

Czech Republic



Statement, opinions and concerns relating to the IOM report 'Beyond ME/CFS Redefining an Illness'

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Translated by PaD and others

Firstly, we would like to express our thanks to the IOM Committee for the enormous effort with which they carried out the assigned tasks, as can be seen in the resulting report.

We welcome the media attention which the report has drawn to the issue of ME/CFS. The IOM report is a high quality and complex scientific overview of ME/CFS.

It contains much information which deserves attention but in the following paragraphs, we would like to focus solely on items which give us cause for concern. We expect these items will be clarified by the leading experts in the field in the future.

We expect that more in-depth analyses conducted by experts in the field will follow. Many questions need to be answered. We hope that the IOM report will result in a rapid increase in funding of biomedical ME/CFS research which will therefore accelerate the fulfilling of clinicians' and patients' needs.

Statement by ME/CFS.cz on the IOM diagnostic criteria

1. We welcome the effort of the Committee to accelerate and simplify the diagnostic process in clinical practice.
2. Nevertheless, we would prefer the recommendation to use the Canadian Consensus Criteria (CCC, 2003), or the International Consensus Criteria (ICC, 2011), at least until such time when the accuracy of the new diagnostic criteria proposed by the IOM can be scientifically verified.
3. For research we unequivocally propose to use the proven CCC.

Our concerns relating to points 2. and 3.:

🚩 Concerns about excessive broadness of the IOM diagnostic criteria

We welcome that the IOM criteria (hereinafter 'IOMC') include post-exertional malaise (hereinafter 'PEM') as the mandatory central symptom, i.e. worsening of symptoms after any exertion. The report explains that the organic nature of PEM is supported by objective evidence. But this evidence still needs to be subjected to further scientific verification and methods which could be used in the routine diagnostic process need to be developed.

Is there no danger that without objective evidence of the organic nature of PEM, confusion with other disorders could happen? For example, confusion of PEM with “feelings of bodily or physical weakness and exhaustion after only minimal effort” which is also included in the definition of neurasthenia according to WHO’s ICD-10. When we compare the definition of neurasthenia <http://bit.ly/1EQdLXK> (F48) and the IOM diagnostic criteria, it seems to us that confusion of symptoms by an inexperienced clinician is quite possible.

Is there not a danger that radical reduction of symptoms in the IOMC (compared to the CCC and ICC) will lead to excessive broadness which has been the problem of most of the concise definitions of CFS? (i.e definitions with a short list of symptoms)

We note the lack of a list of exclusionary diseases for SEID in IOMC. We have read the explanation of this decision and we agree that a patient can suffer with more than one disease. Though, in our opinion, without a widely accessible biomarker, the necessity of excluding some diseases cannot be avoided. CCC solved this problem by recommending to “exclude active disease processes” with emphasis on the word active, “if a potentially confounding medical condition is under control, then the diagnosis of ME/CFS can be entertained if patients meet the criteria otherwise.”

We are concerned that if IOMC allows for an easy inclusion of other diseases, this will again create problems in research. IOMC are designed for clinical practice but what if scientists will start using these criteria in research too?

Furthermore, we are concerned about serious problems in clinical practice such as possible neglect of other diseases requiring more complex diagnosis (e.g. autoimmune diseases), especially by less experienced clinicians.

Concerns about possible distortion of conclusions of IOM’s scientific review caused by limitations on ME/CFS research

The aim of the Committee was to develop evidence-based ME/CFS diagnostic criteria for use by clinicians. We understand that the Committee has developed diagnostic criteria based on evidence in accordance with the assigned task but research of this disease suffers from significant restrictions such as underfinancing, bias = prioritizing of funding for psychiatric and psychological studies, use of diagnostic criteria with varying diagnostic accuracy etc.

Can such research limitations not be expected to negatively impact the results of the review? E.g. a recent article in The Lancet illustrates how such research restrictions can influence results. The Article states that “on the same day as the IOM report was released, a new Cochrane review of exercise therapy for CFS/ME was published.

The Cochrane review includes results of eight randomised controlled trials, with exercise therapy ranging from 12 to 26 weeks. The conclusions of the review state that, “Patients with CFS may generally benefit and feel less fatigued following exercise therapy, and no evidence suggests that exercise therapy may worsen outcomes”.

Under such circumstances, is it not better (see the above-mentioned research problems and the absence of a biomarker) to follow the diagnostic criteria creation process as for the creation of the ICC? ICC is based on 100% consensus by leading experts who together cared for approximately 50,000 patients with ME/CFS. An independent patient

representative also took part in the ICC creation process which we had very much welcomed.

We also have concerns about the IOM criteria being implemented into clinical practice without appropriate scientific research confirming and/or verifying their validity.

Opinion of ME/CFS.cz on the new name

1. We very much welcome the effort of the Committee to end the stigma and the downplaying of the illness partially caused by the inappropriate name CFS.
2. We would prefer the Committee to recommend the usage of the original name myalgic encephalomyelitis (ME), in accordance with recommendation by the authors of the International Consensus Criteria (ICC 2011), instead of creating a new name.

