

Pathways to Prevention:

Weighing the evidence. Identifying the research gaps. Determining next steps.

A Report from the Federal Partners Meeting of the National Institutes of Health Pathways to Prevention Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

Tuesday, May 24, 2016

Sponsored by:

Trans-NIH ME/CFS Research Working Group
Office for Research on Women's Health (ORWH)
Office of Disease Prevention (ODP) National Institutes of Health (NIH)

Summary

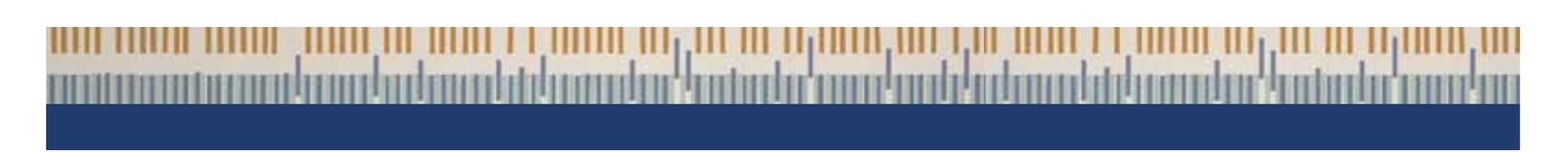
On December 9–10, 2014, the National Institutes of Health (NIH) held the [Pathways to Prevention \(P2P\) Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome \(ME/CFS\)](#) [see [P2P Program](#) for more information about the Office of Disease Prevention (ODP)]. The P2P workshop on ME/CFS was co-sponsored by the Trans-NIH ME/CFS Research Working Group, the ODP, and the Office for Research on Women's Health (ORWH).

This report summarizes the discussion at the May 24, 2016, Federal Partners Meeting that followed

the P2P workshop on ME/CFS and reflects a commitment by the NIH and other federal

agencies to advance research on ME/CFS. The Federal Partners Meeting identified several areas for potential collaboration, resources available from different federal agencies, and potential next steps to address the recommendations from the P2P Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Final Report (Green et al., 2015).

As an outline of the initial priorities to improve treatments and reduce the disease burden for ME/CFS, this summary is intended to be a blueprint for the entire ME/CFS community. All stakeholders,



including academic researchers, companies, government 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 two following symptoms: cognitive impairment or orthostatic intolerance (Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness, 2015). Many individuals with ME/CFS experience significant disability, and some become homebound or bedbound. The etiology and pathogenesis remain unknown; there are no laboratory diagnostic tests, and no FDA-approved treatments for ME/CFS. An estimated 836,000 to 2.5 million people in the United States have ME/CFS (Jason et al., 1999, 2006a; Reynolds et al., 2004). ME/CFS is an unmet public health need with direct and indirect economic costs estimated to range from \$18 billion to \$24 billion annually in the United States (Jason and Richman, 2008). Limited knowledge about the underlying cause(s) of ME/CFS creates an additional burden for individuals with the disease, their families, and caregivers, as well as for health care providers.

The P2P Workshop and Federal Partners Meeting

The Trans-NIH ME/CFS Research Working Group, in collaboration with the ODP and ORWH, organized a P2P Workshop: Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome to facilitate discussion of the research areas to be

addressed for ME/CFS. A multidisciplinary expert group developed the workshop agenda, and an evidence report based on a systematic literature review was prepared by an Evidence-based Practice Center through a contract with the Agency for Healthcare Research and Quality (AHRQ) to facilitate the workshop discussion (Smith et al., 2014).

The workshop was designed to address four key questions:

1. How has the research on ME/CFS using multiple case definitions contributed to the state of the current scientific literature on diagnosis, pathophysiology, treatment, cure, and prevention of ME/CFS?
2. Are the measurement outcomes (tools and measures) currently used to diagnose individuals with ME/CFS sensitive enough to identify subsets of patients according to duration, severity, nature of the illness, onset characteristics, and other categorizations?
3. How will the research on treatments or therapies shown to be effective in addressing symptoms of ME/CFS lead to an understanding of the underlying pathology associated with ME/CFS?
4. How have innovative research approaches provided an understanding of the pathophysiology of ME/CFS, and how can this knowledge be applied to the development of effective and safe treatments?

The workshop took place on December 9–10, 2014, and an unbiased, independent panel prepared a report summarizing the meeting (<https://prevention.nih.gov/docs/programs/mecfs/ODP-P2P-MECFS-FinalReport.pdf>). The P2P panel identified research gaps and future research priorities, and made seven recommendations directed toward federal and non-federal agencies, vendors, health care systems, and clinicians (Green et al., 2015).



