

New International Consensus Criteria for Diagnosis of ME

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A proposed new criteria for diagnosing the illness Chronic Fatigue and Immune Dysfunction Syndrome (CFIDS), also known as Chronic Fatigue Syndrome (CFS), was published under the title, “Myalgic encephalomyelitis: International Consensus Criteria”, in the *Journal of Internal Medicine*, v. 270, n. 4, 295-400, Oct. 2011. “Myalgic encephalomyelitis (ME)” means muscle pain and inflammation of the brain and spinal cord. The following article reviews the basic features of the proposed 2011 diagnostic criteria and compares it with the 2003 criteria—the ME/CFS Canadian Case Definition.

The new Criteria uses only the name ME, and not CFS, because according to the authors:

“In view of more recent research and clinical experience that strongly point to widespread inflammation and multi-systemic neuropathology, it is more appropriate and correct to use the term ‘myalgic encephalomyelitis’ (ME) because it indicates an underlying pathophysiology.”

ME has, historically, been the name used for the multi-systemic illness in Britain, the European countries, Canada, Australia and New Zealand.

The new ME International Consensus Criteria is authored by many of the most respected and committed international CFIDS/ME/CFS researchers and clinicians, including B.M. Carruthers, K.L. DeMeirleir, N.G. Klimas, R. Vallings, L. Bateman, D.S. Bell, J. Miskovits, and A.R. Light.

According to the article, the 2011 Consensus Panel consisted of clinicians and researchers from a wide range of specialties and from thirteen countries. “Collectively, members have approximately 400 years of both clinical and teaching experience, authored hundreds of peer-reviewer publications, diagnosed or treated approximately 50,000 patients with ME...” A number of the authors also contributed to the 2003 Canadian Consensus Criteria, a fact that accounts for much of the continuity between the two Criteria.

Another important aspect of the 2011 Criteria is evidenced by the 119 articles cited by the authors. These citations constitute a major review of much of the significant illness research over the past 20 years—research that has increased the scientific understanding of CFIDS/ME/CFS. This expansion of knowledge was significant enough, according to the authors, to improve the ability to identify and distinguish ME, and thereby provided the basis for the development of the 2011 Criteria.

New 2011 Criteria intends to promote better recognition of ME

The 2011 Criteria is based on the broad array, in recent years, of intense illness research. The authors state that ME “...is a complex disease involving profound dysregulation of the central nervous system...and immune system...dysfunction of cellular energy metabolism and ion transport...and cardiovascular abnormalities.”

“Criteria symptoms [in the Consensus Criteria] are supported by a study of more than 2500 patients that determined which symptoms had the greatest efficacy to identify patients with ME...”

“Investigations into gene expression...and structure...anomalies of including of increased oxidative stress...altered immune and adrenergic signaling...” and other identified pathophysiologies provided the basis for the development of the new Criteria.

A further aim of the new Criteria is to provide for a better selection of only those patients afflicted with ME. A major problem with the 1994 CDC CFS Definition and the more recent 2005 Reeves empirical criteria is that they do not adequately separate patients who are depressed from patients with ME. “Patient sets that include people who do not have the disease lead to biased research findings, inappropriate treatments and waste scarce research funds...” The former 2003 Canadian Criteria “differentiate patients with ME from those who are depressed...” The Canadian Consensus Criteria was used as a “starting point” for the new 2011 Criteria, but significant changes were made, including the diagnostic specifics appropriate to children.

Overall differences between the 2011 ME International Consensus Criteria and the 2003 ME/CFS Canadian Consensus Criteria

The 2011 Criteria incorporates much of the new illness research conducted since 2003, and is structured more on an understanding of the systemic pathological processes of the illness. The 2003 Criteria, however, is organized according to characteristic “symptom clusters.” The new approach may provide a more dynamic and integrated view of the illness.

The 2011 Criteria names the illness solely as ME and drops the name CFS included in the 2003 ME/CFS Criteria. The authors write: “Using ‘fatigue’ as a name of a disease gives it exclusive emphasis and [it] has been the most confusing and misused criterion.”

Another major change in the new ME Criteria is that the 6-month “waiting period” for diagnosis contained in the 2003 criteria (and in the U.S. Centers for Disease Control and Prevention [CDC] Criteria) is eliminated. The authors write: “No other disease criteria require that diagnoses be withheld until after the patient has suffered with the affliction for six months.” However, they write: “Notwithstanding, periods of clinical investigation will vary and may be prolonged, diagnosis should be made when the clinician is satisfied that the patient has ME rather than having the diagnosis restricted by a specified time factor.”