Rationale for point 2:

🚩 Concerns about misunderstanding and negative distortion of the new name by the public

The name systemic exertion intolerance disease (SEID) indicates that it is a disease (no longer a syndrome!) – in which bodily systems are not able to respond adequately to exertion.

Generally, “intolerance” in medicine means an intolerance caused by an organic defect in the body; it cannot be influenced by willpower (e.g. milk intolerance is caused by the inability to digest the milk sugar lactose due to the lack of the enzyme lactase in intestinal cells).

But we doubt, and with good reason, that the public will understand the meaning of the disease name in the same way. Unfortunately, we have had enough experience already with naming of this debilitating, multisystem disease after one feature only, to doubt the appropriateness of this approach.

🚩 Ambiguity about task assigned to the Committee

The Committee’s task was to “recommend whether new terminology for ME/CFS should be adopted”. The Committee was not explicitly asked to develop a new name (The development of diagnostic criteria was assigned explicitly).

Why has the Committee undertaken to deal with the name? Especially when the Committee was not assigned the task of dealing with the aetiology, pathophysiology and pathogenesis of ME/CFS. We feel that a more open process than the one implemented by IOM would be more appropriate for the selection of a new name. We would welcome a wider discussion before implementing a new name into practice – such as statements by other independent experts in the field and input by patients.

🚩 Concerns about distortion of IOM's scientific review caused by limitations on research of ME/CFS by assessing the name ME

The committee deemed the term "myalgic encephalomyelitis," although commonly endorsed by patients and advocates, to be inappropriate because of the general lack of evidence of brain inflammation in ME/CFS patients, as well as the less prominent role of myalgia in these patients relative to more core symptoms. We already mentioned above the limitations of the scientific review of ME/CFS.

We expect the volume of findings of brain and spinal cord inflammation to increase when appropriate research gets better funding for verification of findings from small pilot studies and carefully selected samples. We feel that the Committee could have recommended removing the name CFS and continuing with the commonly used name ME with a note that revision of the name is to be carried out within five years. Furthermore, the report could have recommended research focusing on verification of brain and spinal cord inflammation.

The point is that the commonly used name ME - which sounds more medical than CFS or SEID - does not create an environment suitable for stigmatization. The use of this name is also supported by increasing scientific evidence and above all, by historical experience with this illness which has been considered for many years a variation of poliomyelitis and outbreaks of ME/CFS were often associated with outbreak of the "right" poliomyelitis. Many clinicians who care for patients with ME₇ consider – based on their experience – the illness to be chronic, low grade ongoing inflammation of the central nervous system, especially in the centres governing the internal homeostasis.

🚩 Concerns about delay in healthcare provision due to the introduction of the new name

The system of healthcare provision in our country is based on ICD-10 codes. Clinicians cannot diagnose an illness without a diagnostic code. In our country, ME and CFS have the same code - G93.3. Changes in classification are long-term and demanding processes. For example, the name CFS, which was created in 1988, appeared in ICD only in 1994, and it was in its 3rd volume 'Alphabetical List'.

Although the IOM Committee recommended (see recommendation 1) to assign the proposed name SEID a new code in ICD-10, not connected to "chronic fatigue" or "neurasthenia," it cannot be expected that the new name would be included in ICD-10 much sooner than carrying out of a review of the new criteria is recommended (i.e. within five years – see recommendation 3).

In the absence of a diagnostic code for SEID we see a prospect of refusal of patients by the medical and social security systems. Patients have been waiting for nearly 30 years to get adequate care. It is unacceptable to allow for further reasons to delay patients care.

If the name myalgic encephalomyelitis was recommended, all coding problems in many countries would likely disappear because ME has had a code since 1969, in the chapter of neurological illnesses in ICD-WHO. The IOM report states (on page 27, full version) that ME and CFS are coded separately in WHO's ICD-10 but this seems to be valid exclusively for the United States and their version of ICD. In our country, CFS is coded to G93.3, same as ME (and same as in Canada).

The healthcare system works very well in our country. We have both outstanding clinicians and excellently equipped medical facilities. Patients with ME could get the best available healthcare based on the CCC recommendations. Unfortunately, they do not get this care because of inconsistency of views about this illness among the Czech expert medical societies.

We are concerned that the new diagnostic criteria and the name SEID will not convince our expert medical societies that ME/CFS is a serious, chronic, complex, multisystem disease that frequently and dramatically limits the activities of affected patients. In its most severe form, this disease can consume the lives of those whom it afflicts. It is "real." We urgently need crucial scientific progress into biomarkers and treatment.

Sources:

- ✚ *Beyond Myalgic Encephalomyelitis / Chronic Fatigue Syndrome: Redefining an Illness:* <http://bit.ly/1IMjW2k>
- ✚ *Přehled diagnostických kritérií ME a CFS:* <http://bit.ly/1b3Nf00>
- ✚ *What's in a name? Systemic exertion intolerance disease:* <http://bit.ly/1G3XcZK>
- ✚ *Velký lékařský slovník:* <http://lekarske.slovniky.cz/>
- ✚ *Neurasthenia in ICD-10:* <http://bit.ly/1EQdLXK>
- ✚ *Chronic fatigue syndrome in ICD:* <http://bit.ly/1Dd44ND>
- ✚ *Patient stories/experiences*