

THE INTERNATIONAL CONSENSUS CRITERIA What is it? Do I fit the criteria?

POSTED BY MEADVOCACY ADVISORY-COMMITTEE 5SC ON OCTOBER 29, 2016



MEadvocacy.org understands there is a great deal of confusion about the various criteria for myalgic encephalomyelitis, so we created an easy to follow questionnaire to help patients see if they may fit the 2011 International Consensus Criteria.

Do I fit the International Consensus Criteria?

Questionnaire for patients over age 18

Disclaimer: This questionnaire does not replace the full International Consensus Criteria (ICC) document or the primer. It is based on the symptoms of the criteria and should not be used as a substitute for medical advice from a licensed medical professional. This document is for informational purposes. Consult a physician experienced in diagnosing ME. It is important to evaluate for other diseases before assigning a diagnosis of ME (ICD code G93.3).

According to the ICC a six month waiting period is NOT required for diagnosis of ME. Removing the waiting period is very important so ME patients can be advised to get

complete rest as soon as possible in order to get the best possibility of improved health.

SECTION 1

Must have Post Exertional Neuroimmune Exhaustion (PENE)

PENE is physical inability to produce sufficient energy on demand.

The following are signs you have PENE:

1. Marked, rapid physical and/or cognitive fatigability in response to exertion, which may be minimal such as activities of daily living or simple mental tasks, can be debilitating and cause a relapse.
2. Post-exertional symptom exacerbation: such as acute flu-like symptoms, pain and worsening of other symptoms
3. Post-exertional exhaustion: may occur immediately after activity or be delayed by hours or days
4. Recovery period is prolonged, usually taking 24 hours or longer. A relapse can last days, weeks or longer
5. Low threshold of physical and mental fatigability (lack of stamina) results in a substantial reduction in pre-illness activity level.

Symptom severity must result in a significant reduction of pre-illness activity level.

The 2 day Cardio Pulmonary Exercise Test available at Workwell Foundation (California) and Ithaca College (New York) is a 2 day CPET specifically designed to look for inability to repeat physical activity two days in a row.

If you aren't sure if you have PENE, watching the following video may help you answer the question.

Video by Mark VanNess explaining an abnormal physiological response to exertion and the 2 day test: <https://www.youtube.com/watch?v=FXN6f53ba6k&app=desktop>

Do you have PENE: ___ Yes ___ No

If YES, go to next section.

If NO, stop quiz. You do not fit this criteria.

SECTION 2

Check off the ones that apply to you.

Neurocognitive Impairments

- ____ **Difficulty processing information:** *slowed thought, impaired concentration such as confusion, disorientation, cognitive overload, difficulty with making decisions, slowed speech, acquired or exertional dyslexia*
- ____ **Short-term memory loss:** *difficulty remembering what one wanted to say, what one was saying, retrieving words, recalling information, poor working memory*

Pain

- ____ **Headaches:** *such as chronic, generalized headaches often involve aching of the eyes, behind the eyes or back of the head that may be associated with cervical muscle tension; migraine; tension headaches*
- ____ **Significant pain** *can be experienced in muscles, muscle-tendon junctions, joints, abdomen or chest. It is non-inflammatory in nature and often migrates. In other words have generalized hyperalgesia, widespread pain (may meet fibromyalgia criteria), myofascial or radiating pain.*

Definitions:

Hyperalgesia: *increased sensitivity to pain*

Myofascial: *pertaining to a muscle and its sheath of connective tissue, or fascia*

Sleep Disturbance

- ____ **Disturbed sleep patterns:** *such as insomnia, prolonged sleep including naps, sleeping most of the day and being awake most of the night, frequent awakenings, waking much earlier than before illness onset, vivid dreams/nightmares*
- ____ **Unrefreshed sleep:** *awaken feeling exhausted regardless of duration of sleep, day-time sleepiness*

Neurosensory, perceptual and motor disturbances

- ____ **Neurosensory and perception:** *inability to focus vision, sensitivity to light, noise, vibration, odor, taste and touch; impaired depth perception*
- ____ **Motor:** *muscle weakness, twitching, poor coordination, feeling unsteady on feet, ataxia*

Definitions:

Ataxia: *Inability to coordinate muscle activity*

Did you check at least one box in at least three categories in section 2? ___
Yes ___ No

If YES, go to next section.
If NO, stop quiz. You do not fit this criteria.

SECTION 3

Check off the areas that apply to you.

