



## **To Whom It May Concern:**

**The following is ME International's response to a request for input regarding the proposal to make changes to Postviral Fatigue Syndromes (G93.3) presented at the Sept 15, 2021 meeting of the ICD-10 Coordination and Maintenance Committee Meeting.**

## **ME INTERNATIONAL SUPPORTS THE FOLLOWING CHANGE:**

- Removal of Benign from Benign Myalgic Encephalomyelitis

Removal of "benign" is in accordance with recent changes by the World Health Organization. Removal of "benign" from 8E49 is shown on WHO's May 2021 version of the ICD-11 for Mortality and Morbidity Statistics. (Found here: <https://icd.who.int/browse11/l-m/en#/http://id.who.int/icd/entity/569175314>)

## **ME INTERNATIONAL REJECTS THE FOLLOWING:**

- Change of G93.3 label
- Moving Myalgic Encephalomyelitis to G93.32
- Moving Chronic Fatigue Syndrome to G93.32
- Adding ME/CFS and myalgic encephalomyelitis/chronic fatigue syndrome to G93.32
- Adding SEID to Index terms

## **ME INTERNATIONAL'S POINT OF VIEW**

The purpose of ME International is to educate the general public, medical providers, and governments throughout the world as well as support ME patients, caregivers, advocates, organizations, family and friends.

ME International's position is that myalgic encephalomyelitis is a complex, acquired multisystemic disease apart from CFS and ME/CFS, that all patients need to be screened for ME in accordance with the ME International Consensus Primer (ME IC Primer), and all research labeled "ME" use the ME International Consensus Criteria (ME-ICC).

ME International agrees that there is a problem with the ME/CFS label. The proposal presented was to give ME/CFS its own ICD code. Here ME International will offer an alternate solution which will require minimal changes to the ICD-10-CM coding.

That solution involves educating doctors that proper screening for ME is needed before giving a diagnosis code of either G93.3 or R53.82. This is done by using the ME IC Primer in order to thoroughly screen patients to determine what ICD code is appropriate, leading to a decision



about whether a patient should receive the ME G93.3 code or the CFS R53.82 code. This approach is explained by the ME IC Primer authors on page ii with the following statement.

“Remove patients who satisfy the ICC from the broader category of CFS. The purpose of diagnosis is to provide clarity. The criterial symptoms, such as the distinctive abnormal responses to exertion can differentiate ME patients from those who are depressed or have other fatiguing conditions. Not only is it common sense to extricate ME patients from the assortment of conditions assembled under the CFS umbrella, it is compliant with the WHO classification rule that a disease cannot be classified under more than one rubric. The panel is not dismissing the broad components of fatiguing illnesses, but rather the ICC are a refinement of patient stratification. As other identifiable patient sets are identified and supported by research, they would then be removed from the broad CFS/CF category.”

**ME International’s goal to “LEAVE NO ONE BEHIND”** is accomplished by keeping individual ICD codes for ME and CFS.

Keeping ME and CFS with separate ICD codes leads to better understanding that these separate patient groups deserve screening and accurate diagnosis. Most importantly, people need to be able to receive an appropriate diagnosis in order to get appropriate treatment. Currently there are millions of undiagnosed and untreated patients. All patients need to be thoroughly screened as recommended in the ME IC Primer.

### **WHY ADVOCATE FOR MYALGIC ENCEPHALOMYELITIS TO MAINTAIN A DISTINCT DIAGNOSIS CODE?**

What if a patient has an official CFS diagnosis coded as R53.32 but they actually fit the ME diagnosis and should have a G93.3 code?

This is where it becomes important that patients get a diagnosis of ME using the ME-ICC and receive treatment by a doctor educated using the ME IC Primer. The differences between CFS treatments and ME treatments can mean life and death for many ME patients.

The following are points that need to be considered before changing the current ICD coding.

1. Many patients specifically fit the International Consensus Criteria which involves the cardiac and immune system. What happens to patients with comorbid CVID (common variable immune dysfunction) that requires IVIG infusions to survive but are diagnosed under the chronic fatigue syndrome diagnosis and CVID is overlooked?



