

TESTIMONY

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My name is Jill McLaughlin. I have been involved in advocacy for 10 years. I have attended numerous conferences and meetings and have worked with numerous patient and advocacy organizations, served on a committee of the IACFS/ME and as a patient representative to the CFSAC. I am not a patient but have been a 'carergiver' for several years.

I would like to address the current proposal that has been submitted by the Coalition 4 ME/CFS to NCHS for review. This is a small newly formed group of unelected, un-appointed patients/lay people who made these decisions without the consent or even knowledge of the the majority of stakeholders or the general community. Older, active groups like NJ, CT and MA have not joined their coalition. The IMEA and the ME Society of America have not supported this proposal. There has been no endorsement by the CFIDS Association or the IACFS/ME, the professional organization.

The Coalition 4 ME/CFS submitted a proposal to NCHS asking that Chronic Fatigue Syndrome (CFS) be deleted as an inclusion term under code R53.82 (under general signs symptoms, R50-R69, Malaise and fatigue R53-) and add CFS as an inclusion term to ME at G93.3 (Neurology Chapter, other disorders of the brain). The Coalition 4 ME/CFS proposal would for diagnostic purposes make ME and CFS the same diagnosis and their basic premise is that they are the same. ME and CFS are not the same.

Define the terms - the elephant in the room

It is critical to accurately and specifically define the terms. Absent a testable cause or biomarker, definitions are most important and must be the most accurate and precise description as possible to identify an illness. Definitions really determine the diagnosis and play a role in determining an illness how it will be perceived and treated by the medical community and the general public.

What has been missing is the consistent use of accurate labels, definitions, meanings and ICD codes. The terminology is often used interchangeably and incorrectly. Names, definitions and codes should match. This constant uncoupling and mismatch or combining of terms and meanings and definitions is what has skewed research, contaminated patient cohorts, created inconsistent or contradictory results and prevented any progress or understanding of the illness or, shall we say, whichever illness we are talking about. The definitions of ME and 'CFS' are different and distinctions have real clinical significance.

ME and CFS

M.E. definitions [Ramsay, Dowsettt, Nightingale; *The Definitive description of ME: "MYALGIC ENCEPHALOMYELITIS : A Baffling Syndrome With a Tragic Aftermath. By A. Melvin Ramsay M.D., Hon Consultant Physician, Infectious Diseases Dept, Royal Free Hospital. 1986 <http://www.meactionuk.org.uk/ramsey.html>] require the major criteria of severe muscle fatiguability following minimal exertion with prolonged recovery time, neurological/CNS disturbances, especially autonomic, cognitive and sensory functions, and variable involvement of cardiac and other systems, with a prolonged relapsing course. This is a very specific list of criteria, and a major point is that the dysfunction of M.E. can be measured.

Alternately, CFS definitions present the major criterion of fatigue that lasts 6 months and reduces the level of function by at least 50%. Post-exertional malaise is considered a minor and optional criterion in CFS. This broad heterogeneous definition could encompass many illnesses/conditions in which fatigue plays a role.

Fatigue is a symptom of numerous illnesses, both physical and psychological, but it is also something experienced by healthy people. And there are no reliable objective ways to measure fatigue. CFS is based on a R/O of other illnesses and has been a diagnosis of exclusion for which there are no tests.

Furthermore there are different CFS definitions. CFS was first defined in 1988 (Holmes). This definition was broadened into the more complex Fukuda 1994 definition. CFS definitions now include the Oxford definition, the Australian definition, and a new CDC Empiric Definition (Reeves 2005), all of which differ.

ME and CFS are not the same (see comparison chart below)

Myalgic Encephalomyelitis and 'CFS' are not the same and terms should not be used interchangeably or combined. Fatigue is not a defining nor even essential feature of ME. ME is defined by a variety of serious (testable) neurological, cardiac, cardiovascular, metabolic and other abnormalities - not by mere 'fatigue.' "Where the one essential characteristic of M.E. is acquired CNS [central nervous system] dysfunction, that of CFS is primarily chronic fatigue." Dr. Byron Hyde

The ME/CFS Canadian Case Definition (CCC) actually combined features of both CFS and ME to form a hybrid. According to Dr. Byron Hyde, "the more recent Canadian definition (CCC) talks of ME/CFS as though they were the same illness. They are not."

