May 28, 2014

VIA FACSIMILE AND PRIORITY MAIL

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
1 Center Drive, MSC 0148 (Room 126)
Bethesda, MD 20892-0148

RE: Pathways to Prevention Workshop on ME/CFS

Dear Dr. Collins:

We are writing to request that you cancel the Office of Disease Prevention's Pathways to Prevention Workshop on ME/CFS ("P2P Workshop"). Your immediate action is required to ensure that ME/CFS research and policy is based on the best scientific evidence and processes.

In your April 16, 2014 letter to Representative Zoe Lofgren and colleagues, you said that the P2P Workshop would produce recommendations to move the field forward. We believe that this is not the case, and we offer the following documentation to support our conclusion:

- The Workshop is unnecessary and redundant given the recommendations of disease experts and other NIH efforts to advance ME/CFS research and clinical care. See Attachment 1.
- The Workshop has been structured to address the problem of medically unexplained fatigue, and not the disease(s) known as ME/CFS. See Attachment 2.
- NIH has paid lip service to collecting input from stakeholders, but in reality has not involved them in a meaningful way. See Attachment 3.
- The P2P Workshop process is inappropriate for this disease, particularly because the decision makers will be non-ME/CFS experts. See Attachment 4.
- The goal of this Workshop is unclear as a result of numerous contradictory and confusing public statements by HHS about the purpose of the Workshop. See Attachment 5.

Dr. Collins, we are not objecting to the P2P Workshop simply to make a political point or for the sake of criticizing federal efforts to address the challenges of this disease. We are appealing for your help because we know you recognize that ME/CFS is a serious public health issue that needs the best of what science can offer. We sincerely believe that the evidence included with this letter raises genuine concerns that the P2P Workshop does not represent the best of what science can offer, and may very well take us in the opposite direction.

For all of these reasons, we request that you cancel the P2P Workshop. Further, we request that NIH reexamine how to best collaborate with the ME/CFS research and clinical community to achieve the goals of a research definition and strategy. Those who are researching and treating this disease are in the best position to define how to move forward.

We thank you for your consideration of this issue, and we look forward to your reply.

Sincerely,

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Mary E. Dimmock
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cc: Senator Richard Blumenthal (D-CT)
Senator Bob Casey, Jr. (D-PA)
Senator Chris Murphy (D-CT)
Senator Pat Toomey (R-PA)
Representative Joseph Courtney (D-CT-2)
Representative Zoe Lofgren (D-CA-19)
Representative Patrick Meehan (R-PA-7)
Dr. David M. Murray, Director of the Office of Disease Prevention

ATTACHMENT 1

The P2P Workshop is unnecessary and redundant given the recommendations of disease experts and other NIH efforts to advance ME/CFS research and clinical care. This is wasteful and impedes the ability of NIH and the ME/CFS research community to transparently collaborate to address the most critical issues in the field.

1. In your April 16, 2014 letter to Representative Lofgren and colleagues, you stated that the P2P Workshop would "address how to get ME/CFS researchers working together" on the case definition issue. But this is unnecessary and duplicative because ME/CFS researchers are already working together.

    a. Fifty international ME/CFS researchers already published their agreement on adopting the Canadian Consensus Criteria for both research and clinical use (letter enclosed herewith).
    b. Communication and collaboration among ME/CFS researchers has been stimulated by the 2011 NIH State of the Knowledge meeting, non-profit research networks, and the biannual meeting of the International Association for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis.
    c. More work needs to be done, surely, and an infusion of resources, including NIH research funding, is desperately needed. But it is incorrect to say that the P2P Workshop is needed in order for the ME/CFS researchers to reach agreement on case definition issues, especially since the P2P Workshop will not address the research case definition and the P2P Panel will include no ME/CFS experts whatsoever.

2. One of the stated goals of the P2P Workshop is to "identify research gaps . . . methodological and scientific weaknesses [and] suggest research needs,"[1] but this is duplicative of the same effort made at the April 2011 NIH State of the Knowledge meeting.

    a. On April 8, 2011, you attended the summary session of the State of the Knowledge meeting on ME/CFS. The ME/CFS community applauded your interest in the meeting, especially given the possibility of an imminent government shutdown that day. You may recall that in the session you attended, Dr. Suzanne Vernon provided an excellent summary of the meeting, including identification of the gaps and opportunities to advance ME/CFS research (slides enclosed herewith).
    b. This work of identifying the gaps and needs to move forward was accomplished at the State of the Knowledge meeting by the ME/CFS experts and others in attendance, as President Obama wrote in a July 26, 2012 letter to Mrs. Courtney Miller (enclosed herewith).

