



# Solve M.E.

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Public Comments: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Dear National Academy of Medicine,

Please consider this letter as public comments and recommendations submitted on behalf of the Solve ME/CFS Initiative (Solve M.E.) and the community of people affected by Myalgic Encephalomyelitis (ME), previously called Chronic Fatigue Syndrome (CFS). I strongly encourage you to recognize that people with ME/CFS have unique medical needs and should be considered a high-priority population for study and distribution of potential COVID-19 vaccines. It is imperative that such vaccines are fully researched and tested to affirm the safety and efficacy for those with sensitive or compromised immune systems, as is the case for people who suffer from ME/CFS.

**Specifically, Solve M.E. requests that the National Institutes of Health (NIH), Centers for Disease Control (CDC) and any other agencies involved in the further development of this preliminary framework fully acknowledge that patients with ME/CFS should be prioritized for access to vaccination. This prioritization should include planning and resources for providing appropriate accommodations for those with disabilities or special needs as a result of ME/CFS. Within the current preliminary framework, which includes a four-phase approach during initial vaccine deployment when demand exceeds supply, this prioritization is already indirectly stated. It is based on the premise that individuals with an increased risk of severe COVID-19 disease, including individuals with chronic illness and compromised immune system, would be a greater priority. It is especially important that people with ME/CFS and other chronic illnesses should be included in Phase 1b, again with meaningful and appropriate accommodations. These prioritization and accommodations, should be included in the plan for people of all ages with comorbid and underlying conditions that put them at significantly higher risk.**

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It is essential for the agency developers of this framework to be aware of the facts about ME/CFS, which is a complex disease with an array of debilitating symptoms including cellular energy disruption, orthostatic intolerance, unrefreshing sleep, memory loss, joint pain, inflamed lymph nodes, severe headache, sore throat, neurological abnormalities, and even complete organ system shutdown. The cause of ME/CFS is unknown, and there is no existing cure nor FDA-approved treatment for the disease. Here are a few facts about this serious and often misunderstood condition from the 2015 Institute of Medicine Report “[Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness.](#)”

- An estimated 836,000 to 2.5 million Americans have ME/CFS
- Nearly 80% of ME/CFS cases are reported to follow an acute infection, typically viral infections
- Coronaviruses can trigger ME/CFS<sup>i</sup> and ME/CFS-like symptoms
- ME/CFS affects four times more women than men
- One quarter of ME/CFS patients will become house- or bedbound in their lifetime
- ME/CFS can strike anyone at any time; onset has been reported from ages 8 to 80
- Recovery from ME/CFS is rare and symptoms often persist for life
- Many with ME/CFS have comorbid disorders, such as irritable bowel syndrome, dysautonomia, and fibromyalgia
- Patients with ME/CFS have the lowest median and mean quality of life scores of any disease tested, including lung cancer, rheumatoid arthritis, and brain stroke

In short, **ME/CFS is often a life-long disease** resulting in an extreme reduction of every-day function, long term disability, and moderate to severe chronic pain, manifesting most often in neurological pain, joint pain, musculoskeletal pain and headaches. 89%<sup>ii</sup> report job loss as a result of their illness. For many with ME/CFS, living with severe chronic pain is a daily struggle.

Solve M.E. applauds the federal agencies for establishing this preliminary framework for vaccine distribution and for opening up this framework for stakeholder input, in the form of this public comment.

### **Regarding Potential Links Between COVID-19 and ME/CFS**

According to the CDC, up to 36% of COVID–19 patients are experiencing extended ME/CFS-like symptoms more than 90 days post infection. These symptoms commonly include: muscular/skeletal pain, significant reduced cognitive and physical capacity, brain inflammation, orthostatic intolerance and shortness of breath. Studies of patients infected with previous coronaviruses (SARS and MERS) also find similar results of a subset of patients who experience lasting post-viral symptoms consistent with ME/CFS. In fact, reports are already surfacing of COVID-19 survivors being diagnosed with ME/CFS. Experts expect a significant increase of ME/CFS cases in the next two years in the United States following the COVID–19 epidemic.

Solve M.E. urgently calls for increased research investments regarding the post-viral and long-term impacts of COVID-19, especially in cases resulting in an ME/CFS diagnosis.

### **Regarding Prioritized Access to Vaccination**

People affected by ME/CFS suffer from a serious chronic disease that impacts multiple organ systems and are at an increased risk of severe morbidity and mortality. This population has a greater possibility for developing a severe disease or dying if they were infected with COVID-19 and therefore should be given a high priority for receiving vaccination.



## Regarding Caution and Exemption from Negative Implications of Electing not to be Vaccinated

While the exact pathophysiology underlying ME/CFS is unknown, a disruption or dysfunction of the immune system has been implicated in this disease. Furthermore, many patients with ME/CFS report overlapping symptoms with Multiple Chemical Sensitivity (MCS), also called Idiopathic Environmental Intolerances (IEI). Although it is possible for patients to present with ME/CFS alone, studies indicate MCS can be a common comorbidity<sup>iii</sup>. In several major case definitions of ME/CFS, MCS is identified as both a symptom and a comorbidity.

It is important that future iterations of this draft framework recommend that physicians evaluate patients with ME/CFS and exercise caution in vaccinating, if it is suspected that vaccination could lead to an effect on the immune systems that exacerbates the patient's condition. Patients who experience MCS and ME/CFS can also have severe complications in using prescribed treatments, which can worsen their existing symptoms.

It is possible that certain jurisdictions would mandate vaccination, or make certain benefits be conditioned on vaccination. Therefore, it is important to guarantee that patients with ME/CFS are not adversely impacted if they are not vaccinated, as a measure of precaution, and that they would be entitled to a medical exemption. Every ME/CFS patient should be given adequate time to consult with their healthcare provider about potential impacts of vaccination on their health prior to their vaccination.

I hope this information and insight into the lives and medical needs of those with ME/CFS has been helpful and that the NAM will take these into account consideration in the framework for vaccine distribution.

Please don't hesitate to contact me or my organization if there is any way we can assist.

Sincerely,

Oved Amitay  
President and CEO  
Solve ME/CFS Initiative

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<sup>i</sup> Moldofsky H, Patcai J. Chronic widespread musculoskeletal pain, fatigue, depression and disordered sleep in chronic post-SARS syndrome; a case-controlled study. *BMC Neurol.* 2011;11:37. Published 2011 Mar 24. doi:10.1186/1471-2377-11-37

<sup>ii</sup> IOM (Institute of Medicine). 2015. *Beyond myalgic encephalomyelitis/chronic fatigue syndrome: Redefining an illness.* Washington, DC: The National Academies Press.

<sup>iii</sup> Carruthers, Bruce M.; Jain, Anil Kumar; De Meirleir, Kenny L.; Peterson, Daniel L.; Klimas, Nancy G.; Lerner, A. Martin; Bested, Alison C.; Flor-Henry, Pierre; Joshi, Pradip; Powles, A C Peter; Sherkey, Jeffrey A.; van de Sande, Marjorie I. (2003), "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols" (PDF), *Journal of Chronic Fatigue Syndrome*, 11 (2): 7-115, doi:10.1300/J092v11n01\_02