



December 9, 2021

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National Center for Emerging and Zoonotic Infectious Diseases
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Dear Dr. Unger,

#MEAction wishes to reiterate ahead of your upcoming Stakeholder Engagement and Communication (SEC) conference call on December 16th, 2021 that the **CDC must not move forward with publication of the flawed evidence review on ME/CFS treatments** produced by the Pacific Northwest Evidence-based Practice Center (EPC). Ignoring stakeholders' detailed and repeated warnings that this flawed report will ultimately harm people living with ME and misinform medical providers would be the height of irresponsibility on the part of the CDC.

We have already laid out in our detailed [public comment](#) the most fundamental flaws in EPC's draft evidence review and the reasons why minor revisions would be insufficient to resolve them. Our recommendation not to proceed with publishing the flawed review was co-signed by **more than seven thousand** members of the ME community. We have also pointed out how the UK's National Institute for Health and Care Excellence (NICE) has rejected the applicability of the evidence base for people with ME/CFS. Therefore, your choice of whether or not to publish this flawed review over extensive community objections must be addressed clearly and directly during the December 16th SEC call. Beyond the specific flaws of the review that have been documented, here are four overarching objections we expect the CDC to address:

1. The review's conclusions will misinform doctors and harm people with ME/CFS

The EPC review wrongly concludes that Graded Exercise Therapy (GET) together with Cognitive Behavioral Therapy (CBT) are associated with improved fatigue, function, and other outcomes versus inactive control therapies. As this review was not properly scoped, the primary studies undergirding this conclusion do not apply to people with ME/CFS, as defined by the CDC, which has adopted the IOM diagnostic criteria.

Despite this critical flaw, this review would likely be cited by others, even if not by CDC, as support for prescribing GET and CBT to ME/CFS patients and therefore misinform them about how to properly treat ME/CFS. This will risk harming millions of people living with the disease.

Though the inappropriateness of CBT and GET as treatments for ME/CFS have been well documented and vocalized by the patient community and by numerous studies

demonstrating biological impairment following even minor exertion, this review also does not adequately address the risk of harm these interventions pose to people with ME/CFS.

2. The review’s conclusions represent a reversal from previous CDC commitments to base clinical guidance on IOM diagnostic criteria

The CDC has adopted the IOM’s diagnostic criteria for ME/CFS, which requires the hallmark symptom of post-exertional malaise (PEM), defined as a worsening of symptoms following exertion. The CDC has previously committed in writing to the HHS CFS Advisory Committee (CFSAC) that “the IOM diagnostic criteria will be used as the basis for clinical guidance.”¹

The EPC’s systematic evidence review was intended to be an input for the development of this treatment guidance, but because the IOM diagnostic criteria was not used as a basis for analyzing the evidence, the review is now unusable. The review uses “ME/CFS” in a non-specific manner that conflates various definitions. It thus further entrenches the definitional confusion that has long imperiled the field, moving clinical guidance backwards instead of forwards.

In these ways, the EPC evidence review has been a waste of taxpayer dollars. Publishing it would fundamentally contradict the *good* work CDC has done in recent years to demystify the condition by adopting the IOM diagnostic criteria and updating its medical education materials.

3. Recent systematic reviews contradict the EPC review’s conclusions and highlight the unnecessary flaws in the its approach

The EPC review’s flawed conclusions that GET and CBT offer modest improvements for people with ME/CFS are in direct conflict with the findings of other recent systematic reviews, including those authored by Wormgoor and Rodenburg (2021) and the UK’s National Institute for Health and Care Excellence (NICE 2021). They demonstrate that the problems with the EPC’s evidence review are not simply due to the unavoidable constraints of the “state of the science” at this point in time; rather, they are due to shortcomings in methodology.

Unlike the EPC review, the Woomgoor and Rodenburg and NICE reviews adequately address fundamental concerns regarding the evidence base, such as the [applicability of findings, risk of bias, exclusion of harms evidence, and interpretation of results](#).

These other reviews employ analytical methodologies that appropriately address the challenges and weaknesses of the evidence base; this EPC review does not. The ME community has [repeatedly raised these issues](#) since the prior EPC review of ME/CFS

¹ This response by CDC was to a May 2016 CFSAC recommendation that the “disease as defined by IOM needs to be separated from broader conditions defined by Fukuda/Oxford.”

treatments for AHRQ in 2014; yet EPC's current systematic review for CDC continues to ignore these concerns, and it reproduces the same problems.

As such, this review does serious damage to the reputation and credibility of the CDC's ME/CFS program.

4. You stated that CDC can choose not to publish the review. CDC should exercise that option now.

In August of 2018, #MEAction [petitioned](#) the CDC not to hire the Pacific Northwest Evidence-based Practice Center (EPC) to conduct the evidence review of ME/CFS treatments because of unresolved problems with the prior review EPC performed for AHRQ in 2014. Nevertheless, [CDC hired EPC](#).

#MEAction representative Terri Wilder and other ME advocates met with you at the CDC's 2018 Stakeholder Roundtable to present our concerns that CDC not repeat the same mistakes with this new review. According to contemporaneous notes taken, you offered assurances that CDC could decide not to accept the results of the review if there were serious problems with it and that CDC could prevent its publication if necessary.

Virtually every issue that could go wrong with the review, about which we warned you at the project's outset, has gone wrong. While the new evidence review represents years of wasted money and effort, it must now be acknowledged as fundamentally flawed. If published, it will set the field back. You — and we — have worked too hard to allow that to happen. The CDC should exercise the authority it previously assured us that it has to intervene and prevent the unintended harm the publication of the EPC systematic evidence review would have for people living with ME/CFS.

In conclusion, we look forward to your response to each of the above points during the upcoming SEC call. We again urge you to make a public commitment to the ME community not to move forward with this flawed review, whose publication will misinform healthcare providers and harm patients.

Sincerely,

Ben HsuBorger
U.S. Advocacy Director
#MEAction