

IOM Study on ME/CFS - Dec. 11 Talking Points for CFSAC meeting

Background

As you know, we have asked the Institute of Medicine (IOM) to develop criteria for the diagnosis of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS.)

Today I would like to give you a general overview of that process, provide you with some updates, and answer some of the questions that I have received since the frequently asked questions (FAQs) were developed.

I would like to begin by describing the purpose of the IOM committee and the role the Chronic Fatigue Syndrome Advisory Committee (CFSAC) serves. CFSAC provides recommendations and advice to HHS on a broad range of ME/CFS issues. The IOM committee, on the other hand, has been given a very specific charge of developing consensus recommendations for clinical diagnostic criteria that can be used by the entire U.S. medical community. While CFSAC's charge is more comprehensive, its purpose – to advise the federal government's Department of HHS – is quite discrete. The opposite is true of IOM study. Of note, CFSAC is a committee covered by the Federal Advisory Committee Act (FACA) and must function under applicable federal rules. The IOM is exempt from FACA except for Section 15 of that law. Applied under this section, the law governs the interactions between sponsors and the National Academies, and especially describes the public release of information concerning the study activities and results.

Through this effort, HHS hopes to promote a more widespread awareness and understanding of ME/CFS. Delayed and misdiagnoses are common concerns amongst the ME/CFS patients, making a more efficient diagnostic process one of the most immediate and impactful steps that can be made in this field.

I personally am very excited about the opportunity the recommendations on clinical diagnostic criteria provide for individuals and families affected by ME/CFS. Because of the stature and credibility of the IOM, it will be a big step towards getting health care providers to recognize and take seriously this terrible

condition. For example, just last month, on Nov. 6, the lead article in the Journal of the American Medical Association (JAMA) was a summary of a new IOM report on improving quality of cancer care in the elderly authored by some of the committee members. We can hope that an article about ME/CFS diagnostic criteria will be the lead in JAMA in a couple of years! HHS will work with CFSAC, its agencies, ME/CFS stakeholders and the IOM to disseminate the clinical diagnostic criteria.

Study Process Overview

Now, I will provide a brief overview of the how IOM performs their consensus studies. This information was obtained directly from the IOM website; some of it is in the FAQs on the CFSAC website.

For more than 150 years, the National Academies, which is the IOM's umbrella organization, have been advising the nation on issues of science, technology, and medicine, since a Congressional charter signed by President Lincoln authorized this non-governmental institution.

The National Academies enlists the nation's foremost scientists, health professionals, and other experts to address pressing scientific problems. Each year, more than 6,000 experts are selected to serve on hundreds of study committees that are convened to answer specific sets of questions. All serve without pay.

Federal agencies are the primary financial sponsors of the Academies' work but state agencies, foundations, and other private sponsors also fund studies. A key point is that the Academies provide independent advice. External sponsors **including the federal government** have no control over the conduct of a study once the statement of task and budget are finalized. Study committees gather information from many sources in public meetings, but they carry out their deliberations in private in order to avoid political, special interest, and sponsor influence.

I want to outline 4 stages of the IOM process:

Stage 1: Defining the Study

The statement of task defines the scope of the study, and serves as the basis for determining the expertise and the balance of perspectives needed on the committee. The statement of task is posted on the CFSAC website in the FAQs.

Stage 2: Committee Selection and Approval

All committee members serve as individual experts, not as representatives of organizations or interest groups. Each member is expected to contribute to the project on the basis of his or her own expertise and judgment. The IOM looks for a range of expertise to address the study's statement of task and strives for differences in experiences and perspectives among the committee members. A committee is not finally approved until a thorough discussion on the balance of the committee and any conflicts-of-interest is held at the first meeting, and issues raised in that discussion or by the public are investigated.

Specific steps in the committee selection and approval process are as follows:

- First, IOM solicits suggestions for potential committee members from a wide range of sources, and then recommends a slate of nominees.
- Then, nominees are reviewed and approved within the National Academies.
- The **provisional** committee list is posted for public comment on the IOM website.
- The provisional committee members complete background information and conflict-of-interest disclosure forms. These are discussed at the first meeting.
- Conflicts of interest or issues of committee balance and expertise are considered by IOM and changes to the committee are finalized.
- Of note, committee members continue to be screened for conflict of interest throughout the life of the committee.

Stage 3: Committee Meetings, Information Gathering, Deliberations, and Drafting the Report

Study committees gather information through: 1) open meetings that are announced in advance on the IOM Web site; 2) information submitted by stakeholders; 3) reviews of the scientific literature; and 4) other relevant reports. Efforts are made to solicit input from individuals who have been directly involved

in, or who have special knowledge of, the problem under consideration.

The committee deliberates in meetings closed to the public in order to develop draft recommendations free from outside influences. Committee members are asked to consider the viewpoints of the other members, to reflect their own views rather than be a representative of an organization, and to base their conclusions on the scientific evidence.

The committee comes to consensus on its recommendations, meaning **all** agree on the recommendations; however, a member may issue a dissenting opinion to the report if he or she disagrees with the consensus of the other members.

Stage 4: Report Review

As a final review, all IOM recommendations and reports undergo a rigorous, independent external review by experts who have similar expertise to those on the committee. This review process is structured to ensure that each report addresses its study charge and does not go beyond it, that the findings are supported by the scientific evidence, and that the report is impartial and objective.

Then the committee responds to, but needs not agree with, the reviewer comments by preparing a detailed "response to review" that is examined by one or two independent report review "monitors" responsible for ensuring that the report review criteria have been satisfied. After all committee members and National Academies officials have signed off on the final report, it is transmitted to the sponsor of the study and is released to the public. Sponsors are not given an opportunity to suggest changes in reports.

As you are probably aware, the IOM announced its provisional slate of committee members on December 3. You will see on this slide that it includes at least seven individuals with substantial experience with ME/CFS, including some former CFSAC members.

I hope this helps to answer questions about how the IOM process works. I'd be happy to take questions from CFSAC members at this time.