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[1] Dr. Susan Maier, CFS Advisory Committee Minutes, December 11, 2013, p. 16.

[2] Dr. Susan Maier, CFS Advisory Committee Minutes, May 23, 2013, pp. 11.

[3] Dr. Nancy Lee, CFS Advisory Committee Minutes, December 11, 2013, p. 12.

c. The P2P Workshop is not structured to accomplish this goal of identifying the gaps and opportunities (see also Attachments 2 and 4). With its narrow scope of questions, overly broad evidence base, and reliance on non-ME/CFS experts, the P2P Workshop is unlikely to add anything of substance or value to the work done at the 2011 State of the Knowledge meeting.
d. There is simply no need to revisit the work done at the State of the Knowledge meeting with the inadequate approach of the P2P Workshop. What is needed is the strategy and resources to begin filling in those research gaps with good science.

3. As you know, NIH is funding the Institute of Medicine ("IOM") study to create new clinical diagnostic criteria for ME/CFS, an effort that is in itself redundant given the ME/CFS experts' recommendation to adopt the Canadian Consensus Criteria for clinical use. While the IOM deliberations are confidential, it is obvious that they are conducting a thorough review of ME/CFS case definitions in order to adopt, revise, or create new criteria. The P2P's apparent charge to "address the validity, reliability, and ability of the current case definitions"[2] is redundant and wastefully duplicative of the effort underway at IOM. It makes no sense to pursue both efforts simultaneously because there is significant overlap between the evidence reviews and potential outcomes. Therefore, given HHS's repeated statements that the IOM contract will not be suspended or cancelled[3], the only alternative is to cancel the P2P Workshop.

4. It is inaccurate to state that there is synergy between the IOM and P2P efforts, although NIH and the Office of Women's Health have repeatedly done so. The timelines and procedures of these twin efforts do not permit such synergy.

    a. The IOM process requires that no information about deliberations can be released until their report is published. Therefore, the P2P Workshop is cut off from information, research and questions from the IOM panel.
    b. The reverse may also be true. At the January 27, 2014 IOM meeting, Dr. Cynthia Mulrow requested that the systematic review evidence tables be provided to the IOM panel before the draft report is published. Dr. Susan Maier was uncertain as to whether this would be permitted.[4]
    c. Dr. Nancy Klimas stated at the same meeting that she was on both the P2P Working Group and the IOM panel, but she was completely confused as to what information she could share with each group.[5]
    d. The P2P Workshop is tentatively scheduled for December 2014, which suggests that the Panel's final report will be published in early 2015. By that time, the IOM panel's report will be in finalization for publication. IOM will have reached their own conclusions months before the P2P meeting occurs.

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[2] Dr. Susan Maier, CFS Advisory Committee Minutes, May 23, 2013, pp. 11.

[3] Dr. Nancy Lee, CFS Advisory Committee Minutes, December 11, 2013, p. 12.

[4] http://www.iom.edu/Activities/Disease/DiagnosisMyalgicEncephalomyelitisChronicFatigueSyndrome/2014-JAN-27/Videos/Session%20Background/8-Maier-QA-Video.aspx (retrieved May 19, 2014), Minute 12:04.

[5] Ibid., Minute 11:35.

ATTACHMENT 2

The P2P Workshop has been structured to address the problem of medically unexplained fatigue, and not the disease(s) known as ME/CFS. As can be seen from the enclosed documents, the draft meeting agendas and Systematic Review Protocol focus on medically unexplained fatigue – a symptom – and not ME/CFS. The Protocol is fundamentally flawed because it assumes that all case definitions for CFS and ME represent the same disease or set of diseases whose central feature is fatigue, and that scientifically valid comparisons can be made across these definitions. These assumptions create a significant risk that the Workshop outputs, both the systematic evidence review and the Panel's final report, will muddy the scientific waters by failing to question if more than one disease is captured by the multiple case definitions. This also creates a significant risk to the Institute of Medicine initiative if the P2P outputs are provided to the IOM panel.