2. In addition, ME has been associated with enteroviruses related to polio. If ME was lumped in with CFS under one code, there would be no enterovirus testing or treatment for this serious disease. How would these patients receive the required care?

When doctors view patients as having a fatigue based disease instead of a neuroimmune disease, patient experience has shown these serious health issues associated with myalgic encephalomyelitis are overlooked.

3. The International Consensus Criteria (ICC) was developed and approved by the leading science based, ME educated doctors in 2011 for the purpose of advancing the successful strategy of the Canadian Consensus Criteria (CCC). These clinicians/researchers strongly recommended that only the name myalgic encephalomyelitis be used to identify patients meeting the ME-ICC because a distinctive disease entity should have one name. Patients using broader or other criteria for CFS or its hybrids, should be reassessed using the ICC.
4. Since 1956, the term ME has been used to describe this specific illness, spanning over 65 years as a distinct disease. In 1969, Myalgic Encephalomyelitis was introduced with its own ICD code. CFS was thrown into the mix in the 1980's when an illness similar to what was seen in earlier ME outbreaks occurred in Lake Tahoe. They chose not to use the existing name of ME, but instead gave it the new name CFS and changed the diagnosis description, thus leaving out much of what makes it a distinct disease description.
5. **The Name!** CFS refers to one symptom - chronic fatigue. This gets confused with other diseases that have chronic fatigue as a symptom. Myalgic encephalomyelitis is so much more than chronic fatigue! Not only is it common sense to extricate ME patients from the assortment of conditions assembled under the CFS umbrella, it is compliant with the WHO classification rule that a disease cannot be classified under more than one rubric.
6. Differences between ME and ME/CFS criteria: CFS-Fukuda and ME/CFS-NAM require a 6 month wait period. ME-ICC does not have a wait period and can be diagnosed at onset.

The ME IC Primer states ME is a “complex, acquired multi-systemic disease. The pathophysiology is profound dysfunction/dysregulation of the neurological control system resulting in faulty communication and interaction between the CNS and major body systems, notably the immune and endocrine systems, dysfunction of cellular energy metabolism and ion transport, and cardiac impairments.”



ME/CFS-NAM (what is found on the CDC website) focuses on exertion intolerance with sleep problems and either problems with thinking and/or orthostatic intolerance. The vast difference in description of these two patient groups highlights the various problems combining these two patient groups under one ICD code would cause.

7. PENE from ME-ICC or PEM from CFS and ME/CFS - are they the same?

The answer is NO!

PENE stands for post-exertional neuroimmune exhaustion, which is described in the ME IC Primer as being “characterized by a pathological low threshold of physical and mental fatigability, exhaustion, pain, and an abnormal exacerbation of symptoms in response to exertion. It is followed by a prolonged recovery period. Fatigue and pain are part of the body’s global protection response and are indispensable bioalarms that alert patients to modify their activities in order to prevent further damage. The underlying pathophysiology of PENE involves a profound dysfunction of the regulatory control network within and between the nervous systems. This interacts with the immune and endocrine systems affecting virtually all body systems, cellular metabolism and ion transport. The dysfunctional activity/rest control system and loss of homeostasis result in impaired aerobic energy production and an inability to produce sufficient energy on demand.”

This has an entirely different meaning than PEM, which stands for post-exertional malaise. The words malaise or fatigue used to describe symptoms are not appropriate in describing ME symptoms.

The ME IC Primer states on page ii:

“There is a poignant need to untangle the web of confusion caused by mixing diverse and often overly inclusive patient populations in one heterogeneous, multi-rubric pot called ‘chronic fatigue syndrome’. We believe this is the foremost cause of diluted and inconsistent research findings, which hinders progress, fosters scepticism, and wastes limited research monies.”

