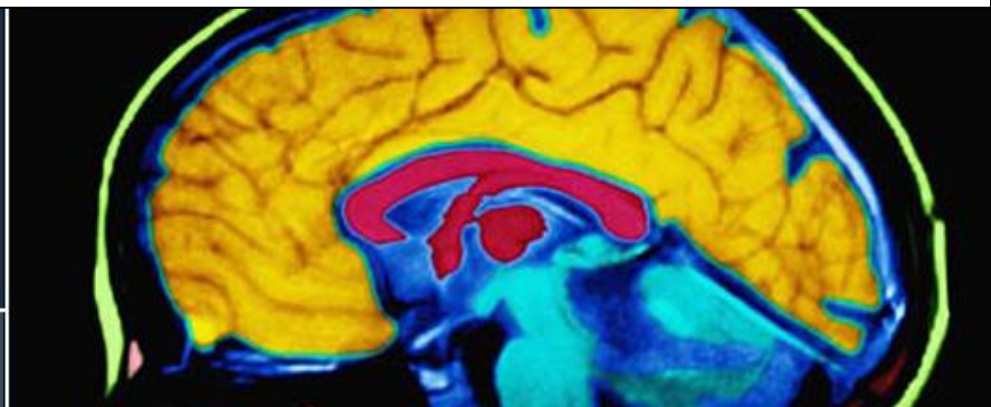
National Institute of Neurological Disorders and Stroke

NINDS Common Data Element (CDE) Project – Investigator Presentation Series

2016



Welcome to the NINDS CDE PROJECT

What is the CDE Project?

- NINDS 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** 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 is a CDE?

- Standardized question and potential answers
- Allows for consistent collection and sharing of data
- Semantic value (the CDE name) with clear definitions and permissible values

Example:

- CDE name: "Birth head circumference value"
- Definition: "Circumferential measurement of the head at the …"
- Data Type: "Numeric Values"
- Input Restrictions: "Free-form Entry"

Case Report Form:

Prenatal and Perinatal History

[Study Name/ID pre-filled] Site Name: _____

Subject ID: _____

1) **Birth weight:** __ __ pounds and __ __ ounces OR __ __ __ __ grams

2) **Birth length:** _____ ☐ centimeters ☐ inches ☐ meters ☐ feet

3) **Birth head circumference:** _____ ☐ centimeters ☐ inches

4) **Gestational age value:** _____ weeks _____ days

CDE Details:

CDE ID	CDE Name	Variable Name	Definition / Description	Question Text	Data Type	Instructions	References	Population	Classification (e.g., Core)	Version #	Version Date	Aliases for Variable Name	CRF Module / Guideline	Sub-Domain	Domain	Previous Title	Input Restrictions
C12940	Birth head circumference value	BrthHeadCircumfVal	Circumferential measurement of the head at the widest point taken at birth - the distance from above the eyebrows and ears and around the back of the head	Birth head circumference	Numeric Values	Record the head circumference of the participant/subject in centimeters. If another unit of measure is preferred, it can be used, however the final data should be converted to centimeters. This is a pediatric-specific element.	Pryor H and Thelander H. (1968). Abnormally small head size and intellect in children J Pediatr. 73:593-598.	Pediatric	Supplemental	3.0	7/24/2013	Aliases for variable name not defined	Prenatal and Perinatal History	General Health History	Participant/Subject History and Family History	Birth head circumference value	Free-Form Entry

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 definitions
  - (including permissible values, range checks, etc.)
- Standardize CRFs and other instruments
- Provide information to researchers for clinical data collection and sharing

Motivation & Overall impact of the NINDS 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

