



ME Vereniging Nederland

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To: National Institutes of Health
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Topic: Pathways to Prevention: Advancing the Research on Myalgic
Encephalomyelitis / Chronic Fatigue Syndrome
Draft Report

L.S.,

The ME Vereniging Nederland is the patient association for myalgic encephalomyelitis in The Netherlands. We are responding to your call for three reasons.

1. It's a global community. This pertains to ME patients, researchers and clinicians alike. Your recommendations will affect policy in Europe, too, and thereby our quality of life.
2. We are in the process of creating a multidisciplinary guideline on ME and may have some insights to offer. This work is conducted at the Stichting ME Research which is linked to our association.
3. We took good notice of the fact that you are calling for an international research network, and consider ourselves a stakeholder.

Below you will find our comments on the draft report.

Yours sincerely,

Guido den Broeder

Chairman

General comments

We believe that while this draft is a genuine effort, unfortunately your premises are off. Furthermore, it seems that you have not been adequately informed about advances in ME research, diagnosis and treatment.

There exists no entity named ME/CFS.

ME is an identified neuroimmune disease currently classified by the WHO as a post-viral disorder of the brain, under G93.3. The first outbreaks of ME occurred in the 1930s and the name myalgic encephalomyelitis was chosen in the 1950s, after it was established that patients suffer from CNS inflammation. The definition of ME has been stable over time.

CFS is not a disease, but a preliminary diagnosis, a name for a set of symptoms. Its precise meaning has changed much over time since its introduction in the 1980s, with very different sets of criteria that describe all kinds of medical problems.

In the ICD-10-CM of 2011, CFS is classified as R53.82, a condition of unexplained fatigue and malaise (R53). The edition was approved by the WHO. This is consistent with how CFS is viewed by the CDC, too, and with the bulk of CFS literature.

As such, it has no relation whatsoever to ME, which is neither unexplained nor characterized by fatigue. Patients with the label CFS should be examined further, until it is established which of many possible diseases causes their symptoms.

You fail to define these terms in your draft report. As a consequence, the comments that you receive are likely to vary wildly. This could make it seem that your text is nicely balanced, but in fact it is not. Rather, your text is a mix of what should have been two reports: one on ME, and one on CFS, with both topics deserving your attention.

We suggest that you make it so.

Please be aware that there are far more CFS patients, researchers and clinicians than there are ME patients, researchers and clinicians. Don't be tempted to think of us as holding a minority view to their majority. We are a different population.

Specific comments

Since we are a ME patient organization, we do not feel qualified to go into details about CFS, and make our specific comments with only ME in mind.

Note that our comments are aimed at improving the text. There are in fact many parts of the draft that we already agree with, or think the CFS community could agree with. Although ME and CFS are different groups of patients, we do to some extent share the same predicament and can on occasion benefit from the same recommendations.

- 2 ME has an acute phase. Before it becomes chronic, patients may still recover spontaneously.
- 3 ME is not characterized by fatigue. For a detailed description of symptoms, we refer to the international consensus criteria of 2011. Keep in mind though that criteria are not the disease. Others could satisfy the same criteria. Patients need to be medically examined before a diagnosis of ME can be made.
- 4 There are many diagnostic laboratory tests for ME. You mention two of them later in the text: fMRI and PET, but there are others including NIRS, xenon SPECT, various blood and urine tests, and tissue biopsies.
- 5 Successes in the medicinal treatment of ME have been reported (e.g. Valcyte, Vistide, Rituximab, Ampligen, interferon, immunoglobulin). Research into a cure should focus on these and similar treatments, especially into a combination of antivirals and immunomodulators.
- 7 All ME patients have multiple major disabilities. There are no mild cases. There are very severe cases, where patients lie in the dark for many years, entirely unable to care for themselves, and then they die.
- 15 There is no need for more than one case definition of ME.
- 20 There are in fact subsets of ME patients, determined by which viruses are involved.
- 28 The draft fails to identify ME literature, ME experts and the ME community.
- 32 ME/CFS does not exist. ME has a clear definition. (CFS has clear definitions as well; the problem with those is that they are all so very different.)
- 33 ME does not overlap with other diseases. Other diseases can (partly) mimic ME, like Lyme, SLE and MS. The ones you mention can't.
- 34 There is currently agreement that the role of viruses should be studied more closely, as well as the drugs we mentioned above.
- 40 There is no lack of specific diagnostic tests for ME. There is room for more efficient diagnostics though, and a need for a diagnostic protocol.

