

Network comments on Common Data Element proposal

Written by Administrator

Saturday, 17 February 2018 00:00 - Last Updated Saturday, 17 February 2018 18:46

The US National Institutes of Health (NIH) has brought together a strong international group of ME/CFS researchers, clinicians, and patient representatives to discuss how aspects of ME/CFS could be measured. The idea is to select the best measures and to encourage their use to facilitate communication and consistency. A draft proposal was released for public comment. Here is the Network's response.

The US NIH has released a proposal for Common Data Elements for ME/CFS and asked for public feedback.

Our key messages, which have implications in Canada:

- Valuable work has been done, but the ME/CFS CDE proposal is not yet ready for full implementation. Key issues should be identified and resolved quickly.

- ME/CFS needs to be incorporated into administrative systems and surveys and well as into patient records.

- Lessons learned in this initiative should be applied to Fibromyalgia as well.

The NIH (specifically the National Institute of Neurological Disorders and Stroke (NINDS)) has led a project to develop common data elements (CDEs) for ME/CFS. A proposed set of CDEs and tools was recently released. Feedback was requested on or before January 31.

Work undertaken at NIH affects people all around the world including in Canada. This project

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could have an additional impact in Canada because of collaboration between CIHR and NIH on ME/CFS issues. We are addressing our comments to CIHR as well as to the CDE team.

As you are aware, the National ME/FM Action Network is a patient-based organization that has been working on behalf of Canadians with ME/CFS, FM or both since 1993. We know the history of ME/CFS and FM and the current state of ME/CFS and FM services in Canada. We also have expertise in statistics.

We recognize the value of developing common data elements for ME/CFS. We wish to thank NIH (and NINDS in particular) for leading this initiative and to thank all the people who have contributed to the project. The team has tackled a very challenging area and has done a remarkable job of exploring important issues and proposing variables and measurement instruments. There will undoubtedly be better research coordination because of the dialogue that has taken place.

Nevertheless, we find that the proposal contains too many ideas, too little integration of the ideas, too little discussion around how the various instruments would be used, too little examination of response burden for patients and clinicians, and too little testing on how well the instruments work for measurement of ME/CFS. Even recognizing that CDE's are living documents which evolve with time, there is quite a bit of work needed to before the proposal is implemented.

We do not want to see ME/CFS research or research funding delayed while these CDE's are being polished. The situation on the ground is far too serious. An analogy would be to delay sending relief aid to an earthquake zone because the reporting requirements of the relief teams had not been fully developed.

Neither do we want to see ME/CFS research flying off in the wrong direction or in all directions. Decades have been wasted because public policy has leaned toward the wrong model of ME/CFS, one that emphasized psychological factors while de-emphasizing biological factors. Very good analysis has been done on why this was able to happen, and a leading reason was case definitions that were so broad that they included patients with other conditions. Unfortunately, research findings based on the combined group have been inappropriately applied to ME/CFS and this has been very harmful. Case definitions have to be carefully considered. It seems obvious to us that someone who responds poorly to exertion should be treated differently than someone who responds well to exertion and thus we think these are

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different research domains. For case definition, we favour the Canadian Consensus Criteria not simply because we were instrumental in its development. We believe it does an excellent job of describing the ME/CFS cohort, it requires post-exertional malaise, and it specifies exclusionary conditions.

It is our hope that the ME/CFS CDE team will reconvene, articulate the purpose of the research, identify the key areas that need common measurement and address those areas as quickly as possible. The remaining CDE issues can be addressed over time.

We would like to step back and look at how the CDE project fits into the overall ME/CFS research program.

The ME/CFS CDE initiative seems to be focusing on the content of patient records. The purpose seems to be around research into biological cause and biomarkers. It is not even clear whether the use of the ME/CFS CDE's in clinical trials is being considered as well. If that is the case, then sensitivity to changes over time becomes an important attribute when evaluating variables.

There are other ME/CFS research questions that need to be investigated using data, notably around health and disability administration. These needs are not being addressed by the current CDE project. Data sources for this research would include administrative data and surveys. ME/CFS data elements need to be incorporated into the administrative systems and survey frameworks to yield useful statistics. Standardization would foster comparability between jurisdictions.

Ontario has an initiative underway to provide health care to Ontarians with ME/CFS, FM and MCS. The Ontario Task Force has the advantage of data from the Canadian Community Health

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Survey which helps define the needs. Among other recommendations, the Task Force has pointed out the need for billing codes. Depending on how this is implemented, the billing database would be a valuable source of data on topics like prevalence, incidence, resource utilization and maybe even co-morbidities. The billing system is not the only possible source of administrative data. Coding for ME/CFS rightly belongs in administrative data files for clinics, hospitals, home care providers, care facilities and first responders where it could be used for research. Standardizing across jurisdictions would allow inter-jurisdictional comparison research.

A different statistical issue that our organization repeatedly encounters is in the realm of disability. Disability can be described in three ways, through a list of impairments in functioning, through a list of activities one cannot do, and through reduced ability to participate. We have noted serious problems in the categories of impairment and activity limitation that are used in disability programs and surveys. Impairment is generally thought of as mapping to a specific activity. People with mild or moderate ME/CFS may be technically able to do all the activities on the activity list but they have to limit the quantity or frequency of activities. The variability and unpredictability of ME/CFS can makes planning even those activities difficult. We are finding many disability surveys and programs based on impairment to be non-inclusive of ME/CFS because they do not list reduced activity levels as an impairment. We find that many surveys and programs based on activities to be non-inclusive of ME/CFS because they demand inability to do particular activities.

Until the classification systems are fixed, the disability survey or program cannot be used for ME/CFS research. There are international initiatives to develop common data elements for disability including the WHO's International Classification of Functioning, Health and Disability (ICF), the InterRAI Home Care Assessment questionnaire and the Washington Group sets of disability questions. The ME/CFS perspective is poorly represented in all three. Until these issues are resolved, ME/CFS will have poor data in the disability area, very much hampering research.

Incorporating ME/CFS data elements into health and disability survey and program data frameworks is important. Is this an extension of the CDE project or is this a new project? Either way, action is needed.

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To summarize, we would like a ME/CFS research program that is

- **Targetted:** Research about ME/CFS should be based on a well defined cohort (our recommendation is to use the Canadian Consensus Criteria) and it should be clearly assumed that ME/CFS has a biological basis (and not simply a problem of deconditioning and attitudes).

- **Holistic:** Research should cover a range of issues including cause and biomarkers, clinical trials, health services and policy, and disability services and policy.

- **Aggressive:** Estimates of fair funding run into the hundreds of millions of dollars a year in the US and into the tens of millions of dollars a year in Canada, without even taking retroactive entitlement into account. The community is suffering because of research under-funding.

- **Strategic:** With no time to lose, research should be well coordinated.

We believe that the current ME/CFS CDE initiative make an important contribution to ME/CFS research by attempting to maximize the research usefulness of patient records.

We also see the need for ME/CFS data elements to be incorporated into administrative systems and surveys on a consistent basis to ensure availability and comparability for research purposes.

As a final note, let us remind you that the National ME/FM Action Network works on behalf of Canadians with Fibromyalgia as well. We are watching ME/CFS research developments very closely. We hope that a complementary research program for FM will be established as soon as possible and that FM be considered when dealing with health and disability administrative systems and surveys.

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Reply from CIHR

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