- ___ **Flu-like symptoms** may be recurrent or chronic and typically activate or worsen with exertion. Such as sore throat, sinusitis, cervical and/or axillary lymph nodes may enlarge or be tender
- ___ **Susceptibility to viral infections** with prolonged recovery periods
- ___ **Gastro-intestinal tract:** such as nausea, abdominal pain, bloating, irritable bowel syndrome
- ___ **Genitourinary:** such as urinary urgency or frequency, excessive urination at night
- ___ **Sensitivities** to food, medications, odors or chemicals

Did you check at least three boxes in section 3? ___ Yes ___ No

If YES, go to next question.
If NO, stop quiz. You do not fit criteria.

SECTION 4

Check off the ones that apply to you:

- **Cardiovascular** - inability to tolerate an upright position - orthostatic intolerance, neurally mediated hypotension, postural orthostatic tachycardia syndrome, palpitations with or without cardiac arrhythmias, light-headedness/dizziness
- **Respiratory** - air hunger, laboured breathing, fatigue of chest wall muscles
- **Loss of thermostatic stability** - subnormal body temperature, marked diurnal fluctuations; sweating episodes, recurrent feelings of feverishness with or without low grade fever, cold extremities
- **Intolerance of extremes of temperature**

Did you check at least one box in section 4? Yes No

If NO, Stop quiz. You do not fit this criteria.
If you have answered YES to each section, you fit the International Consensus Criteria for Myalgic Encephalomyelitis.

Myalgic encephalomyelitis International Consensus Criteria Authors: B. M. Carruthers, M. I. van de Sande, K. L. De Meirleir, N. G. Klimas, G. Broderick, T. Mitchell, D. Staines, A. C. P. Powles, N. Speight, R. Vallings, L. Bateman, B. Baumgarten-Austrheim, D. S. Bell, N. Carlo-Stella, J. Chia, A. Darragh, D. Jo, D. Lewis, A. R. Light, S. Marshall-Gradisbik, I. Mena, J. A. Mikovits, K. Miwa, M. Murovska, M. L. Pall, S. Stevens

Note: pediatric symptoms vary - See source at this link for pediatric:
<http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2796.2011.02428.x/full>

Link to the International Consensus Primer for Physicians which lists tests and treatment options for those who fit the ICC: http://sacfs.asn.au/download/me_international_consensus_primer_for_medical_practitioners.pdf

To better understand the various criteria used for ME. and CFS, please read our blog, Analysis of CFSAC August 2015 Recommendations for the IOM Criteria, from Dec 2015: http://www.meadvocacy.org/analysis_of_cfsac_august_2015_recommendations_for_the_iom_criteria

EDUCATE OTHERS:

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Analysis of CFSAC August 2015 Recommendations for the IOM Criteria

POSTED BY GABBY KLEIN 184.60SC ON DECEMBER 20, 2015



The Chronic Fatigue Syndrome Advisory Committee (CFSAC) provides advice and recommendations to the Secretary of Health and Human Services (HHS) through the Assistant Secretary for Health on issues related to Myalgic Encephalomyelitis and Chronic Fatigue Syndrome (ME/CFS). It meets twice a year.

The last meeting took place August 18 and 19, 2015. The theme of the meeting was HHS' response to the Institute of Medicine (IOM) and Pathways to Prevention (P2P) reports on redefining ME/CFS. A CFSAC working group was created to work on [recommendations](#) for these reports which were presented at the meeting.

Tackling all the recommendations and information provided at the meeting would be too long to include in one blog. Since we believe that the diagnostic and research criteria are a crucial element, we decided to concentrate on the recommendations which reference the criteria.

The Criteria

The 1991 [Oxford criteria](#), published in the U.K., was created to describe both CFS of unknown etiology and a sub-type of CFS called post-infectious fatigue syndrome. This criteria has been used in research for CFS, including in the infamous PACE trial. Because of its inclusiveness and broadness, **the research achieved with the Oxford criteria cannot be relied on.**

The 1994 [Fukuda criteria](#) was a research criteria proposed by the "International Chronic Fatigue Syndrome Study Group", led by the [Centers for Disease Control and Prevention](#). It demands six months of severe fatigue along with **any** four of the following eight symptoms to receive a diagnosis of CFS: substantial impairment in short-term memory or concentration; sore throat; tender lymph nodes; muscle pain; multi-joint pain without swelling or redness; headaches of a new type, pattern, or severity; unrefreshing sleep; or post-exertional malaise lasting more than 24 hours.