On May 24, 2016, government representatives (hereafter called the “federal partners”) met to develop approaches to address the recommendations outlined in the panel report on Advancing the Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. The objectives of the Federal Partners Meeting were to identify opportunities to leverage existing resources and promote collaboration and synergy, while reducing overlapping efforts across the federal agencies, with the ultimate goal of generating rigorous scientific evidence that can lead to improved care for individuals with ME/CFS.

This report summarizes the discussions from the Federal Partners Meeting (see Appendix for a list of participants), which focused on the P2P panel’s recommendations:

1. Define disease parameters.
2. Create new knowledge about ME/CFS.
3. Improve methods and measures used in ME/CFS research.
4. Provide training on and education about ME/CFS.
5. Identify new funding resources.
6. Conduct clinical trials.
7. Improve treatment.

An analysis of research activities or initiatives conducted or supported by the participating federal agencies relevant to these recommendations contributed to the discussion of research and programmatic gaps, as well as the opportunities for collaboration. Participants considered the areas for collaboration that should be given the highest priority and the resources that could be utilized to address these areas.

Summary of Discussion of P2P Panel Recommendation I: Define Disease Parameters

Background: The P2P panel report identified the lack of a specific and sensitive diagnostic test and clearly defined diagnostic criteria as key impediments to ME/CFS research. Fatigue, long considered the defining feature of ME/CFS, does not fully capture the complexity of the disease, treatment response, or the experience of individuals with ME/CFS. While a number of diagnostic criteria are in use—CDC (Holmes et al., 1988), Fukuda (Straus et al., 1994), International (Carruthers et al., 2011), Canadian (Carruthers et al., 2003), and the IOM criteria (Institute of Medicine 2015)—none is uniformly recognized as the diagnostic standard.

Specific Research Focus Areas: One key area where federal partners may help in better defining ME/CFS is the translation of clinical diagnostic criteria into criteria for research studies. To achieve this, the federal partners discussed:

- The methods and research that are required to identify the underlying cause(s) of ME/CFS. When research leads to a biomarker and/or identifies the cause(s) of ME/CFS, then an objective definition of ME/CFS can be created, along with a clinical 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 sample sizes, the inclusion of participants with differing symptoms across studies, and the failure to include men, minorities, homebound individuals, and rural residents 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 identify the heterogeneity of symptoms among people with ME/CFS. Research that uses CDEs across all studies would improve reproducibility considerably. The use of new technologies (e.g., “omics,” imaging, microbiome, epigenetics) combined with patient-reported outcomes should be encouraged.
- Develop biomarkers and diagnostics. The

federal partners emphasized the urgent need in the field for high-quality, objective measures.

- Engage junior and new investigators. Senior investigators should be encouraged to more actively stimulate and support the development of early-career investigators in ME/CFS research, as well as encourage scientists working in related areas to focus on ME/CFS research in order to develop a pipeline of investigators who will continue to pursue work in this field.
- Coordinate research and funding efforts across federal agencies. The NIH and CDC support research on ME/CFS and should coordinate activities and take advantage of available resources.
- Utilize public-private partnerships to leverage existing research infrastructure.

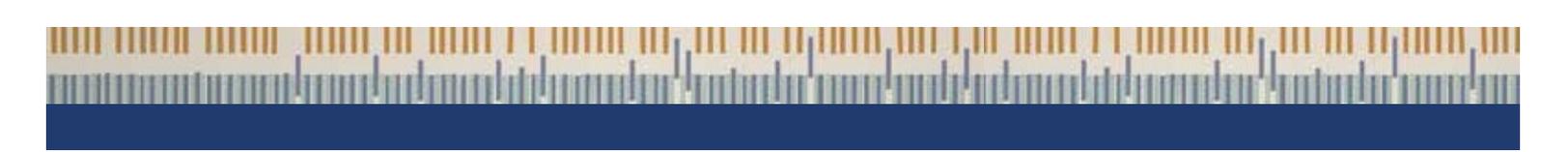
Opportunities for Collaboration Among Federal Agencies, Resource Development, and Next Steps:

The following collaborative opportunities, useful resources, and next steps in advancing research on ME/CFS were identified:

- Expand NIH extramural investigator-initiated research on ME/CFS through the use of administrative supplements to existing NIH grants to support investigators working in or interested in entering the field.
- Develop and implement ME/CFS collaborative research centers with a data monitoring and coordinating center. This will help build research infrastructure, recruit the patient population, and support rigorous research. The [National Center for Advancing Translational Science](#)

[\(NCATS\) Clinical and Translational Science Awards \(CTSA\) Program](#) could be leveraged to assist ME/CFS researchers and clinicians at academic centers across the United States.

