



Beyond Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome

Redefining an Illness

Committee on Diagnostic Criteria for ME/CFS



INSTITUTE OF MEDICINE
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Context

- The study was commissioned in response to a recommendation from HHS's Chronic Fatigue Syndrome Advisory Committee (CFSAC) to “promptly convene ... at least one stakeholders’ (ME/CFS experts, patients, advocates) workshop in consultation with CFSAC members to reach a consensus for a case definition useful for research, diagnosis and treatment of ME/CFS beginning with the 2003 Canadian Consensus Definition for discussion purposes.”

Charge to the Committee (abbreviated)

The Department of Human and Health Services and five other federal agencies asked the Institute of Medicine to convene a committee to:

- Develop **evidence-based diagnostic criteria for ME/CFS** to address the needs of health providers, patients and their caregivers, considering the various existing definitions and the unique diagnostic issues facing people with ME/CFS, specifically related to: gender, across the lifespan, and specific subgroups such as patients with substantial disability.
- Recommend whether **new terminology for ME/CFS** should be adopted.
- Develop an **outreach strategy** to disseminate the definition nationwide to health professionals, and a **plan for updating the new criteria**.

The Committee's Approach

The committee engaged in a number of activities to inform its work:

- Committee's deliberation and consensus process (five meetings: Jan, Mar, May, Jul, and Sep 2014)
- Two public sessions (testimony from patients and experts), and hundreds of public comments
- Input from CDC Multi-site Clinical Study of CFS, but lack of access to NIH P2P Workshop
- Consultants: (1) communications specialist with expertise in dissemination for health care professionals, and (2) statistician who summarized papers on symptom data from ME/CFS patients.
- Comprehensive literature review (January 1, 1950 - May 30, 2014)

Targeted Literature Searches

- Priority research questions were developed.
- Search was conducted from Jan 1950 – May 2014
- Screening: Inclusion and exclusion criteria applied to identify articles addressing diagnosis, prognosis, and manifestations of subgroups.

	Search Results	Fulfilled Criteria	Deemed Relevant
Adults	2,298	359	319
Pediatrics	427	58	49

*Additionally, the committee received a total of **1,291** articles from the **public** and reviewed them all.*

Key Messages

- ME/CFS is a serious, chronic, complex, multisystem disease that often can profoundly limit the health and activities of affected patients.
- A thorough history, physical examination, and targeted work-up are necessary to determine a differential diagnosis and often sufficient for diagnosis of ME/CFS.

Recommendation 1

Physicians should diagnose ME/CFS if diagnostic criteria are met following an appropriate history, physical examination, and medical work-up. A new code should be assigned to this disorder in the *International Classification of Diseases, Tenth Edition (ICD-10)* that is not linked to “chronic fatigue” or “neurasthenia.”

BOX 7-1

Proposed Diagnostic Criteria for ME/CFS

Diagnosis requires that the patient have the following three symptoms:

1. A substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities, that persists for more than 6 months and is accompanied by fatigue, which is often profound, is of new or definite onset (not lifelong), is not the result of ongoing excessive exertion, and is not substantially alleviated by rest, and
2. Post-exertional malaise,* and
3. Unrefreshing sleep*

At least one of the two following manifestations is also required:

1. Cognitive impairment* or
2. Orthostatic intolerance

* Frequency and severity of symptoms should be assessed. The diagnosis of ME/CFS should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity.

Other ME/CFS manifestations

- Pain – very common, but highly variable in presence, nature and severity.
- Certain infections may act as triggers
- Gastrointestinal and genitourinary problems
- Sore throat or scratchy throat
- Painful or tender axillary/cervical lymph nodes
- Sensitivity to external stimuli



A reflection

- These criteria are clear in the literature and in patients' voices

Treating the Symptoms

Even if patients do not meet the criteria for this disorder, clinicians should address their symptoms and concerns. Patients who have not yet been symptomatic for 6 months should be followed over time to see whether they meet the criteria for ME/CFS at a later time.

Recommendation 2

The Department of Health and Human Services should develop a toolkit appropriate for screening and diagnosing patients with ME/CFS in a wide array of clinical settings in which these patients are encountered, including primary care practices, emergency departments, mental/behavioral health clinics, physical/occupational therapy units, and medical subspecialty services (e.g., rheumatology, infectious diseases, neurology, cardiology).

Tools for the future

- It is our hope that this report will educate clinicians and other care providers
 - Patients and physicians should never be asked whether this disease is “real”
 - A clinician guide is already available at <http://www.iom.edu/~media/Files/Report%20Files/2015/MECFs/MECFscliniciansguide.pdf>
 - <http://bit.ly/1BhcAOR> YouTube by Dr. Bateman

Recommendation 3

A multidisciplinary group should reexamine the diagnostic criteria set forth in this report when firm evidence supports modification to improve the identification or care of affected individuals. Such a group should consider, in no more than 5 years, whether modification of the criteria is necessary. Funding for this update effort should be provided by non-conflicted sources, such as the Agency for Healthcare Research and Quality, through its Evidence-based Practice Centers process, and foundations.

Recommendation 4

The committee recommends that this disorder be renamed “systemic exertion intolerance disease” (SEID). SEID should replace myalgic encephalomyelitis/ chronic fatigue syndrome for patients who meet the criteria set forth in this report.

The term “chronic fatigue syndrome” can result in stigmatization and trivialization and should no longer be used as the name of this illness.

Pediatrics—Background

Estimates of the prevalence of pediatric ME/CFS vary widely from 0.03 to 1.29 percent.

ME/CFS clearly hinders the social and educational development of pediatric patients.

-School attendance is significantly reduced in a large percentage of patients. These patients are often misdiagnosed with labels of “school refusal” or “school phobia”.

Pediatrics—Evidence Base

Conclusion:

There is sufficient evidence that:

- orthostatic intolerance and autonomic dysfunction are common in pediatric ME/CFS;
- that neurocognitive abnormalities emerge when pediatric ME/CFS patients are tested under conditions of orthostatic stress or distraction;
- that there is a high prevalence of profound fatigue, unrefreshing sleep, and post-exertional exacerbation of symptoms in these patients.
- and that pediatric ME/CFS can follow acute infectious mononucleosis and EBV.

Comorbidities

The committee decided against developing a comprehensive list of potential comorbid conditions, but points to conditions that clinicians may wish to consider that have been identified by the ME-International Consensus Criteria (ME-ICC) and the CCC, including:

- fibromyalgia
- myofascial pain syndrome
- temporomandibular joint syndrome
- irritable bowel syndrome
- interstitial cystitis
- irritable bladder syndrome
- Raynaud's phenomenon
- prolapsed mitral valve
- depression
- migraine
- allergies
- multiple chemical sensitivities
- Sicca syndrome
- obstructive or central sleep apnea
- reactive depression or anxiety

Areas that Deserve Further Study

Remarkably little research funding has been made available to study the etiology, pathophysiology, and effective treatment of this disease, especially given the number of people afflicted. Thus, the committee was unable to define subgroups of patients or even to clearly define the natural history of the disease. More research is essential.



Some thoughts going forward

- It is my sincere hope that people will use this report which clearly demonstrates the seriousness of this illness for advocacy with policy makers
 - This study was funded by HHS, AHRQ, CDC, FDA, NIH, and SSA

Some thoughts going forward

- It is time to fund more research into this disease's causes, defining subtypes, and effective treatments
- This will require stronger advocacy in- and outside the government

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