The [2003 Canadian Consensus Criteria \(CCC\)](#) was initiated by Health Canada and written by ME/CFS experts. The CCC posits that post exertional malaise and cognitive problems are hallmarks of this disorder and are necessary for a diagnosis. In addition, diagnosis requires two or more neurological/cognitive manifestations and one or more symptoms from at least two of the categories of autonomic, neuroendocrine and immune manifestations, in addition to multiple major criteria of fatigue, post exertional malaise and/or fatigue, chronic pain and sleep dysfunction.

The [2011 International Consensus Criteria \(ICC\)](#), is the most current criteria created by an international group of ME/CFS experts. This is considered an ME criteria, closest to the one described by [Dr. Ramsay in 1956](#). **The six month waiting time for diagnosis is dropped.** There is the mandatory symptom of **PENE** (post exertional neuroimmune exhaustion). It is also accompanied by symptoms from neurological, immune/gastrointestinal/genitourinary, and energy metabolism/transport impairment categories. It demands a reduction of at least 50% of pre-illness activities.

The [2015 Proposed IOM Criteria](#) was created by the Institute of Medicine panel of expert and non-expert professionals. The proposed clinical criteria for diagnosis requires a significant loss of function that persists for six months, post exertional malaise and unrefreshed sleep. In addition, it requires one of two of the following; cognitive impairment or orthostatic intolerance.

History Preceding the Launch of the IOM Criteria

Although there were two newer criteria created (the 2003 CCC and 2011 ICC) since the 1994 Fukuda, the Department of Health and Human services (HHS) persistently insisted on the exclusive use of the outdated, overly broad, Fukuda criteria both for research and diagnostic criteria.

In September 2013, [Clinicians](#), [researchers](#) and [advocates](#) entreated HHS to recognize and adopt the CCC which was an updated and more accurate criteria for the disease. [CFSAC urged HHS](#) to adopt the CCC as well with a recommendation to convene a workshop of ME/CFS stakeholders to work on advising whether it needed any updating. Top ME/CFS researchers started using CCC criteria in addition to the Fukuda criteria for determining patient cohorts. **Since the NIH only recognized the Fukuda definition for grant applications, researchers could not just evaluate per the CCC criteria.**

HHS did not heed the voice of the community and in 2013 stubbornly and secretly contracted with the IOM to create, yet again, another government supported definition for the disease. This contract was heavily disputed by the great majority of medical specialists as well as patient advocates and patients. Yet, HHS forged ahead and the 2015 [IOM criteria](#) was created without guidance on treatments, as instructed by HHS.

Some in the community have accepted the new IOM clinical diagnostic criteria as an improvement to the currently used Fukuda because of its inclusion of the hallmark feature of post-exertional malaise (PEM) as one of the mandatory symptoms. Many others, including MEadvocacy, argue that it actually falls short of the already available CCC and ICC. They feel that this **new criteria from the IOM is too broad, inclusive and does not describe the serious neuro-immune disease, myalgic encephalomyelitis.**

Why are Case Definitions Consequential?

In the preface to the ICC, its authors explain the need for accurate definitions: “*There is a poignant need to **untangle the web** of confusion caused by mixing diverse and often overly inclusive patient populations in one heterogeneous, multi-rubric pot called ‘chronic fatigue syndrome’. We believe this is the foremost cause of diluted and inconsistent research findings, which **hinders progress, fosters skepticism, and wastes limited research monies.***”

Some have argued that since the IOM criteria are to be used for clinical diagnostic purposes, and not for research, there is no need for such “tight” criteria. One problem with this line of thought is the fact that the US government has a history of muddling the aim of previous criteria. For example, the Fukuda criteria were created for research purposes yet, they have been used for diagnosis as well.

No request has been made by HHS to come up with new **research** criteria. Which criteria do you think will be used for federal research going forward? Will they continue to use the inefficient Fukuda? There is evidence, as in Francis Collins’ recent statements of support of the IOM report, that they will start using the new IOM criteria for their research initiatives.

Another complication and confusion will arise when the medical profession starts diagnosing patients with the IOM criteria. Clinicians may observe that many of their ME/CFS patients will have contrasting symptoms or treatment responses compared to the patient populations that are evaluated in the research studies or in other international patient populations such as Canada. Thus, if the research studies find certain treatments successful but the same results are not carried in the clinical settings, the research may be thrown out as uncredible by the medical community.

