



September 21, 2020

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National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dear Dr. Unger,

#MEAction looks forward to the opportunity to receive ME/CFS program updates and ask questions at the Centers for Disease Control and Prevention's (CDC) upcoming Stakeholder Engagement and Communication (SEC) conference call on Wednesday, September 23, 2020.

Stakeholder engagement is essential because what is at stake for us in the ME/CFS crisis is nothing less than our lives. Given the likelihood that many new people will develop ME/CFS after COVID-19, now is the time for robust stakeholder engagement. Our community brings decades of expertise and lived experience with this disease. We remain eager to collaborate with the CDC, as equal partners, in ensuring the delivery of scientific research, medical education, and compassionate clinical care for people with ME.

Thank you for taking steps to make sure all SEC conference calls include both 1) CDC progress updates on ME/CFS program activities and 2) adequate time for live Q&A with community stakeholders. This format facilitates better collaboration with the ME community.

In order to assist you in preparing relevant information for the conference call, we are submitting our most pressing questions to you in advance. While we expect sufficient time to be allocated to progress updates and community questions, we understand that you may not be able to address every question during this call. We welcome timely responses by email or an alternative venue for discussion where our stakeholder questions may be addressed in more detail.

The CDC has a crucial role in addressing the complex public health challenges that confront ME/CFS. Decades of stigma, misinformation and neglect continue to harm people with ME. We need a CDC response that is urgent, comprehensive and proactive. It must address critical issues and dedicate the necessary resources. People with ME deserve nothing less.

Sincerely,

Ben HsuBorger
Campaigns Director
#MEAction

#MEAction stakeholder questions for the September 23, 2020 CDC SEC conference call:

Clarifying Questions:

CDC Treatment Guidelines Evidence Review for Public Comment

1. When do you expect the public will be given an opportunity to comment on the draft of the ME/CFS treatment guidelines evidence review? How long will stakeholders have to give feedback on this review?

Multi-Site Clinical Assessments of ME/CFS (MCAM) - Adult and Pediatric

2. It has now been eight years since the beginning of the adult MCAM study. Can you please update us on approximately when findings from this study will be published? As you did not present at this year's IACFS/ME Conference, can you please briefly summarize what you have learned about your data to date, particularly regarding how it will help the CDC refine the ME/CFS case definition, as well as better characterize the full spectrum of disease severity experienced by patients? Can you also please update us on the pediatric MCAM study, including estimated timelines for completion and study publication?

Pipelines and Partnerships

3. We appreciate your efforts to increase the pipeline of researchers and clinicians who are interested in and knowledgeable about ME/CFS. We understand that the 2018 stakeholder roundtable material was supposed to be published mid-year 2020. When will this be posted, what content will it include, and what audience is it targeting? Can you please share details on what you have done this year to continue strengthening new and existing partnerships, as well as pipelines? What concrete steps do you plan to take in this area in the coming year?

ME/CFS EIP Project

4. We are happy to hear about the new ME/CFS project being initiated within CDC's Emerging Infections Program (EIP). Can you please give us details on the design of this study, including the target sample size, project timelines, instrumentation, and most importantly, how you plan to involve ME experts and patient stakeholders in every phase of research design, implementation and evaluation?

MMWR Report Study Follow-up

5. Thank you for adding an "ME/CFS and COVID-19" section to the CDC's ME/CFS website. Regarding the [31 July 2020 MMWR Report](#): what plans do the IVY Network Investigators and the CDC COVID-19 Response Team have to follow up with the individuals included in this sample? Will follow-ups occur 6 months after the patient's positive test result? Will participants be assessed for ME/CFS at that time, and if so, how? Do you have plans to build similar, larger cohorts that you will follow-up with over time, and will you include children in these longitudinal cohorts? Can you please provide us with information about other long COVID studies being conducted, and whether ME/CFS will be taken into account in them as well?

Topical Questions:

Proactive Outreach to the Medical Community

As you, Dr. Damon, and Dr. Koroshetz gave voice to on August's IAWG call, the long COVID crisis has created a significant window of opportunity for ME/CFS clinical education. We thank you for your efforts involving the website, CMEs, and roundtables. Given the likelihood that a significant minority of people will develop ME from COVID-19, our community sees an enormous need for a widespread, proactive ME/CFS clinical education campaign that would see significant traction in this time period. We therefore ask you to address three interrelated issues:

6. **Please tell us what you are doing to proactively engage the leadership of national medical associations to promote the ME/CFS medical education needed to address the post-COVID ME/CFS crisis on an aggressive timeline.** Your ability to influence these associations, as well as other relevant medical entities (e.g., medical schools, hospital systems, and medical boards) is critical in this time period, as they are responsible for the clinical care needs of people with ME and other post-viral multi-system illnesses resulting from COVID-19.
7. Regarding all aspects of your proactive ME/CFS clinical education campaign: **how will you include ME experts with real clinical experience as well as people with lived experiences (i.e., people with ME and long COVID) in the planning of curricula?** What is Dr. Damon doing to increase your program's medical education capacity in the era of long COVID? What ways are you collaborating with the CDC's domestic COVID-19 Response Team to promote ME/CFS clinical education?
8. The US ME/CFS Clinician Coalition has launched a highly informative website to provide clinicians with expert information on the diagnosis and management of ME/CFS. This coalition has collectively spent hundreds of years treating many thousands of ME/CFS patients and is therefore an invaluable resource. **Can you commit to linking this to your website and actively promoting the Clinician Coalition website, as part of an accelerated clinical education campaign?**
9. The CDC has reported widely on the disproportionate impact of COVID-19 on people of color. Additionally, as you know previous studies have found that rates of ME/CFS are actually higher among black and latinx respondents compared to whites, and that persons of middle to lower income socioeconomic status are at higher risk for this illness. **Given these realities, can you please address what concrete steps the CDC ME/CFS program is taking to reach doctors who serve people of color, including outreach to historically black medical associations and schools?**
10. There is evidence that COVID-19 long-haulers at risk of developing ME/CFS will experience harm if they undergo cognitive behavioral therapy (CBT) and graded exercise therapy (GET) and yet, medical entities continue to recommend them. These treatments, as applied to ME/CFS, are based on a deeply flawed, psychogenic disease theory that attempts to convince patients they are not sick, just deconditioned. 'Graded' exercise, or a gradual increase in activity regardless of increased symptoms, must be clearly differentiated from supportive strategies such as pacing, where the patient is