The ME IC Primer also states on page ii:

“Name: Myalgic encephalomyelitis, a name that originated in the 1950s, is the most accurate and appropriate name because it reflects the underlying multi-system pathophysiology of the disease. Our panel strongly recommends that only the name ‘myalgic encephalomyelitis’ be used to identify patients meeting the ICC because a distinctive disease entity should have one name. Patients diagnosed using broader or other criteria for CFS or its hybrids (Oxford, Reeves, London, Fukuda, CCC, etc.) should



be reassessed with the ICC. Those who fulfill the criteria have ME; those who do not would remain in the more encompassing CFS classification.”

## **ADDITIONAL CONCERNS REGARDING ADDING G93.32 AS A NEW CODE**

The following are questions raised about the repercussions to patients should the proposed changes be incorporated.

### **What happens if we can't get our doctors to change the code in our records?**

Those with the R53.82 code will be attached to the label as “Chronic fatigue, unspecified.” The label in the records would no longer be attached to chronic fatigue syndrome. Could this affect disability rulings based on chronic fatigue syndrome? In a few years will anyone understand that R53.82 was anything other than chronic fatigue unspecified?

Those with the G93.3 code will be attached to the label as “Postviral and related fatigue syndromes.” Imagine having a doctor who understands ME with the G93.3 code and then switching doctors or landing in an ER. They see the G93.3 code and equate that with postviral and related fatigue syndromes. Will a doctor viewing patients with that label consider the special needs attached to ME?

### **What do doctors understand about ME/CFS?**

Those doctors who had knowledge of ME/CFS prior to 2015 will likely understand that label was attached to the Canadian Consensus Criteria (CCC) which is the precursor to the International Consensus Criteria (ICC). While this was an improvement over the vague Fukuda definition, the ME IC Primer still recommends anyone with this diagnosis be re-screened to verify they have ME.

Those doctors who are newer to the field are being educated that ME/CFS is the label used in place of the systemic exertion intolerance disease (SEID) label. This is the information now posted on the CDC website. That criteria is based on the report by the Institute of Medicine (IOM) which is now known as National Academy of Medicine (NAM).

A comparison of the ME International Consensus Criteria (ME-ICC) and the IOM report (ME/CFS-IOM/NAM) show that there is a significant difference in the diagnosis of ME and ME/CFS. The IOM report recommendations were the outcome of using only those aspects of the illness that were common between ME and CFS. A comparison chart showing the difference between the ME-ICC and the ME/CFS-IOM/NAM criteria can be found at [www.MEadvocacy.org/resources](http://www.MEadvocacy.org/resources).



Several distinct features of ME, which include the neurological changes, immune dysfunction and cardiac abnormalities, are not part of ME/CFS-IOM/NAM diagnosis.

As patients, we often see that a doctor's understanding of a disease is based on the name and what symptoms are listed in the diagnostic criteria. The patient community has seen first hand how having the chronic fatigue syndrome label with vague symptoms led to a psychological/behavior modification approach to treatment. And even more concerning, is the fact that even now, most general practitioners have no idea what ME or CFS are!

In the 6 years since the IOM/NAM report was rolled out, doctors continue to follow the general advice given of treating patients with behavior modification, while very little medical intervention is offered other than recognition of the need for specialists to assess orthostatic intolerance.

**Will a doctor who has been trained to see chronic fatigue syndrome as a disease treated using cognitive behavior therapy (CBT) and graded exercise therapy (GET) change their approach to diagnosis and treatment?**

A doctor who has been basing his/her medical approach on the vastly distributed CDC CFS toolkit that recommended GET and CBT may see this combining to a single code as recognition that there is no difference between CFS and ME, thus leading to ME patients finding themselves in front of a doctor who thinks the CDC recommendations to use GET & CBT apply to all G93.32 patients.

IMPORTANT TO NOTE: This CFS toolkit has never been retracted. And while there has been an update to the CDC website, doctors can not be expected to check the CDC website. In addition the website states the following: *"Disclaimer: The content of this ME/CFS website is for informational purposes only and does not represent a federal guideline or recommendation for the treatment of ME/CFS. The information provided on this website is not intended to be a substitute for the medical judgment of the healthcare provider and does not indicate an exclusive course of action or treatment."*

With that disclaimer, it is unlikely doctors who have felt confident they were following CDC guidelines when prescribing CBT and GET would change their approach. Patient experience in too many cases shows that a multitude of doctors continue to think that CFS is treatable using behavior modification methods. In fact, many of those doctors insist they have helped many patients using that protocol. If so, those patients did not have ME and should never have been included in the ME patient group.