Incidentally, **CFSAC recommendation #4 advocates for the use of the CCC criteria for federally funded research**: *“CFSAC recommends that federally-funded research specify use of the 2003 Canadian Consensus Criteria as a research case definition for patient selection (in addition to other requirements established for specific research purposes) using standardized and uniform assessment methods and measures for applying the definition.”*

The importance of selecting the correct patient group in criteria for the disease has been highlighted in the newest paper by Norwegian scientists titled: ‘What exactly is myalgic encephalomyelitis’. *The paper states: “The use of **broad inclusion criteria** has created a heterogeneous patient population, also within research. **This has increased the risk of erroneous conclusions, misdiagnosis and incorrect treatment** . For myalgic encephalomyelitis, the Canadian criteria and the international consensus criteria have in our view increased the accuracy of diagnosis due to their greater specificity and clearer delineation of the disorder from other forms of fatigue.”*

How Well Does The IOM Criteria Select ME Patients?

In his paper ‘[Reflections on the IOM's systemic exertion intolerance disease](#)’, ME/CFS researcher, Dr. Leonard Jason, ran an analysis to answer this specific question. In his study of patients who are referred to a specialty clinic and those who self identify to have CFS, the same group was found to have the disease with the IOM criteria as with the Fukuda criteria. Most in this group were already diagnosed as having ME or CFS by clinicians who already accounted for exclusionary conditions. Since the IOM criteria does not require the exclusion of other conditions, a group using IOM criteria will be more inclusive of misdiagnosed patients. Jason’s paper ‘[Unintended Consequences of not Specifying Exclusionary Illnesses for Systemic Exertion Intolerance Disease](#)’ suggests that his *“**findings indicate that many individuals from major depressive disorder illness groups as well as other medical illnesses were categorized as having SEID.**”*

Frank Twisk published a paper; ‘[A Critical Analysis of the Proposal of the IOM to Replace ME and CFS by a New Diagnostic Entity Called SEID](#)’. In the paper, he proposes that some of the characteristic symptoms of ME, as described by [Dr. A. Melvin Ramsay](#), are not present in the IOM criteria. These include muscle fatigability,

circulatory impairment and exhaustion of the central nervous system after minor physical activity, as well as the chronic relapsing course of the disease. There are two reasons for these omissions, Frank proposes. 1- These symptoms have not been adequately investigated. (lack of quality research and studies) 2- **It is mainly CFS diagnosed patients that have been studied, in the research relied upon [during the IOM's evidence based evaluation], as opposed to ME patients.**

This second point made by Twisk is really key to our subject. If most of the research and studies that the IOM panel relied upon used CFS patients as per Oxford or Fukuda criteria, the resulting criteria will reflect those findings. **In essence, the IOM criteria then is a CFS criteria, not ME.**

CFSAC Recommendations for Improving the IOM Criteria

Recommendation [#4](#) specifies use of the 2003 CCC criteria be used for any federally-funded research. If this is implemented, the patient population used for research would be a significant improvement over previous studies.

Please read [recommendations #8, 9 and 10](#) to see the details of what CFSAC has added to the IOM criteria. See video of the presentation of these recommendations [here](#).

In her preface to these recommendations, patient advocate and CFSAC voting member, Donna Pearson stressed that the CFSAC working group that created the recommendations did not attempt to “revise” the IOM criteria. Their effort went toward suggesting more details to be included so that the clinician can better diagnose patients. The following recommendations therefore mainly provide for more guidance to be included with the literature of the IOM criteria.

The main concerns that the group found with the IOM criteria were the following:

- **The nature of the disease is not reflected in the criteria.**
- **The criteria are broad with no objective measures and tests and diagnostic tools.**
- **Lack of exclusions.**
- **Common early symptoms not reflected.**
- **PEM is not understood by primary physicians.**
- **Immune impairment, neurological impairment and pain are not included in the core symptoms.**
- **Patients with other ailments will be diagnosed because the symptoms are subjective and because differential diagnosis are lacking.**
- **There is no specificity toward the different stages and different levels of the disease.**

Recommendation #8 provides for:

- Inclusion of an “overview” of the disease.
- Objective testing identified in the IOM report be included.
- The language “unrefreshed sleep” be changed to “sleep abnormalities”.
- More descriptive language, from the IOM report, to be included with the core symptoms.
- Immune dysfunction, neurological dysfunction and pain symptoms among other frequently reported symptoms be reflected with the core symptoms in all materials.
- The expanded version of the criteria be used in criteria material.