1. The draft meeting agendas, obtained through a Freedom of Information request and enclosed herewith, state that the Topic Overview will frame the meeting as "Overwhelming fatigue or malaise as a public health problem." Yet this is a completely different public health problem from that of ME/CFS. As stakeholders have repeatedly expressed to NIH and other federal agencies, ME/CFS is not "overwhelming fatigue." It is a disease characterized by post-exertional malaise and cognitive dysfunction, and accompanied by neurological, autonomic, and immunological abnormalities. To frame the problem as fatigue imposes a dangerous paradigm on the Workshop and the initiative overall, especially given concerns addressed in more detail in Attachment 4.

2. The Systematic Review Protocol[6] focuses the evidence review on adults with fatigue, without other underlying diagnosis (unspecified). This, and the explicit inclusion of all case definitions, casts an overly broad net. At least one case definition requires no more than unexplained fatigue for a diagnosis of CFS, despite the mounting evidence that such case definitions capture a different study population than definitions that require post-exertional malaise, cognitive dysfunction or other multi-system impairments.[7] The very fact that the ill-defined and ubiquitous symptom of unexplained fatigue is the *only* symptom shared by all the definitions listed by the Systematic Review Protocol should cause us all to question the scientific validity of the approach.

3. The Systematic Review Protocol states that it is focused on the "clinical outcomes surrounding the attributes of fatigue, especially post-exertional malaise and persistent fatigue and its impact on overall function… because these are unifying features of ME/CFS that impact patients."[8] However, post-exertional malaise is not an attribute

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[6] http://www.effectivehealthcare.ahrq.gov/ehc/products/586/1906/chronic-fatigue-protocol-140501.pdf (retrieved May 19, 2014).

[7] Brown AA, Jason LA, Evans MA, Flores S. Contrasting case definitions: the ME International Consensus Criteria vs. the Fukuda et al. CFS criteria. North Amer J Psych. 2013; 15(1): 103-120.

[8] Systematic Review Protocol, p. 2.

of fatigue, but rather a distinct symptom of ME/CFS that is associated with dysfunction of energy production and exacerbation of other disease symptoms. Further, symptoms of ME/CFS like unrefreshing sleep and cognitive impairment are not listed as part of the report's stated focus, and are not mandatory for some of the definitions to be used as evidence even though they are mandatory for ME/CFS definitions like the Canadian Consensus Criteria and were recognized by the FDA in its Voice of the Patient report.[9]

4. The Draft Key Questions, as described by Dr. Susan Maier to the Institute of Medicine on January 27, 2014 (slides enclosed herewith), included the fundamental question of how CFS and ME differ and whether they represent more than one disease. This is the most important foundational question confronting both the clinical and research fields. Yet that question has been completely excised from the final Key Questions presented in the Systematic Review Protocol. Instead, "ME/CFS" is treated as a single diagnosis, with any differences between definitions treated as subtypes of the same illness. The focus has been shifted to assessing the accuracy and concordance of diagnostic methods and the benefits and harms of interventions across definitions. Such comparisons are invalid if these definitions do not actually represent the same illness.

[9] FDA Voice of the Patient, Chronic Fatigue Syndrome and Myalgia Encephalomyelitis, September 2013, pp. 5-10.

ATTACHMENT 3

NIH has paid lip service to collecting input from stakeholders, but in reality has not involved them in a meaningful or substantive way. In many cases, the recommendations of subject matter experts and other stakeholders has been ignored.

1. The critical need to resolve case definition issues was identified by the ME/CFS experts at the April 2011 State of the Knowledge meeting hosted by NIH, as you acknowledged in your April 16, 2014 letter to Representative Lofgren. In response to that need, the CFS Advisory Committee (CFSAC) recommended a workshop of ME/CFS experts, patients and advocates to reach consensus on a case definition beginning with the Canadian Consensus Criteria.[10] Instead, NIH ignored that recommendation and has elected to use a P2P Panel of non-ME/CFS experts to make recommendations that may or may not be related to identifying a research case definition. When NIH informed the CFSAC about this plan, CFSAC members expressed serious disapproval and dismay[11], yet NIH has forged ahead over their objections.

2. In September 2013, fifty international ME/CFS experts recommended the adoption of the Canadian Consensus Criteria for both research and clinical use (see Attachment 1). Patients supported this recommendation with thousands of signatures on petitions. Yet again, NIH rejected these recommendations and, failing to substantially engage with any of the stakeholders, has continued the P2P Workshop.