Two major changes in an understanding of the illness are apparent from the 2011 Criteria. First is a recognition of the body’s pathological inability to produce sufficient energy, and that the symptoms resulting from the response to exertion or recovery from it are given much more significance and made more explicit in the new Criteria. **Second**, the 2011 Criteria reformulates many of the 2003 autonomic and neuroendocrine symptoms under a new, more inclusive, pathological category of energy production/transportation impairments.

The 2011 Criteria overall requires a greater *number* of minimum symptoms with emphasis on flu-like symptoms, susceptibility to viral infections, genitor-urinary, gastro-intestinal, and various sensitivities. The 2003 Criteria, in contrast, distributed its minimum number of required symptoms more broadly among immune, autonomic and neuroendocrine symptom-complexes. It also required fewer minimal total symptoms.

The two definitions vary in how symptoms are categorized or grouped together, as well as in the number or combination of symptoms needed in order for the patient to meet the criteria.

A Comprehensive Comparison of the Two Criteria

A more detailed, comprehensive comparison is somewhat difficult because a different structure for classifying illness symptoms and pathologies is used by each of the two Criteria.

A Column Chart best illustrates the diagnostic requirements between the analogous 2011 *systemic processes* groupings and the 2003 *symptom cluster* groupings, as presented below:

M.E. International Consensus Criteria 2011

M.E./C.F.S Clinical Working Case Definition (2003 Canadian)

Note: The 2011 definition drops CFS from the illness name.

No waiting period before diagnosis. Periods of clinical investigation will vary and may be prolonged—diagnosis should be made when a clinician is satisfied that the patient has ME.

Six-month waiting period before diagnosis can be made.

Systemic Processes:

Symptom-Complexes:

A. Postexertional Neuroimmune Exhaustion (PENE): Compulsory

A. Fatigue: Compulsory significant degree of new onset, unexplained ongoing physical and mental fatigue that substantially reduces activity level.

Characteristics: (all required)

1. Marked, rapid physical and/or cognitive fatigability in response to exertion;
2. Postexertional symptom exacerbation—acute flu-like symptoms, pain, worsening of other symptoms;
3. Postexertional exhaustion: may occur immediately after activity or be delayed by

B. Postexertional malaise and/or fatigue: Compulsory: Loss of physical and mental stamina, rapid muscular and cognitive fatigability, pain. Slow recovery

hours or days

period —24 hrs. or longer.

4. Recovery period is prolonged—24 hrs. or longer (days, weeks or longer)
5. Low threshold of physical and mental fatigability results in substantial reduction in pre-illness activity level. Reduction must be at least 50% of pre-illness level of activity

In the 2011 Criteria, fatigue, exhaustion, loss of mental stamina, and increased pain due to exertion is grouped within PENE. Under the 2003 Criteria, the same general symptoms were required but were organized under two separate categories of fatigue and postexertional malaise/fatigue. The term “malaise” is found to be deficient and incorrect when describing the systemic processes associated with postexertional-triggered symptoms. Please also notice that pain due to increased exertion is a requirement under the PENE group, while pain as an *ongoing* symptom is optional under the Neurological impairments group (see below).

B. Neurological impairments: At least one symptom from each of 3 of the following 4 symptom categories (3 symptoms total):

1. Neurocognitive impairments
 - a. Difficulty processing information: slowed thought, impaired concentration
 - b. Short-term memory loss
2. Neurosensory, perceptual and motor Disturbances
 - a. Neurosensory and perceptual: inability to focus vision, light sensitivity, noise, odor, taste, touch, etc.
 - b. Motor: muscle weakness, twitching, ataxia, poor coordination, unsteady on feet
3. Pain
 - a. Headaches
 - b. Significant pain: in muscles, muscle-tendon junctions, joints, abdomen, chest
4. Sleep disturbance
 - a. Disturbed sleep patterns
 - b. Unrefreshed sleep

C. Neurological/Cognitive impairments: 2 or more of the following of the following symptoms:

Confusion, impairment of concentration, short-term memory loss, disorientation, difficulty with information processing/word retrieval;
Perceptual and sensory disturbances—spatial instability and inability to focus vision. Sensitivity to noise, light, emotional overload, “crash”

Ataxia, muscle weakness

D. Pain: Compulsory significant muscle pain; joint pain, headaches.

E. Sleep dysfunction: Compulsory Unrefreshed sleep, disturbed sleep patterns

In the 2003 Criteria, the patient is required to have at least 2 or more symptoms in the “neurological/cognitive symptom-complex” group, a group that is essentially similar to the 2011 neurological subgroups 1 and 2 above. However, in the 2011 Criteria a patient could qualify with just one symptom in *either* of the neurocognitive or neurosensory subgroups.