NINDS CDE Disease Areas – over 11,000 CDEs & 575 Instruments

General CDEs

Epilepsy*

Cerebral palsy *(new)*

Chiari I Malformation *(new)*

Headache

Mitochondrial disorders*

Movement disorders

- Parkinson's disease
- Huntington's disease

Multiple sclerosis

Spinal cord injury (SCI)*

Stroke*

** Pediatric Specific Recommendations*

Traumatic brain injury*

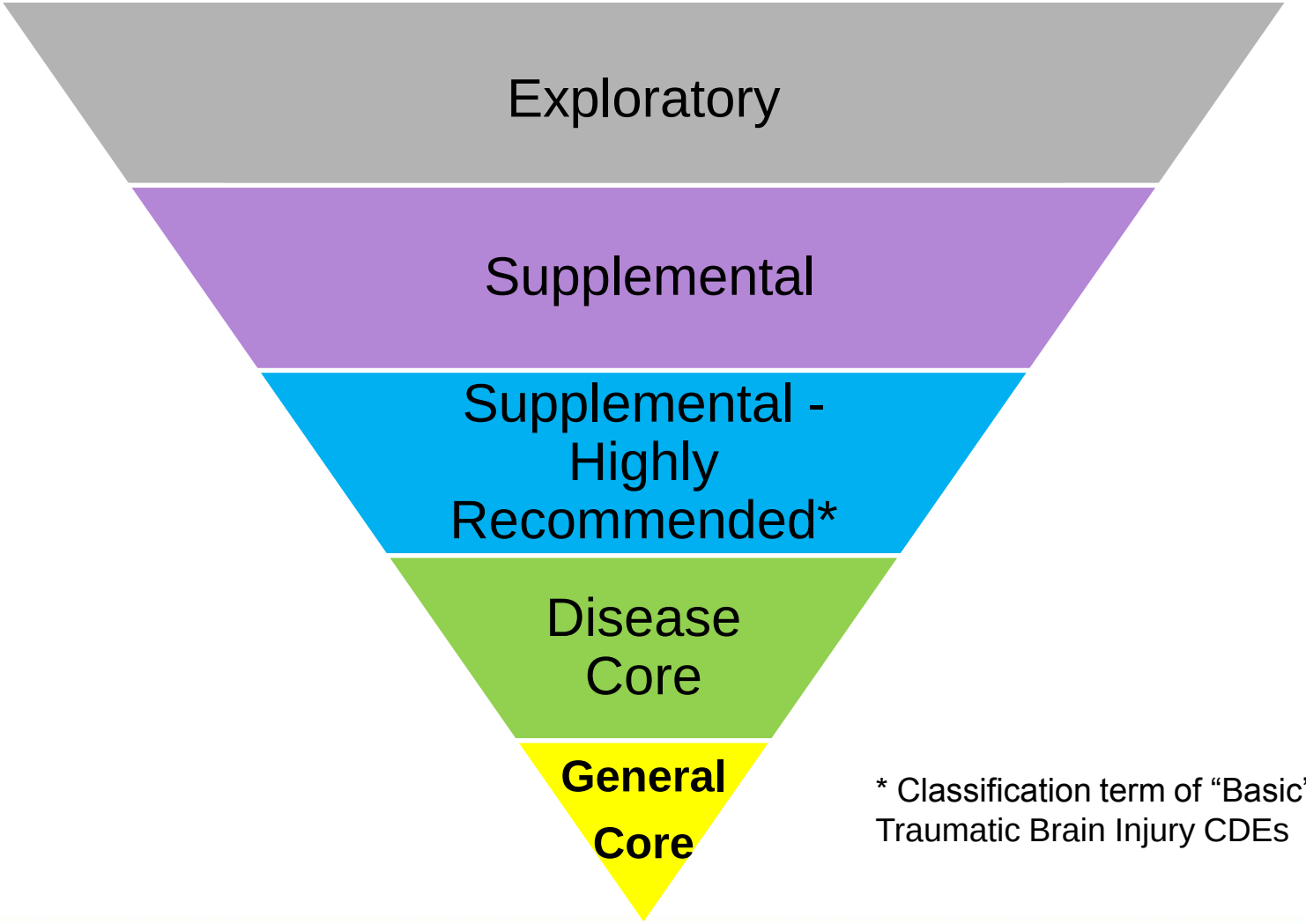
Neuromuscular disorders*

- Amyotrophic lateral sclerosis
- Friedreich's ataxia
- Muscular dystrophies
  - *Congenital, Duchenne/Becker, Facioscapulohumeral, Myotonic*
- Myasthenia gravis
- Spinal muscular atrophy

Subarachnoid hemorrhage (in development)

Sports-Related Concussion (in development)

CDE Terminology – Classifications



* Classification term of “Basic” used for Traumatic Brain Injury CDEs

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PROJECT OVERVIEW | CDE SEARCH | CRF SEARCH | FORM BUILDER | CONTACT

NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

▼ CDEs | ▼ Tools | ▼ Learn

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.

Launch Your Own Studies Faster

- Case report form modules
- Standardized data element definitions
- Instrument recommendations

Incorporate CDEs Into Systems

- Search for current CDEs
- Download CDE metadata
- Download Case Report Forms

Learn About the CDE Project

- Project overview and background
- Meetings and Presentations
- Collaboration with developers around the world

CDEs Now Available | CDEs Under Review | CDEs in Development

- General (CDEs that cross diseases)
- Amyotrophic Lateral Sclerosis
- Cerebral Palsy
- Chiari I Malformation
- Epilepsy
- Friedreich's Ataxia
- Headache
- Huntington's Disease
- Mitochondrial Disease
- Multiple Sclerosis

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NINDS Common Data Elements — Harmonizing information. Streamlining research.

NIH National Institute of Neurological Disorders and Stroke

NIH National Institutes of Health — Turning Discovery Into Health

USA.gov

NINDS Vision for CDEs

- NINDS-funded trials use CDEs or are CDE-compatible – it is part of FOA and Terms of Award
- 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
- Clinical research progress will be accelerated
  - New investigators can build on consensus data elements
  - Start-up of multi-center and international clinical research efforts will be facilitated