3. The P2P Workshop planning is proceeding in secrecy without adequate transparency to the public, or even among the disease experts who are involved from one step in the process to the next.

    a. First, the names of the members of the P2P Working Group have not been released by NIH, except through a Freedom of Information Act request[12] and even then only in draft form.
    b. Second, the names of the members of the Technical Expert Panel and Peer Reviewers advising on the systematic evidence review will not be released until the draft report is published.
    c. HHS has repeatedly made assurances that true experts and patients are involved in the P2P Working Group, Technical Expert Panel and Peer Reviewers for the evidence review, but there is no transparency or accountability to the public until it is too late for anyone to object.
    d. Third, these different compartmentalized panels are acting in sequence with no apparent continuity of disease experts from one panel to the next. For example, the questions first refined by the Working Group were then modified by the Technical Expert Panel with no input from the original Working

[10] http://www.hhs.gov/advcomcfs/recommendations/10032012.html (retrieved May 19, 2014).
[11] CFS Advisory Committee Minutes, May 23, 2013, pp. 11, 48- 49.
[12] This request was filed by another advocate, and the documents are no longer available to the public.

Group. Somewhere along the way, the critical question on the equivalency of the definitions was dropped.

4. NIH appears to be ignoring at least some of the advice it received from the ME/CFS experts on the Working Group.

    a. On May 23, 2013, Dr. Susan Maier said, "The purpose of the workshop is to evaluate the research evidence surrounding the multiple case definitions and to address the validity, reliability, and ability of the current case definitions to identify individuals with the illness, identify individuals within the subgroups with the illness who can be differentiated by a case definition, and/or to identify responders or non-responders based on some element of the case definition as informed by the evidence."[13] This statement is surprisingly similar to the Key Questions stated in the Systematic Review Protocol months later, raising the question of whether the ME/CFS experts truly had any influence on the final Protocol.
    b. Several sources indicated to us personally that the Key Questions in the Systematic Review Protocol were not the questions defined by the Working Group. It appears there was no final review or signoff opportunity for those subject matter experts before the Key Questions were handed off to the Evidence Practice Center. Other aspects of the systematic review, such as the exclusion of studies on pediatric patients, were reportedly included over the objections of some Working Group members.

5. Your letter to Representative Lofgren stated that "ME/CFS scientists, clinicians, patients and patient advocacy groups" are actively involved in all phases of the initiative. But in fact, those opportunities are limited and complicated by barriers.

    a. First, the composition of the Working Group disproportionately emphasized federal and non-ME/CFS expert members. According to the draft roster released to another advocate, only five of the twenty members were ME/CFS experts.
    b. Second, the input of the ME/CFS experts on the Working Group has been dismissed on several issues (see #4 above). It appears they will not be engaged again as the agenda is finalized and speakers selected.
    c. Third, there was no opportunity for public input into the Systematic Review Protocol, despite that being a routine part of the process in other evidence reviews. The public will not be able to offer input into the review until the draft report is issued in the fall, simultaneous with when it is provided to the P2P Panel and potentially to the IOM.
    d. Fourth, the Workshop draft agendas indicate that only 20 minutes of the entire meeting will be devoted to the patient perspective, and the ability of stakeholders to participate in open discussion is unclear.

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[13] Dr. Susan Maier, CFS Advisory Committee Minutes, May 23, 2013, pp. 11.

e. Fifth, only two weeks is provided for public comment on the P2P Panel Draft Report, tentatively scheduled near the December 2014 holidays. This is completely inadequate, given the disability of many patient advocates.
f. Sixth, the P2P Panel is selected by NIH with no public input or comment opportunity. The screening process for bias is completely opaque, and it is not even clear when the Panel will be announced. Given the importance of the Panel's work, and the potential for damaging bias (see Attachment 4), it is not acceptable for NIH to appoint these individuals by fiat without public input or accountability.

ATTACHMENT 4

The P2P Workshop process is inappropriate for this disease. ME/CFS is a controversial topic, and confounding bias is a known risk when involving non-ME/CFS experts. Furthermore, the P2P Workshop is not designed to deliver the urgently needed recommendations and decisions most needed in the field.

1. The Pathways to Prevention website states that the workshops are designed for topics that "are generally not controversial."[14] It should be obvious to any casual observer that the field of ME/CFS, particularly regarding case definition, is extraordinarily controversial. Therefore, the decision to use the P2P process for such a controversial field is highly questionable, especially given P2P's heavy reliance on non-experts.

