (CDEs) for ME/CFS. CDEs will allow researchers and clinicians to standardize the collection of data in order to facilitate comparison of results across studies and more effectively aggregate information into significant metadata results. The NINDS Common Data Elements Project can serve as a guide for the development of CDEs for ME/CFS. This process will take advantage of existing resources in the community (the CDC-funded Multi-site Clinical Assessment of CFS study), as well as at NIH [Patient-Reported Outcomes Measurement Information System (PROMIS), the NIH ToolBox, OMERACT, and the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network].

- Community-based participatory research and patient reported outcome (PRO) measures offer opportunities for capturing the assessment of symptoms and function by individuals with ME/CFS.

- Future studies could take advantage of emerging technologies, such as telemedicine, in order to reach home- and bed-bound individuals with ME/CFS.

Summary of Discussion of P2P Panel Recommendation II: Create New Knowledge

Background: Studies of ME/CFS are fraught with methodological problems, preventing a clear understanding of who is affected by ME/CFS: there are no universally agreed-upon parameters for defining ME/CFS, no accurate ways of identifying and diagnosing ME/CFS and, as one participant pointed out, 163 possible combinations of symptoms associated with the disease. In addition, small

limits generalizing the results of current studies. Some instruments used to evaluate ME/CFS are not validated, are inappropriate, and may be misleading. All of these issues contribute to inconclusive research results and a lack of definitive knowledge about incidence, prevalence and potential causes and treatments (Green et al., 2015).

Specific Research Focus Areas: The following research priorities were identified by the federal partners:

- Invest in bench-to-bedside research. Research that provides detailed analysis of multiple measures in large numbers of individuals with ME/CFS would help investigators to

Through a contract with the Center for Advanced Professional Education, the CDC developed a set of videos for the MedEdPORTAL focusing on the doctor-patient interaction and pediatric/adolescent ME/CFS. This resource could be expanded to include additional ME/CFS materials. It would be important also to develop educational materials for other health care providers including nurses, physician assistants, etc.

- Developing educational materials with broad stakeholder collaboration: Individuals with ME/CFS, advocates, medical professional and educational organizations, clinicians with expertise in ME/CFS, and government (HHS ex officio CFSAC members) could work together to develop educational materials. One way to foster collaboration between academic centers and the federal government is to identify grants and funding opportunities for development of educational programs and materials for health care professionals and for individuals with ME/CFS and their caregivers.

Opportunities for Collaboration Among Federal Agencies, Resource Development, and Next Steps:

Developing ME/CFS educational materials offers several collaborative opportunities:

- Working together on educational materials would help promote communication among stakeholders and improve dissemination of educational materials to the health care provider community.
- Educational materials should incorporate the recommendations from the IOM ME/CFS report.
- Topic/delivery method needs for continuing medical education (CME) resources should be assessed as they relate to ME/CFS.
- Educational materials should communicate consistent messages and the federal partners should present accurate, evidence-based, and up-to-date information on ME/CFS.
- Stakeholders should partner on agency-developed CME courses and reach out to primary care providers to promote these resources. The optimal outreach strategy will need to be determined.
- The HHS Health Resources & Services Administration (HRSA) supports community health centers that seat sen agey cd

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