History

The lack of clarity and accuracy of the dominant, but somewhat amorphous 1994 Centers for Disease Control & Prevention (CDC) definition for the Chronic Fatigue Syndrome (CFS) led a number of the leading researchers and clinicians from the U.S. and other nations to develop and publish in 2003 a new and much more accurate case definition/diagnostic criteria for the illness:

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Definition, Diagnostic and Treatment Protocols

As this definition was published partially under the auspices of the Canadian Ministry of Health, it is informally called the Canadian Definition. The Canadian government assisted in organizing a committee following "input from invited world leaders in the research and clinical management of ME/CFS patients." (The combined experience of the committee was with over 20,000 patients.)

The Canadian Definition and Diagnostic protocols draw together the most rigorous findings both from the CFS-CDC sponsored research and the ME European research. Authors include CFS/ME experts Dr. Kenny De Meirleir of Belgium and Drs. Martin Lerner, Daniel Peterson, and Nancy Klimas of the U.S., among others.

To date, in our opinion the Canadian Definition is the most medically accurate and detailed case definition for the Chronic Fatigue Syndrome/Chronic Fatigue and Immune Dysfunction Syndrome/Myalgic Encephalopathy/Myalgic Encephalomyelitis (CFS/CFIDS/ME) available to physicians and patients. A patient and his/her physician will best determine presence of the illness using the Canadian Diagnostic Criteria.

If necessary, a patient can print out the Canadian Definition provided by the link http://www.cfids-cab.org/MESA/ccpc.html
and take it to his or her physician.

The Canadian Definition and Diagnostic Criteria

The M.E. Society of America has a short summary of the Canadian definition, as well as short biographies of its various authors at its website. http://www.cfids-cab.org/MESA/ccpc.html .

The Diagnostic Protocol includes the "Clinical Working Case Definition"; a section on "Applying the Case Definition to the Individual Patient"; a "Discussion of the Major Features of ME/CFS"; "Features of ME/CFS in Children"; a guide for the "Clinical Evaluation of ME/CFS", which includes procedures for taking a patient history and for conducting the physical examination; the "Laboratory and Investigative Protocol" (general and more specialized lab tests); sections on differential diagnoses; along with a section on prognosis and disability assessment.

The entire diagnostic and case protocol is an extensive 22 pages, and requires careful reading. We will present a brief summary here with the hope of making the full document more accessible.

The first section contains the actual signs and symptoms criteria by which a patient achieves a diagnosis after other excluding illnesses are eliminated. Throughout, the definition makes clear that this clustering of symptoms, symptom-complexes, and pathophysiological signs is not random or disorganized, but is a coherent and recognizable cluster pattern of a specific and identifiable disease syndrome. As an analogy—before the nature and possible causes of Muscular Sclerosis (MS) were discovered, medical science identified MS primarily through its (unfortunately) reproducible symptoms.

Required Canadian Diagnostic Criteria for CFS/ME (in summary)

To have CFS/ME, a patient must meet all four of these criteria:

1. "the criteria for fatigue, post-exertional malaise and/or fatigue, sleep dysfunction, and pain" explained below
2. "have two or more neurological/cognitive manifestations"
3. "one or more symptoms from the categories of autonomic, neuroendocrine and immune manifestations"
4. "the illness persists for at least six months usually having a distinct onset, although it may be gradual." A "preliminary diagnosis may be possible earlier."

The definition also makes clear that the symptom criteria cannot be used as a mere template for diagnosis, but must be applied according to stated guidelines (to be summarized shortly.)

Thus, to be diagnosed the person must qualify under each and all of the following symptom categories (as qualified in the further application categories):

1. "Fatigue: The patient must have a significant degree of new onset, unexplained, persistent, or recurrent physical and mental fatigue that reduces activity level. Three months is appropriate for children."
2. "Post-exertional malaise...There is an inappropriate loss of physical and mental stamina, rapid muscular and cognitive fatigability, post-exertional malaise...and/or pain and a tendency of other associated symptoms within the patient's cluster of symptoms to worsen. There is a pathologically slow recovery period—usually 24 hours or longer."
3. Sleep dysfunction: There is non-restorative sleep or decline in sleep quantity or dysregulation of normal sleep rhythms.
4. Pain. "There is a significant degree of myalgia." The word means muscle pain, and is often the type of deep muscle pain experienced during the flu. "Pain can be experienced in the muscles/joints, and is often widespread and migratory in nature." There are often headaches of a "new type, pattern or severity".
5. "Neurological/Cognitive Manifestations" To qualify in this category *two or more* of the listed symptoms must be present. Please see the specific list of symptoms in the actual document. They are grouped into a) cognitive deficits including problems with memory, information processing, difficulties with thinking, and perceptual disturbances; and b) more classical neurological symptoms, including difficulty walking and muscle weakness; sensory hypersensitivity, including lower threshold for emotional overload.