2. CDC's 2011 survey data show that 85% of healthcare professionals believe that ME/CFS is a wholly or partially psychiatric condition.[15] This is just one example of the prejudice and bias faced by ME/CFS patients and experts every day. The prevalence of such bias creates a significant risk for the P2P process. The Panel, selected by NIH with no public input or accountability, will be non-ME/CFS experts. As Dr. Susan Maier said in describing the Panel, "They don't know, they don't know anything. 'I've heard of [ME/CFS] but I'm not sure.'"[16] This inspires no confidence among stakeholders that the Panel will be adequately screened for preconceptions, bias, or attitudes that may negatively impact their views of ME/CFS science. If even one Panelist believes that ME/CFS is attributable to a psychiatric condition, deconditioning, or poor coping skills, then the entire process is contaminated. Not only will the Panel's conclusions be scientifically invalid, but the recommendations and any actions based on those recommendations will be rejected by the stakeholders. Instead of advancing the field, such a report would set the field back for years to come.

3. The highest priority need in ME/CFS research is to reach agreement on a research case definition capable of defining patient cohorts who actually have ME/CFS, but the P2P Workshop will not deliver it although HHS staff has indicated that the output could be used for a future, as yet unplanned effort to define the research case definition.

    a. The 2011 NIH State of the Knowledge meeting concluded that, "working toward a single, more usable, and accurate case definition for this illness would create a more solid foundation for research and ultimately benefit people living with this illness."[17]

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[14] https://prevention.nih.gov/programs-events/pathways-to-prevention (retrieved May 19, 2014).
[15] http://www.iacfsme.org/LinkClick.aspx?fileticket=%2bG6GTkbP33I%3d&tabid=499 (p. 130, retrieved May 19, 2014).
[16] http://www.iom.edu/Activities/Disease/DiagnosisMyalgicEncephalomyelitisChronicFatigueSyndrome/2014-JAN-27/Videos/Session%20Background/8-Maier-QA-Video.aspx (retrieved May 19, 2014).
[17] State of the Knowledge Workshop, ME/CFS Research April 7-8, 2011 Workshop Report p. 8.

b. As noted earlier, fifty international experts reached consensus on the use of the Canadian Consensus Criteria as the research case definition for ME/CFS.
c. As you stated in your April 16, 2014 letter to Representative Lofgren, research progress has lagged, in part due to inconsistent inclusion criteria. The use of multiple, overly broad research case definitions has resulted in heterogeneous, biologically unrelated patient cohorts that have confounded research and stalled drug development.
d. Early statements by HHS suggested that the P2P Workshop would create this desperately needed research case definition, but subsequent statements indicate it will not (see Attachment 5). Instead, the P2P Workshop risks confounding the situation even further because it is running concurrently with the Institute of Medicine effort to create such a definition.

4. Beyond the research case definition, the second most important need is a research strategy to most effectively focus scarce research dollars. But such a strategy has not been forthcoming, and the P2P Workshop cannot support the development of one.

    a. In your comments at the April 8, 2011 State of the Knowledge Workshop, you said, "We would not be having a workshop of this sort if we didn't expect new ideas to come out of it and we would not be NIH if we didn't expect that those new ideas might suggest new research."[18]
    b. According to an HHS status report, the Trans-NIH ME/CFS Working Group developed priorities based on the recommendations from the State of the Knowledge Workshop.[19] Inexplicably, this strategy has never been shared with the public.
    c. The Key Questions in the Systematic Review Protocol are focused on the nature and efficacy of diagnostic methods, and the benefits and harms of treatments across various definitions. But the reality is that most of the evidence for these questions focuses on behavioral and exercise interventions using the non-specific Oxford definition. Further, such a restricted focus means that other critical research areas will not be examined at all. Given the inadequacies and restricted focus of the Key Questions in the Systematic Review Protocol, the controversial nature of the evidence base, the lack of clarity on the nature of the disease and the use of non-ME/CFS experts to draft the P2P recommendations, the P2P Workshop is incapable of providing information on critical research gaps and needs that could help inform the research strategy for ME/CFS.

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[18] http://videocast.nih.gov/summary.asp?Live=10114&bhcp=1 (retrieved May 19, 2014), Minute 6:27:09.

