Development Overview

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)
Common Data Elements
Overview - Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Recommendations

- Background
- Objectives
- Terminology
- Current Status
- CDE Development Process
Streamline Your Neuroscience Clinical Research using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). Learn more about the CDE Project.
Welcome to the NINDS/CDC CDE PROJECT

What is the CDE Project?

• NINDS/CDC initiated the development of Common Data Elements (CDEs) as part of a project to develop data standards for funded clinical research in neuroscience.

• The CDEs are content standards that can be applied to various data collection models and are intended to be dynamic and may evolve over time.

• CDEs are not a database.
What are the goals of the CDE Project?

- Develop **common definitions** of each data element and **standardize** case report forms (CRF) and other instruments

- Help investigators conduct clinical research through the development of these uniform formats by which clinical data can be **systematically collected, analyzed** and **shared** across the research community
What are the objectives of the CDE Project?

- Identify CDEs used in clinical research
  - (age, gender, race, etc.)
- Present data elements in a standard format available to all
- Identify common meanings of each data element
  - (including permissible values, range checks, etc.)
- Standardize CRFs, when needed, and instruments
- Provide information to researchers for clinical data collection and sharing
Motivation & Overall Impact of the NINDS/CDC CDE Project

**Motivation**
- Trials were costing too much: no one believed in re-use of CRFs
- Trials were taking too long and costing too much to get up and going
- Data quality varied, no standards
- Data collection was not consistent
- Comparisons of data between studies was not possible

**Impact**
- Reduce time/cost to develop data collection tools
- Reduce study start-up time and cost of overall trial
- Improve data quality
- Facilitate collection of data
- Facilitate data sharing/comparisons between studies and meta-analyses
What is a CDE?

- CDEs are a logical unit of data pertaining to one kind of information
  - Name
  - Precise Definition
  - Permissible Values (if applicable)
What is a CDE:
• Standardized question and potential answer
• Allows for consistent collection and sharing of data
• Semantic value (the CDE name) with clear definitions and permissible values

Examples:
CDE Name: “Type of TBI”
Definition: “Broad classification of the type of traumatic brain injury experienced by participant/subject”
Data Type: “Alphanumeric “
Input Restrictions: “multiple Pre-Defined Values Selected”

Case Report Form:
CDE Details include but are not limited to...

- Metadata name (CDE name)
- Definition
- Example Question Text
- Permissible Values/Permissible Value descriptions
- Data Type
- Instructions
- References
- Population
- Classification
- Input Restriction
- Size
- Min Value and Max Value
- Measurement type
Developing New Recommendations for Clinical Research CDEs

• Working Groups and NINDS/CDC CDE Team work together to develop disease specific research CDEs/CRFs:
  
  ▪ Collect and review data report forms from disease-specific and other outcomes databases
    • Registries, clinical research projects, etc.
  
  ▪ Assess what can be shared between disorders from within the NINDS CDE website or other CDE-type activities
    • The greater the overlap and reuse of CDEs, the greater impact on future data-mining and data sharing
  
  ▪ Identify appropriate outcome measures
## Initial CDE Development Process

<table>
<thead>
<tr>
<th>Development Step</th>
<th>Typical Timeframe</th>
</tr>
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<tbody>
<tr>
<td>NINDS/CDC invites Working Group (WG) members and WG Chair(s)</td>
<td>2-4 weeks</td>
</tr>
<tr>
<td>NINDS/CDC works with Chair(s) to divide WG into Subgroups and to nominate Subgroup Chairs</td>
<td>2-4 weeks</td>
</tr>
<tr>
<td>Introductory meeting of WG at national/international conference or via Web conference*</td>
<td>1-2 hours</td>
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<tr>
<td>Subgroups meet every 3-5 weeks via conference call to develop CDEs for assigned areas</td>
<td>6-9 months</td>
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<tr>
<td><strong>Internal WG Review</strong> of all Subgroups’ CDEs</td>
<td>1 month</td>
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<tr>
<td>Subgroups revise CDEs based on feedback from Internal WG Review</td>
<td>1-2 months</td>
</tr>
<tr>
<td><strong>Public Review</strong> of WG’s CDEs</td>
<td>6-8 weeks</td>
</tr>
<tr>
<td>Subgroups revise CDEs based on feedback from Public Review</td>
<td>1 month</td>
</tr>
<tr>
<td>Post Version 1.0 of CDEs on Web site</td>
<td>2-4 weeks</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>12-18 months</strong></td>
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</tbody>
</table>

*If the WG does not meet in-person at the beginning of the process the NINDS/CDC schedules the in-person meeting to coincide with a large meeting/conference later in the process.*
Exploratory

Supplemental

Supplemental - Highly Recommended*

Disease Core

General Core

* Classification term of “Basic” used for Traumatic Brain Injury CDEs
## Example of a Case Report Form

### Electrocardiogram (ECG)

1. **Date and time of ECG:** yyyy/mm/dd  
   - [ ] am  
   - [ ] pm  
   - [ ] 24-hour clock

2. **Ventricular rate / Heart rate:** beats/min

3. **PR interval:** msec

4. **QRS duration:** msec

5. **QT interval:** msec

6. **QTc interval:** msec

7. **QRS axis:**

8. **ECG results:** (Choose one)
   - [ ] Normal
   - [ ] Abnormal, not clinically significant
   - [ ] Abnormal, clinically significant
   - [ ] Unable to evaluate