6. To qualify under this category, the patient must have *at least one symptom from two of the following three subcategories.*

Often a patient will have multiple symptoms:

a) "Autonomic Manifestations: orthostatic intolerance, neurally-mediated hypotension; postural orthostatic tachycardia; light-headedness; extreme pallor; nausea and irritable bowel syndrome; urinary frequency and bladder dysfunction; difficulty breathing upon exertion; palpitations with or without cardiac arrhythmias."

b) "Neuroendocrine Manifestations: loss of thermostatic stability—subnormal body temperature...sweating episodes, recurrent feelings of feverishness and cold extremities; intolerance of heat and cold, marked weight change—anorexia or abnormal appetite; loss of adaptability and worsening symptoms with stress."

c) "Immune Manifestations: tender lymph nodes, recurrent sore throats, recurrent flu-like symptoms, general malaise, new sensitivities to food, medications and or chemicals."

Exclusionary Conditions

The Diagnostic Protocol next provides a list of *active* disease processes that may explain most of the major illness symptoms. If one of these diseases is diagnosed it would likely exclude a diagnosis of CFS/CFIDS/ME. However, "If a confounding medical condition is under control, then the diagnosis of CFS/ME can be entertained if patients meet the criteria otherwise."

See the protocol list in the actual document for these exclusionary illnesses. They include diseases of various endocrine organs, cancers, blood diseases, deficiency diseases, known sleep disorders, and known immune, infectious, and neurological disorders.

Non-exclusionary Conditions

The protocol then provides a list of c*o-morbid entities*—that is, illnesses that may, and often do, accompany CFS/ME. Presence of these conditions does not exclude CFS/ME. Such illnesses include fibromyalgia (FM) (as a separate, coexisting condition); irritable bowel syndrome; depression; multiple chemical sensitivities, etc.

Guidelines for Using The Symptom Listings

The protocol next provides *Guidelines* for the application of the symptom listings to the patient. For instance: "The widely distributed symptoms are connected as a coherent entity through the temporal and causal relationships revealed in the history. If this coherence of symptoms is absent, the diagnosis is in doubt."

The Case Definition then includes a detailed discussion section on each of the symptom groupings and its major features. It includes a short section on features of CFS/CFIDS/ME in children.

Clinical Evaluation and Laboratory Testing

The next major section describes the steps in the clinical evaluation of CFS/CFIDS/ME (that is, how the physician proceeds to assess the patient's illness):

"Assess the total illness burden, taking a thorough history, physical examination and investigations as indicated to confirm clinical findings and to rule out other active illness processes. The patient evaluation is to be used in conjunction with the clinical definition." The section presents a detailed protocol for the *patient history* and *physical examination.*

Finally the definition lists the *Laboratory and Investigative Protocol*. First is a listing of routine lab tests for general diagnostic purposes. These tests are normally given to test for infections, various deficiencies, abnormal pathophysiological processes, organ function, autoimmune disease, etc. Abnormalities could indicate exclusionary conditions. CFS/CFIDS/ME often shows near normal routine lab tests; although some tests may be somewhat abnormal and thereby be a sign of CFS/CFIDS/ME.

The protocol then lists further specialized laboratory and other testing. This testing falls into two categories:

(a) specialized testing for other exclusionary conditions

(b) testing for further exploration of specific CFS/CFIDS/ME symptom complexes and pathophysiology. This testing can also be used to identify co-morbid conditions.

Specialized tests are indicated when the routine lab tests, or history/examination, indicate that testing be undertaken for other exclusionary conditions such as: infectious diseases (HIV, hepatitis, western blot for Lyme disease, parasites, TB, etc.); neurological disease (MRI for MS and cervical stenosis); specific endocrine testing; autoimmune testing; sleep studies for sleep

apnea and other possible exclusionary conditions.

Specialized testing may also be done for the further exploration of CFS/CFIDS/ME symptom complexes and pathophysiology; and also for co-morbid conditions. The tests may be indicated by the seriousness of the symptom-complex or for possible treatment. Such tests could include: immune testing (when available); brain scans; tilt table testing for orthostatic symptoms; sleep studies for CFS/CFIDS/ME sleep pathology; 24-hour Holter monitoring for cardiac symptoms; and neuropsychological testing for cognitive dysfunction.

Finally, the protocol discusses in some detail the differential diagnoses between CFS/CFIDS/ME and fibromyalgia; and CFS/CFIDS/ME and psychiatric disorders.

As there are, at the present time, no clear, readily available true diagnostic markers for the illness (which would constitute a diagnostic "gold standard"), we consider the Canadian Criteria to be a "silver standard" for CFS/CFIDS/ME diagnosis and currently provide the most accurate diagnostic tool for CFS/CFIDS/ME.

More Resources

AACFS Clinical Conference Report 2003

Cardiac Symptoms and Abnormalities Documented in CFS Patients: (A summary of 4 studies by Lerner et al.)

Komaroff, Progress on Chronic Fatigue Syndrome Research, 2008

The Physical Basis of CFS

Canadian Expert Consensus Panel Clinical Case Definition for ME/CFS