1994 CDC Definition

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The Primary U.S. Case Definition

The major case definitions and diagnostic criteria for the Chronic Fatigue Syndrome (CFS) were developed from clinical experience and medical research over the past two decades in the United States, Canada, Australia and Europe.

In the United States, the case definition in most widespread use in 2012 was developed in 1994 under the auspices of the U.S. Centers for Disease Control & Prevention (CDC), the primary federal public health agency.

The Criteria were published as an article, "The Chronic Fatigue Syndrome: A Comprehensive Approach to its Definition and Study" in 1994 in the *Annals of Internal Medicine*, a prestigious medical journal. This definition identified the illness as "Chronic Fatigue Syndrome"—the name the CDC gave to the illness in its first CFS definition in 1988. (Hence the 1994 criteria are termed the "revised" definition.)

This definition remains the "official" and "authoritative" definition of the U.S. public health and research agencies and is the one most widely distributed among and subscribed to by many researchers and clinicians in the U.S. and other countries.

The CDC diagnostic criteria are also the standard used by the U.S. Social Security Administration (SSA) in determining ME/CFS disability, although in 2014 it issued a ruling accepting the 2003 Canadian criteria as well as some of the 2011 International Consensus Criteria.

To date, in our opinion the 2003 Canadian Definition is the most medically accurate and detailed case definition available to physicians and patients. A patient and his/her physician will best determine presence of the illness using the Canadian Diagnostic Criteria.

So we suggest the that the 1994 Case Definition and the subsequent 2006 CDC Guidelines (an abridgement of the 1994 case definition) not be used as the sole method of diagnosing a case of the Myalgic Encephalomyelitis/chronic Fatigue Syndrome (ME/CFS).

CDC Guidelines for the evaluation and study of CFS

The Centers for Disease Control website presents a summarized version of the 1994 definition (originally published in the 1994 *Annals of Internal Medicine)* at their site.

As a reference guide, it is useful to print out the summarized version. Patients may also want to give a copy to their physicians.

In 2010 and 2012, the CDC substantially improved its website information on the CFS diagnostic process. Patients and Health Care Professionals should review the CDC website's most comprehensive explanation of the diagnostic process.

1. ***Diagnosis*** **(http://www.cdc.gov/cfs/diagnosis/index.html (/component/weblinks/weblink/47-me-cfs-web-links/212-cdc-suggestions-for-examining-a-patient-for-me-cfs-using-the-1994-definition?Itemid=267&task=weblink.go))—**this section of the CDC website covers the following topics: Diagnostic challenges, Exams and Screening Tests for CFS, and Criteria for Diagnosing CFS. It also includes information for patients who think they might have CFS.
2. ***Diagnostic Tests to Exclude Other Causes*** **(http://www.cdc.gov/cfs/diagnosis/testing.html (/component/weblinks/weblink/47-me-cfs-web-links/211-cdc-recommended-diagnostic-tests-for-applying-the-1994-me-**

cfs-definition?Itemid=267&task=weblink.go))—this section includes tests that will exclude other causes of fatiguing illness and diagnose illness other than CFS.

For the ease of our readers, we are making these sections available here; however, patients may wish to print-out the information at CDC web pages for their providers.

Diagnosis

Diagnostic Challenges

For doctors, diagnosing chronic fatigue syndrome (CFS) can be complicated by a number of factors:

1. There's no lab test or biomarker for CFS.
2. Fatigue and other symptoms of CFS are common to many illnesses.
3. For some CFS patients, it may not be obvious to doctors that they are ill.
4. The illness has a pattern of remission and relapse.
5. Symptoms vary from person to person in type, number, and severity.

These factors have contributed to a low diagnosis rate. Of the one to four million Americans who have CFS, less than 20% have been diagnosed.

Exams and Screening Tests for CFS

Because there is no blood test, brain scan, or other lab test to diagnose CFS, the doctor should first rule out other possible causes.

If a patient has had 6 or more consecutive months of severe fatigue that is reported to be unrelieved by sufficient bed rest and that is accompanied by nonspecific symptoms, including flu-like symptoms, generalized pain, and memory problems, the doctor should consider the possibility that the patient may have CFS. Further exams and tests are needed before a diagnosis can be made:

- A detailed medical history will be needed and should include a review of medications that could be causing the fatigue and symptoms
- A thorough physical and mental status examination will also be needed
- A battery of laboratory screening tests will be needed to help identify or rule out other possible causes of the symptoms that could be treated
- The doctor may also order additional tests to follow up on results of the initial screening tests

A CFS diagnosis requires that the patient has been fatigued for 6 months or more and has 4 of the 8 symptoms for CFS for 6 months or more. If, however, the patient has been fatigued for 6 months or more but does not have four of the eight symptoms, the diagnosis may be idiopathic fatigue.