"M. E. has a clearly defined disease process while CFS by definition has always been a syndrome." Dr. Byron Hyde [http://www.nightingale.ca/documents/Nightingale_ME_Definition_en.pdf]

A syndrome (for example CFS) is defined by symptoms. A disease (such as ME) is defined by symptoms plus objective and measurable findings. Each ICD code represents a specific diagnosis, based on the corresponding definition. Evidence based medicine requires an appropriate treatment plan which must correspond to the patient's diagnosis. If a doctor fails to properly indicate the true nature of the patient's illness through proper coding it will inevitably result in difficulty getting approval for appropriate treatment. Patients with a discreet neurological illness will not be properly identified and treated if diagnosed with a fatigue syndrome.

ME/CFS, CFS/ME

ME/CFS is the most confusing and unscientific. It is used haphazardly but is almost never defined or specified. ME/CFS is the term used for the Canadian ME/CFS definition, but more often ME/CFS may be used differently or mean different things. It is often simply and arbitrarily substituted for either ME or CFS. Then there is CFS/ME, the Wessely/FSS biopsychosocial construct.

There are no ICD codes for ME/CFS or CFS/ME. No version of the WHO ICD classifies the terms 'ME/CFS' or 'CFS/ME.' Not only does the ICD not classify these terms, it does not mention them at all. Thus according to the ICD, 'ME/CFS' and 'CFS/ME' do not exist.

Even with coding, "Chronic Fatigue" is signs and symptoms, malaise and fatigue (R53.82), "Fatigue syndrome" is coded with neurasthenia in a Mental Health chapter (F48.0). As is, this overlap and diagnostic confusion with existing terminology is unavoidable and insurmountable.

The WHO and the American Psychiatric Association (APA) are collaborating on the revision process for ICD-11 and DSM-V to ensure consistency to achieve 'harmonization between ICD-11 mental and behavioural disorders and DSM-V disorders and their diagnostic criteria. The concern with the harmonization of the ICD and DSM is related to the overlap and mixing of these fatigue based terms and definitions that allow the constant shifting. The mixing and connecting of ME to CFS is what would CAUSE the possibility of inclusion of ME in the DSM. If ME is recognized as a distinct neurological illness with testable pathology and not an unexplained fatigue syndrome it would not belong in the DSM.

Differences between ME and CFS, Codes and Definitions

CDC states:

<http://www.cdc.gov/cfs/education/wb3151/chapter1-1.html>

"The name myalgic encephalomyelitis (ME) was coined in the 1950s to clarify well-documented outbreaks of disease; however, ME is accompanied by neurologic and muscular signs and has a case definition distinct from that of CFS."

CDC states: "CFS is essentially a diagnosis of exclusion."

[<http://www.cdc.gov/cfs/education/wb3151/chapter2-1.html>]

Then why would ME be excluded from the exclusion?

The NCHS committee report recognizes that there are "several case definitions in use, some separating CFS from ME and others mixing the two conditions together." [ICD-9-CM Coordination and Maintenance Committee Meeting September 14, 2011 page 10.

<http://www.cdc.gov/nchs/data/icd9/TopicpacketforSept2011a.pdf>]

All CFS definitions are heterogeneous and very broad. If ME were included in some, there would be other things besides ME that would fit the definition. In the Fukuda (1994) CFS criteria, it is possible for patients to not have the characteristic features of ME. So this ME=CFS=ME/CFS paradigm does not take into account the "non-ME" CFS cases and thus would not support making them the same and giving them the same ICD code/diagnosis.

NCHS has given the following explanation for not conforming to the WHO ICD-10 classification of ME and CFS to G93.3:

"While it appears most appropriate to classify chronic fatigue syndrome in ICD-10-CM in the same way that it is classified in ICD-10, this placement is not without problems. The primary concern with the current WHO placement in ICD-10 has been that the abnormalities of the brain in chronic fatigue syndrome patients most often cited in the literature are not found in all chronic fatigue syndrome patients. While chronic fatigue syndrome may be a heterogeneous group of disorders, some but not all are neurological in nature. Likewise, not all patients have experienced a viral infection prior to being diagnosed with chronic fatigue syndrome, nor are immune system anomalies universally found. Also of potential concern is the similarity between the type of neurological findings in chronic fatigue syndrome and in depression, which is a psychiatric disorder."

[A Summary of Chronic Fatigue Syndrome and Its Classification in the International Classification of Diseases Prepared by the Centers for Disease Control and Prevention, National Center for Health Statistics, http://www.co-cure.org/ICD_code.pdf]

A Name Change Workgroup (NCW) that was formed under the CFSCC (the former version of the CFSAC) likewise recommended the separation. The CFSCC and HHS appointed experts to this workgroup which worked very diligently for a couple of years. Rather than a name change, they recognized the need for the establishment of separate entities. They split out ME, ME/CFS (Canadian Criteria CCC) and CFS (Fukuda). Their recommendation rejected the one size fits all lump them all in together and rename it.