- 41 There exists a decent set of criteria (the ICC) that can be used to study ME, provided that participants have been medically examined.
- 46 There may be a genetic component that determines who has a higher chance to get ME. Also, various acquired risk factors are known.
- 50 ME has an identified set of main symptoms (and btw in line 107 you mention a consistent constellation of symptoms).
- 52 Research focus is on women, not men (later in the text you have that right).
- 54 ME does not discriminate between races, but it is largely a developed-world disease.
- 56 Prevalence of ME is estimated as somewhat below 0.1% (in the developed world), but larger and more accurate prevalence and incidence studies are indeed wanted.
- 58 Research into ME (recent or otherwise) does not typically focus on fatigue.
- 76 Over the last 20 years, there have been major breakthroughs in ME research, in part from research that did not target ME specifically. Lacking, because of low or no funding, is confirmation.
- 106 Fatigability, not fatigue, is a characteristic of ME.
- 107 The consistent constellation of symptoms in ME furthermore includes dysautonomia, bloodflow deficits, sleep pattern disturbances, muscle weakness, broken (hormonal) feedback, sensory processing issues.
- 113 There are no studies into CBT and GET for ME (the studies that were done are all CFS studies, often explicitly excluding neurological patients) but experience indicates that patients tend to get worse, much worse, from GET. The same outcome results from CBT if the purpose is that patients forget they're ill, as it so often is.
- 126 The confusion stems first of all from deliberate attempts to obscure the existence of ME.
- 166 The symptoms that ME patients consider clinically meaningful are present in the scientific literature on ME. (They are usually not present in the much larger body of CFS literature, whether studies included ME patients or not.)
- 172 The current model of ME (since the 1980s) is that the immune system is compromised by the presence of a latent virus (mostly EBV), which interferes with the immune system's ability to respond to new infections. Enteroviruses are thought to then trigger ME. Documented outbreaks of ME coincided with enteroviral outbreaks.
- 183 ME has an objective nature.
- 199 Findings in ME literature are usually consistent. (In contrast, obviously, ME findings cannot be consistent with CFS findings.)
- 206 There is also quite a lot of scientific literature on EBV that is of relevance to ME.

275 Biopsychosocial studies into ME are not wanted and would only continue to deter from what is really needed at this time.

Research focus should now finally be on the medicinal treatment for ME, with the purpose of establishing its cure.

- 289 Exploring psychiatric co-morbidities is not critical. They can be treated in the same manner as they are normally treated. What is critical though, is attention for ME patients developing other diseases in general, such as cancer. These are often overlooked because the symptoms (such as pain) are considered to simply be part of their ME. Many ME patients have died from other diseases, or needlessly suffered from them (more), because the diagnosis was missed.
- 304 The multidisciplinary team that ME patients need, would first of all consist of a range of specialists such as a neurologist, a cardiologist, an internist, a rheumatologist, an immunologist. They should preferably all work together in a center of expertise, with lodging facilities so patients don't have to travel all the time. This should primarily be a diagnostics, cure and prevention team.
- 318 There is mostly a need for funding. Partnerships and new scientists will arrive soon enough once the money is available. Research into ME is attractive; scientists studying ME find themselves at the frontier of medical research.
- 334 Nobody recovers from ME except during the acute phase or due to medicinal treatment, which is still only rarely provided.
- 335 Collaborative studies should not be restricted to Americans only. Elsewhere you plead for an international effort. It follows that patients must be international as well.
- 340 There are quite a few websites with educational material already, created by researchers, clinicians and patients. Also, in the past Medscape had an introductory course on ME. A good start would be to create an overview of existing resources.
- 349 There is no need to study 'the modest benefits from CBT' for ME. Let's study the vast benefits from medicinal treatment instead.
- 363 There are no significant differences between ME case definitions.
- 365 The Oxford definition was never presented as a definition of ME.

We thank you for listening to us.