For Doctors and Other Healthcare Professionals: Criteria for Diagnosing CFS

Consider a diagnosis of CFS if these three criteria are met:

1. The individual has severe chronic fatigue for 6 or more consecutive months that is not due to ongoing exertion or other medical conditions associated with fatigue (these other conditions need to be ruled out by a doctor after diagnostic tests have been conducted)
2. The fatigue significantly interferes with daily activities and work
3. The individual concurrently has 4 or more of the following 8 symptoms:

- post-exertion malaise lasting more than 24 hours
- unrefreshing sleep
- significant impairment of short-term memory or concentration

- muscle pain
- multi-joint pain without swelling or redness
- headaches of a new type, pattern, or severity
- tender cervical or axillary lymph nodes
- a sore throat that is frequent or recurring

For Patients Who Think They Might Have CFS

It can be difficult to talk to your doctor or other health care professional about the possibility that you may have CFS. A variety of health care professionals, including doctors, nurse practitioners, and physician assistants, can diagnose CFS and help develop an individualized treatment plan for you.

CFS can resemble many other illnesses, including mononucleosis, Lyme disease, lupus, multiple sclerosis, fibromyalgia, primary sleep disorders, and major depressive disorder. Medications can also cause side effects that mimic the symptoms of CFS.

Because CFS can resemble many other disorders, it's important not to self-diagnose CFS. It's not uncommon for people to mistakenly assume they have chronic fatigue syndrome when they have another illness that will respond to treatment. If you have CFS symptoms, consult a health care professional to determine if any other conditions are responsible for your symptoms. A CFS diagnosis can be made only after other conditions have been excluded.

It's also important not to delay seeking a diagnosis and medical care. CDC research suggests that early diagnosis and treatment of CFS can increase the likelihood of improvement.

Diagnostic tests to exclude other causes

Tests for Routine Diagnosis of CFS
While the number and type of tests performed may vary from doctor to doctor, the following tests constitute a typical standard battery to exclude other causes of fatiguing illness:

- alanine aminotransferase (ALT)
- albumin, alkaline phosphatase (ALP)
- blood urea nitrogen (BUN)
- calcium
- complete blood count with differential
- creatinine
- electrolytes
- erythrocyte sedimentation rate (ESR)
- globulin
- glucose
- phosphorus
- thyroid stimulating hormone (TSH)
- total protein
- transferrin saturation
- urinalysis

Further testing may be required to confirm a diagnosis for illness other than CFS. For example,
• If a patient has low levels of serum albumin together with an above-normal result for the blood urea nitrogen test, kidney disease would be suspected. The doctor may choose to repeat the relevant tests and possibly add new ones aimed specifically at diagnosing kidney disease.
• If autoimmune disease is suspected on the basis of initial testing and physical examination, the doctor may request additional tests, such as for antinuclear antibodies.

Assessing the Impact of Fatigue on Cognition
For some patients, it may be beneficial to conduct tests to assess how fatigue is affecting their cognitive skills such as concentration, memory, and organization. This additional testing can be useful in the differential diagnosis process or in identifying specific areas in which therapy may help. This may be particularly helpful to children and adolescents with CFS. Academic attendance and performance are important in these patients, and their specific educational needs should be addressed.

Tests for Differential Diagnosis and Management
CFS remains a diagnosis based on medical history, illness symptoms, physical examination, and exclusion of certain illnesses using a standard group of laboratory tests (1994 case definition). Additional tests such as imaging and physiological assessments can also be used to diagnose underlying illnesses:
• specific cultures or serological tests if an ongoing infection is considered
• MRI or other neuroimaging procedures to test for diseases such as multiple sclerosis
• physiological testing such as sleep studies, exercise testing (including VO_2 max), or tilt table testing to address specific questions, often in consultation with a specialist

Be aware that a patient can have CFS as well as a co-existing illness that cause fatigue or other CFS symptoms—for example, depression or low blood pressure. If treatment of those other illnesses does not resolve the symptoms, then the person can still have CFS.

Assessment of the 1994 CDC Definition

Recently, the CDC has very substantially improved its guidelines for the application of the 1994 CFS Criteria, and the Agency has stated it is reviewing the efficacy of more recent Diagnostic Criteria.

The CDC Criteria had very substantial flaws at its inception, so it is helpful to review both (1) some supplemental lab tests available to physicians for diagnostic purposes, and (2) the substantial limitations of the Criteria in accurately diagnosing ME/CFS.