[<http://www.iacfsme.org/CFSNameChange/tabid/99/Default.aspx>, Recommendations of the Name Change Workgroup]

Treatment

The NCHS summary report stated: "One commenter, representing Coalition 4 ME/CFS, indicated that ME and CFS should not be separated since it goes against the definition of the 2011 ME ICC (an international committee). Her opinion was that treatment is the same for both conditions, literature refers to ME and CFS together, and that the U.S. is behind the international recognition of these two conditions being the same."

[ICD-9-CM Coordination and Maintenance Committee Meeting Summary of Volumes 1 and 2, Diagnosis Presentations September 14, 2011, <http://www.cdc.gov/nchs/data/icd9/2011SeptemberSummary.pdf>]

These statements are questionable at the very least, but treatment is definitely not the same for both conditions. That a representative of this Coalition 4 ME/CFS would say that treatment for both is the same demonstrates a complete lack of knowledge or understanding of key issues.

Studies have shown exercise to be helpful for patients with CFS. CDC lists GET and CBT as treatments for CFS. [<http://www.cdc.gov/cfs/general/treatment/index.html>] Exercise intolerance is a defining feature of ME and makes ME patients physically sicker. If you improve with exercise, you do not have ME.

Graded exercise programs (GET) are probably the single most inappropriate and harmful 'treatment' for ME patients. ME patients cannot improve with something that has been proven to worsen or exacerbate the pathological features. Exercise may cause permanent damage as well as disease progression. Patients who were mild or moderately affected have become bedridden and severely worsened by exercise or overexertion, often for prolonged periods of time or even permanently. In addition to the risk of relapse, sudden deaths have also been reported in a small percentage of M.E. patients following exercise. Dr. Elizabeth Dowsett explains: '20% have progressive and frequently undiagnosed degeneration of cardiac muscle which has led to sudden death following exercise.'

Saying that treatments are the same for both ME and CFS is not true. Exercise cannot be the cause and cure for ANY entity. Thus combining them as the same diagnosis (via the same ICD coding) is unscientific as well as unethical. Giving patients a diagnosis which may be harmful is a human rights violation.

Proposed changes to the US ICD codes

The proposal by the Coalition 4 ME/CFS to recode ME and CFS together at G93.3 and combine them is not supportable and should not be considered (specific objections and counter-arguments to the proposal listed below).

A main goal of the Coalition 4 ME/CFS proposal seems to be to differentiate CFS from chronic fatigue. This has been addressed for years. The real solution to the "Chronic Fatigue Syndrome is not chronic fatigue" problem would be to change the name CFS and call it something else. It is not acceptable to usurp another illness. Throwing ME into the mix in order to change the CFS ICD codes to falsely elevate it or make it sound better will not solve this problem.

The NCHS Coordination and Maintenance Committee presented a second option which subdivided G93.3 into ME and CFS. [<http://www.cdc.gov/nchs/data/icd9/TopicpacketforSept2011a.pdf> page 11, Option 2]

This is preferable to the Coalition 4 ME/CFS proposal as the Committee's option did keep ME and CFS separate, but put them both under "chronic fatigue syndromes." ME should not be a subgroup of "chronic fatigue syndromes." ME is not a fatigue syndrome. ME has been in the ICD as the same stable neurological classification for several decades and should not be changed or subdivided.

Dr. E.G. Dowsett, world renowned expert and epidemiologist, stated, "To the very few physicians still practicing today who began seeing patients with this illness some 40 years ago and who have continued to record and publish their clinical findings throughout, the current enthusiasm for renaming and reassigning this serious disability to subgroups of putative and vague 'fatigue' entities, must appear more of a marketing exercise than a rational basis for essential international research. It was not always so unnecessarily complicated!" "A Rose By Any Other Name," Dr E.G Dowsett
<http://www.25megroup.org/Information/Medical/Rose%20by%20any%20other%20Name.htm>

Conclusion

The US government currently has ME and CFS coded correctly and separately. NCHS noted "that including chronic fatigue syndrome NOS at code G93.3 would make it difficult to disaggregate cases that are now distinguishable through the use of two separate codes."

[<http://www.cdc.gov/nchs/data/icd9/2011SeptemberSummary.pdf>]

Distinguishing ME from CFS is necessary to provide accurate data, diagnosis, recognition and acceptance and thus will improve funding for research and treatments.

The classification for M.E. should be and remain G93.3 Myalgic Encephalomyelitis under Diseases of the Nervous System. Based on science and policy, it is not clinically valid to classify CFS at code G93.3 as the Coalition 4 ME/CFS has recommended. Such changes should not be made to ICD-9 or 10CM or to the future ICD-11.