encouraged to be active when able and rest when necessary. Coping with pain, chronic symptoms, and grief is a normal part of learning to live with a chronic illness. Where recommendations to support good mental health are included, they should never be presented as curative. **When will CDC issue a firm statement refuting GET and CBT treatments, knowing their potential to do harm?**

Comprehensive, Equitable Epidemiological Strategy

11. As you know, COVID-19 presents an unparalleled opportunity to study people with new onset post-infectious ME/CFS. **Does the CDC have any plans to conduct a large, racially-diverse, prospective epidemiological study that investigates incidence of post-infectious ME/CFS, about which so little is known?** What plans does your team have to collect knowledge about post-COVID ME/CFS risk factors, symptom patterns, and natural history? If you don't have plans to study post-COVID ME/CFS, why not?
12. It is deeply important to us that all of CDC's ME/CFS epidemiological efforts are racially, ethnically, and socioeconomically diverse, as well as inclusive of pediatric populations. This is a special concern because two of the main epidemiological tools used in the current ME/CFS program - the MCAMs and the BRFSS survey - are not racially and socioeconomically representative. While we understand that the new EIP project will likely be more so, we question whether this will be a good tool to assess ME/CFS prevalence nationally, about which there is very little accurate information. **Can you please tell us what the CDC is doing to accurately and reliably capture prevalence statistics, given that neither the BRFSS nor the NHIS questions (which rely on self-reported diagnosis) do so? In general, can you please speak to how your program plans to address systemic biases in your approach to epidemiology in the coming year?**
13. We are encouraged to hear that CDC's domestic COVID-19 Response Team is designing studies to investigate reports of long-haul symptoms in COVID-19 patients. That said, we are concerned that at the recent IAWG call, Dr. Giovanni mentioned no specific strategies they will use to measure ME/CFS across these studies. **Will you please let us know what specific ways you are working with Dr. Giovanni and other research teams to ensure that ME/CFS is accurately, reliably and consistently taken into account and measured in all long COVID research?** How are you involving stakeholders, including disease experts and patients, in research design efforts?
14. When the patient community asks what progress the CDC and NIH have made towards standardizing ME/CFS diagnostic criteria and instrumentation standards for research and clinical purposes, we are often pointed to the CDE Oversight Committee. Yet, year after year, the products most sorely-needed from this committee remain outstanding. **As projects launch across the globe to study long COVID, we are deeply concerned that there is still no standard way for researchers to study ME/CFS arising from COVID-19. How does the CDC plan to address this alarming limitation?**
15. To be included in long COVID research, participants typically need to test positive for SARS-CoV-2 via a PCR or antibody test. We are concerned that this methodology

excludes COVID long-haulers who have the appropriate symptoms but were either unable to get tested, or received a false-negative test. Additional, non-routine diagnostic tests requiring specialized labs could aid in confirming a COVID-19 diagnosis and thus more accurately characterize the complete pool of COVID long-haulers within research and clinical settings. **Does the CDC have any plans to use alternative tests — such as memory T-cell assays — once they have been approved?**

16. We have asked before about whether the CDC has a document that fully describes its epidemiological strategy. If so, can you please provide it to us. If you don't, why not?

Widespread Public Education

17. CDC's Vital Signs did an excellent job this year of, for instance, promoting comprehensive information on acute flaccid myelitis through an MMWR Early Release, a fact sheet and website, a media release, and a series of announcements via social media tools. Can CDC's Vital Signs promote public education on ME, as well? People struggling with lingering symptoms for months after COVID need information on ME now. Health care providers, health departments and patients need to know the best ways to diagnose, manage, and prevent the worsening of their symptoms. **If not through the Vital Signs program, what is the CDC doing to create and promote the desperately-needed widespread public education campaign about ME?**
18. As you said in August's IAWG meeting, long-haulers have caught the media's attention this year, and the time is right to capitalize on the new knowledge and attention that ME/CFS has with the public as well as with health care providers. In the past your communication office's Christine Pearson said that efforts to submit communications to the media have not gotten traction because of competing areas of interest for science writers. Now that this is not as large an issue, **what efforts are underway to systematically reach out to the press?**

Meaningful Community Engagement

19. A core theme at Research America's 2020 Virtual National Health Research Forum was the need to bring patient engagement to the center of the research process. Patient engagement and transparency is increasingly seen as critical to all public health program efficacy. While our community has asked consistently for meaningful, program-level engagement and transparency, we continue to have limited information about the current status and future plans and lack opportunities to provide formal input on ME/CFS programs. **What do you plan to do now to address the urgent need for greater engagement and transparency in all areas of ME/CFS programming, and at all phases of program design, implementation and evaluation?**