**Will a doctor who has little or no training about CFS or ME approach patients using the CFS diagnosis, or the ME/CFS diagnosis, or an ME diagnosis?**

Each of these different patient groups require a different treatment approach. Those who have ME as described in the ICC need the testing and treatments presented in the ME IC Primer.

Those who have CFS as defined by the 1994 Fukuda definition need to be thoroughly screened using the ME IC Primer. If they fit the ME-ICC, then they need the G93.3 code and the testing and treatments put forth in the ME IC Primer.

Those who fit the ME/CFS criteria as defined in either the Canadian Consensus Criteria or the IOM/NAM report (as shown on the CDC website) also need to be thoroughly screened using the ME IC Primer. If they fit the ME-ICC criteria they need to be given the ME diagnosis and the G93.3 label. If they do not have ME as per the ICC they would be given the CFS label and the R53.82 code.

For anyone who is left with the CFS diagnosis, ME International recommends pursuing testing to rule out all causes for chronic fatigue. It is widely known that many patients given a CFS diagnosis have been misdiagnosed or had a missed diagnosis.

**Will a patient who currently has an ME diagnosis with the G93.3 code, be switched to the CFS or ME/CFS label in their medical records?**

With all labels having the same ICD code, it is entirely possible that a doctor who does not know how to screen for myalgic encephalomyelitis and whose background is based on the CDC toolkit's CFS diagnosis will fall back to what they know and use the CFS label.

On the other end of the spectrum - where does it leave patients with a CFS diagnosis that fit the ICC criteria? Will they be re-evaluated for ME or will they be dumped into the ME/CFS-IOM bucket with limited testing/treatments?

**Will this inclusive G93.32 code, that includes multiple patient groups, lead to continued lack of clarity in research?**

Many long-term patients have had to live with the decisions being made for them over the decades, by NIH and CDC. As advocates, we read and share posts daily regarding the suffering - the suffering that is due to the lack of clarity with ME and CFS! The current information available is so unclear, that physicians avoid diagnosing, and the patients go without any treatment! This is the crisis we are currently experiencing.

The rationale for the development of the ME-ICC was to utilize current research knowledge to identify objective, measurable and reproducible abnormalities that directly reflect the



interactive, regulatory components of the underlying pathophysiology of ME, thereby clarifying the differences between ME and CFS. Including multiple patient groups under the proposed ICD code G93.32, will only add to the confusion and none of the patient groups lumped together will receive the proper research to find a biomarker or treatments they require.

**Will researchers who are not familiar with this field believe it is reasonable to assume that anyone with a CFS, ME/CFS or ME diagnosis with the G93.32 code can all be lumped together and still achieve accurate results?**

Researchers base their research on like-patient groups. CFS, ME/CFS and ME are different patient groups. Giving them all the same code will exacerbate a situation that has caused decades of misunderstanding about the reality of ME.

### **EXCLUDE SEID IN THE INDEX TERMS**

Systemic Exertion Intolerance Disease is the label created by the IOM/NAM report released in 2015. After the release of the report, the ME and CFS community widely rejected this label. Following that agreement based on widespread negative reactions, the CDC used the ME/CFS label in its place. ME International feels adding the SEID label would add a level of confusion that is unhelpful to the already difficult and confusing situation caused by multiple labels with conflicting criteria.

### **DR. FRANCIS COLLINS HIGHLIGHTS THE ISSUE OF LUMPING PATIENT GROUPS TOGETHER:**

An October 5, 2021 MEDPAGE Today article quotes Dr. Francis Collins, Director of the NIH as stating:

*"He added, however, that "there are problems [in that] CFS has become such a blurry diagnosis, that in there amongst hundreds of thousands or millions of people who carry that diagnosis is a whole heterogeneous group and there may be individuals ... who have something else entirely or even people who are suffering from depression and are therefore feeling fatigue for that [reason]. I think that's added to the difficulty that the medical care system has had coming to grips with this as a real disease that has a desperate need for new treatments."*

This recognition by Dr. Francis Collins regarding the reality that many of those diagnosed with CFS having something else entirely underscores the importance of NOT putting ME and CFS under the same code.