9. **Heart rhythm:** [ ] Normal sinus rhythm

If not normal:

- [ ] Sinus tachycardia
- [ ] Sinus bradycardia

- [ ] Atrial arrhythmia, specify type:  
  - [ ] Atrial fibrillation
  - [ ] Atrial flutter
  - [ ] Other

- [ ] Ventricular arrhythmia, specify type:  
  - [ ] Ventricular fibrillation
  - [ ] Ventricular tachycardia
  - [ ] Other

- [ ] Other, specify:
Example of an Instrument Recommendation

### NINDS CDE Notice of Copyright
**Borg Rating of Perceived Exertion (RPE) Scale**

|                    | Information about this instrument can be found at [Borg Rating of Perceived Exertion (RPE) Scale Instrument Link](#) |
| Classification:     | Supplemental – Highly Recommended: Exercise Studies in Mitochondrial Disease  
|                    | Exploratory: Spinal Cord Injury (SCI) and SCI-Pediatric (age 10 and over) |
| Short Description of instrument: | Construct measured: Perceived exertion  
|                    | Generic vs. disease specific: Generic  
|                    | Intended respondent: Participant |
| Comments/Special instructions: | Scoring: Participants are asked to rate their perception of exertion during physical activity. The severity is measured on either the original scale of 6–20 (“6” meaning “no exertion at all” and “20” meaning “maximal exertion”), or the modified scale of 0–10.  
|                    | **Original 6-20 Scale:**  
|                    | **Rating:** Perceived Exertion  
|                    | 6: No Exertion at all  
|                    | 7  
|                    | 7.5: Extremely light  
|                    | 8  
|                    | 9: Very light  
|                    | 10  
|                    | 11: Light  
|                    | 12  
|                    | 13: Somewhat hard  
|                    | 14  
|                    | 15: Hard (heavy)  
|                    | 16  
|                    | 17: Very hard  
|                    | 18 |
**NINDS CDE Disease Areas – over 13,000 CDEs & 800 Instruments**

<table>
<thead>
<tr>
<th>General CDEs</th>
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<tbody>
<tr>
<td>Chiari I Malformation (new)</td>
</tr>
<tr>
<td>Cerebral palsy (new)</td>
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<tr>
<td>Epilepsy*</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Mitochondrial disorders*</td>
</tr>
<tr>
<td>Movement disorders</td>
</tr>
<tr>
<td>• Parkinson’s disease</td>
</tr>
<tr>
<td>• Huntington’s disease</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>Spinal cord injury (SCI)*</td>
</tr>
<tr>
<td>Stroke*</td>
</tr>
<tr>
<td>• Unruptured Cerebral Aneurysms and Subarachnoid hemorrhage (new)</td>
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<tr>
<td>Traumatic brain injury*</td>
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<tr>
<td>• Sports-Related Concussion (new)</td>
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<tr>
<th>Neuromuscular disorders*</th>
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<tbody>
<tr>
<td>• Amyotrophic lateral sclerosis</td>
</tr>
<tr>
<td>• Friedreich’s ataxia</td>
</tr>
<tr>
<td>• Muscle dystrophies</td>
</tr>
<tr>
<td>• <em>Congenital, Duchenne/Becker, Facioscapulohumeral, Myotonic</em></td>
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<tr>
<td>• Myasthenia gravis</td>
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<tr>
<td>• Spinal muscular atrophy</td>
</tr>
</tbody>
</table>

*Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) (under review)*

*Biomechanical Sensors in Traumatic Brain Injury (under review)*

*Includes pediatric-specific recommendations*
NINDS/CDC Vision for CDEs

- ME/CFS studies would use the CDEs and research progress will be accelerated
  - NIH-funded research studies use CDEs or are CDE-compatible – it is part of FOA and Terms of Award
  - New investigators can build on consensus data elements
  - Start-up of multi-center and international clinical research efforts will be facilitated

- All types of clinical research can use part of the CDEs
  - Observational clinical studies can be linked to trial datasets
  - All human subject grantees are asked to consider using CDEs
Submitting Feedback on CDEs

• Feedback from users is key to ensuring project goals are met
  • Submit feedback form on NINDS CDE website
    www.commondataelements.ninds.nih.gov
Timeline of ME/CFS CDEs

- January 23 and February 13, 2017
  - Orientation teleconferences
- February 2017
  - All members split into subgroups
  - Chairs for each Subgroup designated
- March – October 2017
  - Working Group members work on their respective subgroup assignments
  - Monthly meetings are scheduled for each subgroup
  - Main contact: NINDSCDE@emmes.com
- October – November 2017
  - Internal review
- December 2017– January 2018
  - Public review
- February 2018
  - Posting of ME/CFS CDEs on the NINDS CDE Website
Accessing the NINDS/CDC CDEs

NINDS Common Data Elements Website
www.commondataelements.ninds.nih.gov

Submitting Feedback on CDEs

Feedback form on NINDS CDE website
https://www.commondataelements.ninds.nih.gov/ProjRevie
w.aspx

For more information on the NINDS/CDC CDEs, please contact: NINDSCDE@emmes.com