- Establish a data repository with appropriate informatics tools and utilize CDEs that could provide a platform for collecting data across studies on ME/CFS and promote data sharing.
- Build on existing biorepositories for the collection and sharing of biospecimens. The focus should be on efficiently leveraging existing biorepositories rather than creating new ones. A centralized biorepository would be invaluable for diagnostic standardization, which is currently lacking in the field. The sample collection approach utilized by the CDC's multisite ME/CFS study should be considered; it may be helpful to encourage investigators to build their research grants on this study's framework. The biorepository established by the Solve ME/CFS Initiative could also be considered. It will be important to learn from the experience of other NIH biorepositories.
- Solicit input from and inform the public about federal partners' activities in the area of ME/CFS through webinars, conference calls, and requests for information. Options discussed include expanding the current CDC webinars to include other federal partners and/or establishing additional forums that are specific to individual federal agencies. It is important to continue to actively participate in the HHS' [Chronic Fatigue Syndrome Advisory Committee \(CFSAC\)](#). It is essential to coordinate the content of federal ME/CFS webpages: partners should develop clear communications materials about ME/CFS that link to the relevant HHS partner sites.
- Initiate a federal partners working group that meets on a regular basis to continue to foster communication and collaboration across the agencies, with periodic meetings open to



ME/CFS stakeholders.

Summary of Discussion of P2P Panel Recommendation III: Improve Methods and Measures

Background: The P2P panel report noted that many current ME/CFS studies suffer from multiple methodological problems including an absence of accurate clinical measures, small sample sizes, inconsistent inclusion criteria, and lack of diversity among participants. These deficiencies contribute to an inadequate understanding of disease mechanisms, and inhibit the development of treatments.

Specific Research Focus Areas: To address some of these methodological gaps, the federal partners proposed to adopt the patient-focused drug development (PFDD) framework utilized by the FDA. PFDD is an FDA initiative that focuses on the experiences of individuals with the disease and systematically engages with them as stakeholders to obtain their perspective on a given condition and its treatment options. Establishing the therapeutic context is an important aspect of benefit-risk assessment when considering treatments, and individuals with ME/CFS are uniquely positioned to inform the understanding of this context. In April 2013, the FDA convened a two-day workshop to assess the perspectives of people with ME/CFS. Two outcomes from this workshop were [The Voice of the Patient](#) report and [guidance for industry on developing drugs for ME/CFS](#).

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

Clinicians have observed that for some individuals with ME/CFS, treating the symptoms of the disease can improve how they

feel and can enhance their quality of life. A recent systematic review of treatments used by individuals with ME/CFS concluded that there is no clear recommended pharmaceutical therapy for ME/CFS based on the heterogeneity of the study participants, the large number and variety of questionnaires and scales used in these studies, the small sample sizes, and the methods used to measure treatment effectiveness in individuals with ME/CFS (Collatz et al., 2016). The federal partners emphasized the need to develop outcome measures for clinical studies and eventual clinical trials of potential treatments that are both objective (measure biological changes) and subjective (measure how the individual feels and their functional capacity and quality of life).

A biomarker can be considered as a clinical outcomes assessment measure in a trial, but the primary efficacy endpoints should also reflect the individual's quality of life. It is not necessary to know the exact disease mechanism or to have ideal preliminary data and a perfect biomarker in order to initiate treatment trials. Instead of targeting underlying disease mechanisms, one approach may be to focus on treating specific symptoms, which may have a profound impact on the individual's quality of life.

- Draft guidance for drug development to treat ME/CFS has been released by the FDA ([Guidance for Industry – Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis: Developing Drug Products for Treatment](#)). There currently are no FDA-approved treatments for ME/CFS, so investigators need to develop standard outcome measures to test potential new treatments. Collaborations between the federal agencies with an interest in research and development of new treatments for ME/CFS are needed to develop common data elements and common outcome measures that can be utilized in future clinical trials.

Summary of Discussion of P2P Panel Recommendation IV: Provide Training and Education

Background: The P2P panel report noted that many clinicians do not fully understand ME/CFS. Hence, workforce training is critical. Specifically, there is a need for inclusion of education about ME/CFS in medical school curricula. Invested federal agencies, health care providers, and professional medical societies will need to partner to help develop and disseminate information about ME/CFS to the health care workforce—both those in practice and those in training.

