ME/CFS Common Data Elements Project Frequently Asked Que

this information, specifically the Project Overview and Tutorials

2. Why have NIH and CDC undertaken the ME/CFS CDE effort? What value is it anticipated to deliver?

   The goal for the project is to have faster and more efficient study start-ups, better data sharing, and data mining. This is part of

   initiative organized?

   The ME/CFS working group is divided into 11 subgroups to develop recommendations. The full working group roster includes all subgroups and is available on the NINDS Website as part of the public review package.

4. Who has been involved in the CDE initiative? What types of participants? Are there representatives from all fields?

   Please see the working group roster in the Public Review package, which includes each committee u u Ein[stitutions and/or affiliation. Note that each subgroup has a patient advocate on it.

   a. What role have the patients/patient advocates played on these subgroups?

      Their role is to participate alongside the investigators and comment on documents as they were being developed

   b. Have patients and patient advocates been involved in the development of CDEs for other diseases, either within NINDS or other institutes? If not, why not?

      There has not been a

      been several members of disease working groups who, besides having an expertise in the field, have also been a patient or advocate. After seeing the benefits of patient advocate input, NINDS now makes a more concerted effort for their representation

(e.g., the Cerebral Palsy Oversight Committee being created will include patient advocates).

5. How will the ME/CFS CDEs be validated?

   It takes time and use of the CDEs to evaluate their usefulness. Based on experience with prior CDEs, research conducted over at least 3-5 years will gather data on the use of CDEs as well as other measures. Refinements to CDEs will be an ongoing process.

6. When will the first version be released and how will that be communicated to researchers?

   Release is scheduled for late February 2018 and will be announced on the NINDS CDE website and via email blast. We will also promote the CDEs through conference presentations, posters, and eventually a journal publication.

7. What are the expectations for investigators to use the ME/CFS CDEs in research? For instance, is it considered during review of grant requests?

   It is anticipated that the CDEs will be adopted for ME/CFS research and public health studies. NINDS strongly encourages researchers who receive funding from the Institute to use these common data elements (CDEs) in their clinical research. Researchers who receive funding from NINDS are asked to use the CDEs

We

This is a collaborative project with CDC NINDS and CDC are looking for any type of comment applicable to the measures and instruments being recommended Anyone can provide comment as the public review packet is posted to a publicly

The ME/CFS research conducted at the ME/CFS Collaborative Research Centers and coordinated by the DMCC will utilize the ME/CFS CDEs. The NIH funded studies will be utilizing the CDEs when appropriate for their studies and there will be mapping from the study to the CDEs recommended.

17. Will the DMCC use these CDEs as their baseline or are they going to establish their own standards?

    Yes, they will use the CDEs.

18. Explain the varying roles of the DMCC and the ME/CFS CDE advisory committee in the evolution of the ME/CFS CDEs?

    The DMCC will not develop CDEs, but will utilize the ME/CFS CDEs developed by this initiative. The DMCC will harmonize and organize data collection, storage, analysis and distribution across the ME/CFS CRCs.

E. Case definition

19. What case definition or definitions are being used as part of the CDE initiative? Is the CDE initiative intended to achieve consensus on the case definition? If not, why not now and when will this be done?

    In the absence of an agreed upon research case definition (or at least inclusion/exclusion criteria), how do we ensure that ME/CFS study cohorts include only people with ME/CFS?
    How will the CDE initiative help address problems with lack of standardization if common inclusion and exclusion criteria are not agreed to since lack of consistency on these criteria is one of the biggest sources of heterogeneity across studies?

    Researchers conducting the studies using CDEs will determine the case definition and enrollment criteria that best fit their research objectives. The CDEs are methods of collecting data in a standardized manner. The working groups include members with knowledge of 1 8W* n BT /F1 12 n BT /F1 12 n BT /F1 12 n BT /F1 12 n BT /F1 12 n BT

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