[19] HHS Department Actions Addressing Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 2013, p. 2.

ATTACHMENT 5

The goal of the P2P Workshop is unclear because HHS has made numerous contradictory and confusing public statements about the purpose of the Workshop. As a result, stakeholders are legitimately concerned that the framing of the meeting and charge to the Panel is unfocused, and there is no accountability as the process moves forward.

1. Early statements by Assistant Secretary for Health Dr. Howard Koh and Deputy Assistant Secretary for Health Dr. Wanda Jones indicated that the purpose of the Workshop was to address the research case definition for ME/CFS.

    a. "The NIH has made a commitment to conduct an evidence-based review of the status of ME/CFS research and also convene a dedicated workshop to address the research case definition for ME/CFS." Dr. Koh, October 3, 2012 CFS Advisory Committee Minutes, p. 5.
    b. "To focus that toward a research-based case definition and using evidence-based methodology will really stand the work of that workshop in a position that will bear fruit for many, many years to come." Dr. Jones, May 22, 2013 CFS Advisory Committee Minutes, p. 7.

2. Subsequent statements by Dr. Susan Maier (NIH) indicated that the Workshop would not create a research case definition, but would address the validity and reliability of current case definitions. Dr. Nancy Lee (OWH) indicated that the output could be used for an as yet unplanned future effort to develop the research case definition.

    a. "The goal of the workshop is not to derive a new definition. The goal of the evidence-based methodology workshop is to understand and identify how the evidence shows up for case definitions, for outcomes, for interventions, and for treatments." Dr. Maier, May 23, 2013 CFS Advisory Committee Minutes, p. 11.
    b. "The purpose of the Pathways to Prevention Program for ME/CFS is to evaluate the research evidence surrounding the outcome from the use of multiple case definitions for ME/CFS and address the validity, reliability, and ability of the current case definitions to identify those individuals with or without the illness or to identify subgroups of individuals with the illness who might be reliably differentiated with the different specific case definitions. The purpose of the Pathways to Prevention Program and the ME/CFS workshop is not —and I repeat, not—to create a new case definition for research for ME/CFS." Dr. Maier, December 11, 2013 CFS Advisory Committee Minutes, p. 16.
    c. "It may not be the goal of the workshop to come out with a research case definition, but there will be so much good evidence that that can be the next step." Dr. Nancy Lee, December 11, 2013 CFS Advisory Committee Minutes, p. 48.

3. After the Office of Disease Prevention completed its rebranding process in 2013, the purpose of the P2P Workshop changed again to identifying research gaps and suggesting research needs.

    a. "The goal of the Pathways to Prevention Program is to host workshops that identify research gaps in a selected scientific area, identify methodological and scientific weaknesses in that scientific area, suggest research needs, and move the field forward through unbiased, evidence-based assessments of a complex public health issue." Dr. Maier, December 11, 2013 CFS Advisory Committee Minutes, p. 16.

4. Dr. Susan Maier (NIH) has not ruled out the possibility that the Workshop will produce clinical recommendations.

    a. Dr. Ganiats: "Are those recommendations then for a research agenda for the NIH or is it recommendations for practice?" Dr. Maier: "It has the potential to be both, but understanding that we are a research organization and our focus is to improve the, um, the integrity of the science that is used for translation into clinical care means that we have to focus on besting the science that is used for the evidence." Institute of Medicine, January 27, 2014 Question & Answer, video at 0:19.[20]

5. The final Systematic Review Protocol is focused on identifying the methods available to clinicians to diagnose patients and on identifying the benefits and harms of therapeutic interventions.

    a. "An examination of the comparative effectiveness and harms of treatments for ME/CFS is important to guide clinical practice, which underscores the need for a systematic review on this topic." (p. 2)
    b. Following from this statement, the Key Questions being used in the review include:
        i. "What methods are available to clinicians to diagnose ME/CFS and how do the use of these methods vary by patient subgroups?"
        ii. "What are the (a) benefits and (b) harms of therapeutic interventions for patients with ME/CFS and how do they vary by patient subgroups?" (pp. 2-3)

[20]http://www.iom.edu/Activities/Disease/DiagnosisMyalgicEncephalomyelitisChronicFatigueSyndrome/2014-JAN-27/Videos/Session%20Background/8-Maier-QA-Video.aspx (retrieved May 19, 2014).