Specific Training and Education Focus Areas: The following focus areas where federal partners could improve ME/CFS training and education were identified:

- CDC CFS Patient-Centered Outreach and Communication Activity (PCOCA) Conference Calls: These calls were established by the CDC to provide outreach to individuals in the ME/CFS community through public call-in lines. The calls provide updates on CDC activities and cover topics of interest to the ME/CFS community. PCOCA calls offer an opportunity to share information with and about other agencies. The calls could be expanded and improved, including to target new audiences such as researchers, clinicians, etc. Other federal agencies could also help advertise the calls.
- Medical School Educational Initiatives: 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 serve populations with limited access to health care. Federal partners should collaborate with HRSA and these clinics to disseminate educational materials to limited-access populations.

Summary of Discussion of P2P Panel Recommendation V-VII: Find New Funding Resources (V), Conduct Clinical Trials (VI), and Improve Treatment (VII):

While the Federal Partners Meeting focused on the first four recommendations from the P2P panel, recommendations V–VII also represent important needs and were discussed throughout the meeting. Several opportunities to address them were identified.

One way to bring in new funding is to leverage the fundraising efforts of non-governmental organizations such as the Solve ME/CFS Initiative and the Open Medicine Institute, which supports seed grants and early-stage research.

The existing CTSA infrastructure could be utilized for the initiation of clinical trials. Similarly, the CDC’s multisite study is a valuable resource that could help fast-track ME/CFS research. The [FDA guidance for industry on developing drugs for ME/CFS](#) has set in place many trial guidelines that may be operationalized. Repurposing drugs developed for related conditions could help advance ongoing treatments before new ME/CFS therapies become available. The NIH supports the planning and execution of clinical trials through standing grant mechanisms that are investigator-initiated and peer-reviewed. ME/CFS investigators should be encouraged to discuss

plans for clinical trials with NIH program staff in the appropriate NIH Institute.

New treatments for ME/CFS will rely on research to identify the underlying mechanism(s) of disease and changes in physiological systems over the course of the disease that can be altered or prevented. Biomarker studies that define measurable changes in these systems and can identify specific sub-types of ME/CFS may lead to the development of targeted treatments for these individuals.

Conclusions and Next Steps

The key recommendations from the Federal Partners Meeting are:

1. Develop Common Data Elements utilizing existing resources at the NIH, CDC and from ME/CFS clinicians and researchers where possible.
2. Operationalize the FDA Guidance for Industry on Developing Drugs for ME/CFS to more fully capture the patient’s perspective in interventional clinical trials.
3. Leverage the resources and infrastructure developed to support the CDC multisite ME/CFS study.
4. Enhance collaboration between federal agencies through increased communication and partnering opportunities where feasible.
5. Enhance communication with ME/CFS stakeholders through shared webinars, conference calls, and other methods as appropriate.

These efforts will provide collaborative opportunities for the federal partners to address the key P2P panel recommendations—to define the ME/CFS disease parameters, increase knowledge about the condition, improve available clinical methods and measures, and better educate and train stakeholders—with the ultimate goal of relieving the personal and societal burden of ME/CFS.

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Appendix: Tools and Resources:

NIH

- [Resources from the Trans-NIH ME/CFS Working Group](#)
- [Pathways to Prevention Workshop Resources](#)
- [Multidisciplinary Approach to the Study of Chronic Pelvic Pain \(MAPP\) Research Network](#)
- [Common Data Elements \(CDEs\)](#)
- [NCATS Clinical and Translational Science Awards \(CTSA\) Program](#)
- [NIH ToolBox](#)
- [ME/CFS Scientific Interest Group](#)
- [Patient-Reported Outcomes Measurement Information System \(PROMIS\)](#)

CDC

- [CDC Chronic Fatigue Syndrome \(CFS\) Resources](#)
- [Multi-site Clinical Assessment of CFS Study](#)

FDA

The 2013 ME/CFS Workshop Outcomes:

- [The Voice of the Patient Report](#)
- [Guidance for Industry – Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis: Developing Drug Products for Treatment](#)

HHS:

- [Chronic Fatigue Syndrome Advisory Committee \(CFSAC\)](#)

Social Security Administration:

- [Disability Evaluation Under Social Security](https://www.ssa.gov/disability/professionals/buebook/evidentiary.htm)
<https://www.ssa.gov/disability/professionals/buebook/evidentiary.htm>
- [Providing Medical Evidence to the Social Security Administration for Individuals with Chronic Fatigue Syndrome – Fact Sheet](https://www.ssa.gov/disability/professionals/cfs-pub063.htm)
<https://www.ssa.gov/disability/professionals/cfs-pub063.htm>

Non-federal:

- [Institute of Medicine Report: Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome](#)

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