Other Laboratory testing: Given more recent research and clinical experience, as well as the Social Security Administration Ruling on CFS, 2014, other tests may be indicative of CFS. A number CFS expert researchers and clinicians have developed protocols of laboratory and other tests that are helpful in adding confirmatory weight to a ME/CFS diagnosis. These tests are not directly diagnostic; however, in a percentage of cases they can positively contribute to a diagnosis after all other steps are taken under various diagnostic criteria.

It should be noted that in other sections of this website are references to various recent papers which provide evidence of viral and other microbial involvement in ME/CFS. Experienced clinicians and researchers are beginning to make use of various tests to determine the presence of active virus, including EBV, CMV, HHV-6, as well as other microbes. Clinicians certainly can run the protocols below as part of their effort to diagnose ME/CFS.

Dr. Anthony Komaroff, a leading specialist in ME/CFS cites the following laboratory abnormalities as supportive of a ME/CFS diagnosis:

Laboratory Abnormalities and Chronic Viral Fatigue Syndrome (CFS)*:

- Mild leukopenia (3000-5000/mm)
- Moderate monocytosis (7%-15%)
- Relative lymphocytosis (>40%)
- Atypical lymphocytosis (1%-20%)
- Slight elevation in SGOT and SGPT
- Erythrocyte sedimentation rate unusually low (0-4mm)
- Partial reduction in immunoglobulins
- Circulating immune complexes (low levels)

- Increased CD4/CD8 ratio
- EBV antibodies:

  Viral capsid antigen-IgG > 1:640
  Viral capsid antigen-IgM-not detectable
  Early antigen- 1:40
  EB nuclear antigen <1:5

**It is unusual for more than one or two of these findings to be present in any single patient.*

Flaws in the 1994 Case Definition

The 1994 CDC definition, unfortunately, has proven to be partially flawed. First, the Criteria was originally intended as a research definition and for that reason excluded CFS cases that might have certain dual diagnoses, for instance CFS and obesity and CFS and bi-polar disorder.

The CFS definition, however, had come into wide use clinically—that is to diagnose patients in normal medical settings. Hence, a number of research exclusions would prevent patients, with additional diagnoses, from properly receiving a CFS diagnosis. To its credit the CDC has currently recognized this problem.

The CDC definition refers to a "mental status examination". In the past, many physicians have been unclear as to how, and by whom, such an examination should be performed. The CDC now suggests this exam can be performed by the patient's examining physician.

The 1994 Criteria, itself, does not with acceptable accuracy, clinically identify and distinguish the actual illness. (This has been shown in convincing research studies. See some references mentioned in the **Canadian Guidelines.** For this reason, research results that use the 1994 definition may also be flawed, as some subjects who do not have the illness are invariably included.

The 1994 definition puts too much emphasis on the existence of a major symptom—fatigue—while not taking into sufficient account other major symptom complexes or the peculiar characteristics of the fatigue (which include post-exertional malaise mimicking that found in mitochondrial disease occurring the day after minor exertion).

The definition clouds the now research-validated difference between psychiatric illnesses and the multi-systemic, physiological, and coherent disease entity which is ME/CFS—an illness with common immune, endocrine, cardiovascular, and neurological dysfunction.

More and more research is also identifying the involvement of viruses and other potential microbes, as well as involvement of the RNase-L system in cells. The 1994 definition is diagnostically not sufficiently rigorous as it permits the misdiagnosis of individuals with psychiatric illness as having ME/CFS, and conversely, permits individuals who actually have ME/CFS to be misdiagnosed as having psychiatric illness.

Moreover, the name itself, Chronic Fatigue Syndrome, is inaccurate and not only distorts the medical nature of the illness but also badly serves a real understanding of the illness by patients, physicians and the general public. Many of the U.S. and international researchers most knowledgeable about the illness clearly recognize the deficiencies of the case definition and the 1994 diagnostic criteria.

In an attempt to overcome the harm created by the name Chronic Fatigue Syndrome, patients in the United States, beginning in the early 1990s, have termed the illness Chronic Fatigue Immune Dysfunction Syndrome (CFIDS), since immune abnormalities in patients have been demonstrated by many definitive research studies. In 2012, the patient community in the United States has been advocating to the federal agencies the use of the name Myalgic Encephalomyelitis.

For a more detailed analysis of the flaws in the 1994 CDC Definition, see **Critique of the CDC Case Definitions** and **Detailed explanation of the 1994 CFS Definition. (2.25 edit - see elsewhere in the Archive.)**

When the 1994 CDC Case Definition should be used

There are a number of situations in which the patient will clearly need a diagnosis that relies upon the 1994 CDC definition. This definition is the only one recognized by some long-term disability insurance companies, and other agencies providing financial, medical, housing and food assistance. In these cases, diagnosis according to both the 2003 Canadian definition and the 1994 CDC definition is preferable, and the doctor may rely on the 1994 definition in providing disability documentation.