Recommendation #9 advocates for the proposed IOM criteria to be validated and refined if needed within two years by disease experts.

In recommendation #10, the following are suggested to be included in the guidelines:

- A disease overview including a statement that the disease includes immune, neurological and cognitive impairment, sleep abnormalities, and autonomic dysfunction.
- Clinical guidelines for assessing post-exertional malaise (PEM).
- Information about appropriate treatments and care.

- List of differential diagnosis.
- List of co-morbid conditions that are experienced with the disease.
- Statement about the inappropriateness and dangers of cognitive behavior therapy (CBT) and graded exercise treatment (GET) as treatments for this disease.
- Resource list with links back to the IOM report.

How Does the IOM Criteria Compare to the CCC Criteria?

You can read about the comparison of the IOM and CCC criteria [here](#).

The differences between the two criteria are highlighted in the graphic below:

IOM	CCC
Does not include pain and immune dysfunction.	Includes pain and immune dysfunction.
Does not need to manifest any neurological dysfunction.	Includes two symptoms from a list of cognitive/neurological manifestations.
Does not include autonomic, neuroendocrine and immune manifestations.	Includes one symptom of the following: autonomic, neuroendocrine and immune manifestations.
Does not require exclusions of other conditions making it more likely that other fatiguing illnesses as well as primary psychiatric ones will be included.	Includes a list of exclusionary diseases and comorbid entities.

Will the improvements of CFSAC recommendations to the IOM criteria bring us closer to the CCC criteria?

We commend the CFSAC working group for their monumental achievement in creating all these important recommendations to HHS. Their effort has brought about (if implemented by HHS), many improvements to the IOM criteria and may cause the cohort of diagnosed patients to contain a larger percentage of patients that would meet

ME criteria. However, MEadvocacy believes that more needs to be done to bring the IOM criteria in-line with ME criteria.

The one proposed alteration to the actual IOM criteria language by CFSAC was to change “unrefreshed sleep” to “sleep abnormalities”. The other recommendations involved the addition of data, such as explanations how PEM affects ME/CFS patients as well as the additional information of symptoms like immune dysfunction (but not as an inclusion in the core symptoms). The essential list of exclusionary diseases as well as co-morbid manifestations are recommended to be included as well.

A final analysis shows that the CFSAC recommendations are an improvement to the original IOM criteria by the fact that it is more descriptive and includes the much needed list of exclusionary diseases and comorbidities. Unfortunately, it fails in achieving the accuracy of the CCC by not demanding that neurological manifestations, immune dysfunctions and muscle pain be part of the mandatory core symptoms.

Taking Frank Twisk’s analysis into consideration, the IOM criteria (even when improved with the CFSAC recommendations) does not describe the core neuroimmune symptoms of myalgic encephalomyelitis; “(long-lasting) post-exertional **muscle** fatigue/weakness and signs of **cerebral** dysfunction”.

Looking Forward to Future Progress

If implemented, the CFSAC recommendation #4 should ensure that going forward, the 2003 CCC will be the sole criteria used for all research. This should technically retire the use of the Oxford and Fukuda criteria for research purposes.

We are hopeful that 2016 will see real progress toward research on patients who have ME. We are excited to see the success and growing support that Dr. Davis’ End ME/CFS Project is experiencing. Their “Giving Tuesday” fundraising effort has come through with over \$100,000. In addition they have received some large private anonymous donations which will definitely make a difference. The Open Medicine Foundation (OMF) has recently announced that due to the generous donations and added knowledge, they have added more tests to the [OMF ME/CFS Study](#). They have uploaded an [updated list of tests](#) and an [updated full description of the study](#).

We hope that the next few years will bring biomedical diagnostic criteria that will clean the muddied waters left from the varied poorly defined diagnostic criteria.

What Can You Do?

1. If you are in the United States, contact Congress using our convenient [One Click app](#), telling Congress to endorse the well-defined, globally-accepted Canadian Consensus Criteria (CCC) for U.S. ME diagnosis and research. In addition, the

letter asks Congress to urge the NIH to raise funding for ME/CFS commensurate with other similarly burdened diseases.

2. Help us educate patients so they can become their own advocate by sharing/liking this blog on social media platforms; liking/and or sharing the [MEadvocacy facebook page](#) posts; and liking/retweeting [MEadvocacy tweets](#).
3. Donate to research of severe ME patients, such as the [Open Medicine Foundation](#) (OMF).