## INPUT FROM COMMUNITY MEMBERS

*“The strategy of the group of chronic fatigue-related organizations promoting these changes seems to be that socially promoting "CFS" and "ME/CFS" to the neurological section of the US ICD, without scientific justification, will somehow increase the credibility and legitimacy of these poorly defined mixed fatigue conditions.*

*However, the result most likely will be that ALL diseases and conditions under their new G93.3 heading, "Postviral and related fatigue syndromes," will lose credibility with doctors and researchers by association—and because of the obvious manipulation of the US ICD for political purposes.*

*The entire G93.3 group will become wastebasket diagnoses—subject to medical skepticism and psychiatric interpretation—for everyone. Both under the new code G93.32, ME will become the ostensible equivalent of the "ME/CFS" that was called "SEID" and much more broadly defined than ME in the 2015 IOM/NAM report. Surely, such harm and confusion cannot be what this consortium is intending? ~ Jerrold Spinhirne*

*“We patients have been fighting for decades for clarity for M.E. as a distinct Dx and it is tragic (and very draining to our own precarious health) that we must repeatedly also fight against the actions and motives of both government agencies and advocacy organizations that are supposed to prioritize medical science and patients' best interests, but instead seem to prioritize the growth of their own membership numbers, social media 'popularity', and status.*

*These questionable motives are evidenced (as they have been repeatedly over the decades) by their approval of an ever-increasing category of patients labelled with ME/CFS (or whatever the current funding trend is) when these patients actually suffer from diverse diagnoses. We see the problem over & over in online support groups : patients who've been suffering for years without care, discover they've had another illness or condition all along, and it has gone untreated and allowed to get worse.*

*This proposal goes against scientific and medical taxonomy and against the principal of differential diagnosis, and will cause further misdiagnosis of very ill patients.*

*The current WHO coding & classification created in the 1950s as explained by Wendy above is excellent, and is supported by the ICC, and the Nightingale Research Foundation definition. These prioritize the correct Dx of the patient via testing and complete patient history, and via the ruling out of other illnesses/conditions with similar symptoms.*



*It is unacceptable to create a Dx code based on a group of symptoms when a distinct code already exists with appropriate exclusions. It is also unacceptable when such a major change is proposed without appropriate consultation with patients.*

*The priority of govt's and patient groups should be a precise Dx for each patient. This coding proposal is the opposite of precision and in turn leads to the opposite of care. Pwme do not deserve more suffering and neither do all the others who will be incorrectly herded into the proposed Dx code.” ~ Allison Haynes May*

*“Myalgic encephalomyelitis or ME translates to "inflammation of the brain and spinal cord with muscle pain" and first appeared as "benign myalgic encephalomyelitis" in a Lancet editorial by Sir Donald Acheson in 1956. In a 1959 review he referred to several older reports that appeared to describe a similar syndrome. The neurologist Lord Brain included ME in the 1962 sixth edition of his textbook of neurology. A 1978 British Medical Journal article stated the Royal Society of Medicine conference to discuss the illness during that year clearly agreed Myalgic Encephalomyelitis was a distinct name for the disease. The article also stated the previous word (benign) used with ME was rejected as unsatisfactory and misleading because the condition may be devastating to the patient.*

*In 1988 both the UK Department of Health and Social Services and the British Medical Association officially recognized it as a legitimate and potentially distressing disorder.*

*Autopsies show evidence of enterovirus infection in the pontomedullary junction and midbrain (both are in the brainstem), medial temporal lobe, lateral frontal cortex, occipital lobe and cerebellum. This disease has nothing to do with any of the fatigue related illnesses.” ~ Wendy*

ME International thanks the committee for taking the time to consider the concerns expressed here.