The patient was also required in the 2003 Criteria to meet the symptom requirements in *both* the separate pain and sleep disturbance symptom-complex groups. In the 2011 Criteria, sleep disturbance or primary pain is *optional*, since a patient can exclude symptoms in one of the four subgroups.

A comparison of the each of the last two 2011 diagnostic categories, 1) Immune, gastro-intestinal, and genitourinary impairments, and 2) Energy production/transportation impairments, can only be made in relation to 3 separate 2003 diagnostic categories: 1) Immune manifestations; 2) Autonomic manifestations; 3) Neuroendocrine manifestations.

The immune system symptoms are substantially *the same* under both definitions. The 2011 Criteria creates two separate subcategories of gastro-intestinal tract and genitourinary symptoms, while the 2003 Criteria lists many of these symptoms under one autonomic manifestations group. Also, the 2011 Criteria lists respiratory symptoms as energy production/transportation impairments, while the 2003 Criteria lists respiratory symptoms as autonomic manifestations. Finally, in 2011, neuroendocrine manifestations are listed under the energy production/transportation category, while the 2003 Criteria lists neuroendocrine manifestations as an entirely separate category.

Hence, the 2011 Criteria groups many of the 2003 autonomic and neuroendocrine symptoms under a new, more inclusive category of energy production/transportation impairments.

F. At least One symptom from two of the following categories:

C. Immune, gastro-intestinal, and genitourinary impairments—at least 1 symptom from three of the five symptom categories:

1. Flu-like symptoms, recurrent or chronic activate with exertion;
2. Susceptibility to viral infections, with prolonged recovery time;
3. Gastro-intestinal tract: nausea, abdominal pain, bloating, irritable bowel syndrome;
4. Genitourinary: urinary urgency/frequency, nocturia
5. Sensitivities: food, medications, odors, chemicals

1. Immune manifestations: tender lymph-nodes, recurrent sore throats, recurrent flu-like symptoms, new sensitivities to food, medications, chemicals.

D. Energy production, transportation impairments

At least 1 symptom from any of the subgroups:

1. Cardiovascular; e.g., inability to tolerate upright orthostatic intolerance, neurally-mediated hypotension, postural-orthostatic tachycardia, palpitations with/without arrhythmias, light-headedness/dizziness
 2. Respiratory: air-hunger, labored breathing, fatigue of chest wall muscles
 3. Loss of thermostatic stability—subnormal body temp., marked diurnal fluctuations, sweating episodes, recurrent feelings of feverishness with or without low grade fever, cold extremities
 4. Intolerance of extremes of temperature
2. Autonomic Manifestations: O.I., N.M.H., P.O.T.S., light-headedness, extreme pallor, nausea, i.b.s., urinary freq., bladder dysf., palpitations, with/out arrhythmias, exertional dyspnea.
 3. Neuroendocrine manifestations: Loss of thermostatic stability, subnormal body temp. and marked diurnal fluctuations, sweating episodes, recurrent feelings of feverishness, intolerances of temp. extremes, marked weight change, worsening of symptoms with stress.

The 2011 definition requires at least 1 symptom from each of at least 3 of the 5 immune, gastrointestinal, genitourinary and sensitivity categories; and at least one symptom from the energy production/ transportation category, with a total of *at least 4 compulsory symptoms*. On the other hand, the 2003 definition required at least one symptom from 2 of the 3 categories: immune, autonomic and neuroendocrine—for a total of *at least 2 compulsory symptoms*.

Pediatric diagnostic considerations in the 2011 Criteria

In a separate section, the 2011 Criteria discusses how ME may manifest itself somewhat differently in children. The authors write: “Symptoms may progress more slowly in children than in teenagers or adults. In addition to postexertional neuroimmune exhaustion, the most prominent symptoms tend to be neurological: headaches, cognitive impairments, and sleep disturbances.”

Headaches are severe or chronic. Migraine headaches “may be accompanied by a rapid drop in temperature, shaking, vomiting, diarrhoea and severe weakness.” Neurocognitive symptoms may include difficulty with eye-focusing and reading.

“Children may become dyslexic, which may only become evident when fatigued.” There will be slow information-processing which will create difficulty following oral instructions or taking notes. “All cognitive impairments worsen with physical or mental exertion.” Young people with the illness will not be able to maintain a full school program. Also, “Pain may seem erratic and migrate quickly...Joint hypermobility is common.”

The fluctuation and severity of numerous major symptoms may change in their relative severity and prominence “more rapidly and dramatically than in adults.”

The Wiley online library provides access, at no cost, to the full text article, [*Myalgic encephalomyelitis: International Consensus Criteria.*](#)