U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Neurological Disorders and Stroke

A Common Data Language for Clinical Research Studies: Revised Stroke Common Data Elements

Joanne Odenkirchen, MPH
Office of Clinical Research
NINDS

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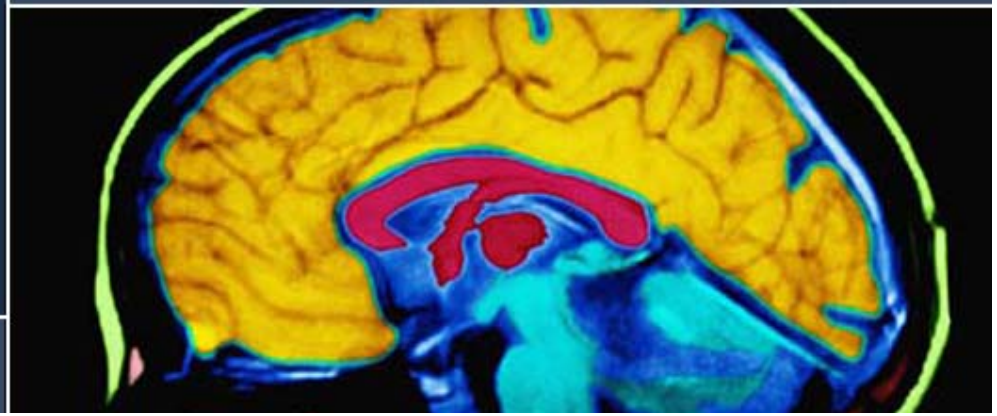
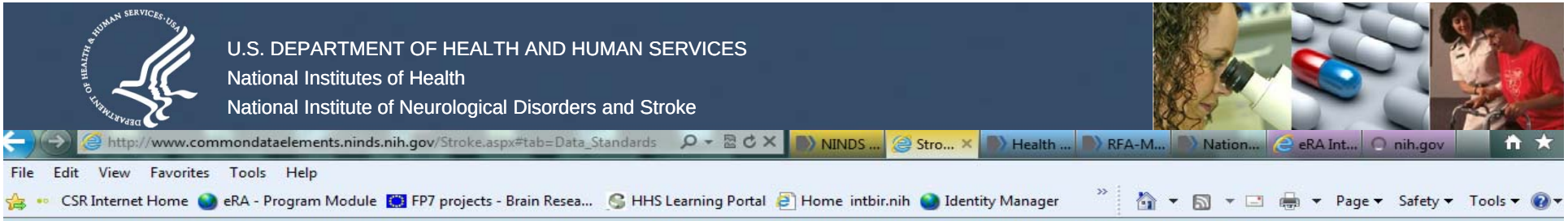




NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

Stroke

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Stroke was developed in 2010. The Core data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in the **Start-up Resource Listing.** *Note: Start-Up Resource listing is in draft mode (revised in February 2014) and these changes to Core CDEs are not reflected in the CDE details or associated CRFs at this time.*

Many of the CDEs will overlap across study types, which allows for comparisons and meta-analysis across studies. Consistency of the data elements and the CDE formats is kept in order to ensure the ability to transfer critical medical information electronically from one center to another. This consistency also allows for continuity across different disease areas. The goals of the NINDS CDE initiative are to increase the efficiency and effectiveness of clinical research studies and clinical treatment, increase data quality, facilitate data sharing, and help educate new clinical investigators.

Organized by domains and sub-domains, often used in clinical studies, data standards include:

- **CDEs** — Classified as Core, Supplemental, or Exploratory
- **CRF Modules** — logically organize CDEs for data collection
- **Guidelines** — to provide further information about the CDEs.

An overview of all Stroke CDE recommendations can be found in the Stroke CDE Highlight Summary document. For your reference, a zip file containing all the current Stroke CDE template CRF modules can be downloaded below.

Download Stroke CDE Recommendations

The outline that follows includes all the CDEs associated with the CRF modules, organized by domain and sub-domain.

NIH Resources

CDE Development Process

- Stroke CDE committee was created by members from NIH, other federal agencies, national and international organizations
- Stroke CDE Committee first met in **July 2009.**
- Committee set out to nominate and bring a diverse list of members for the CDE working groups
- First set of CDEs for Stroke was developed and completed by **May 2010** by the working groups

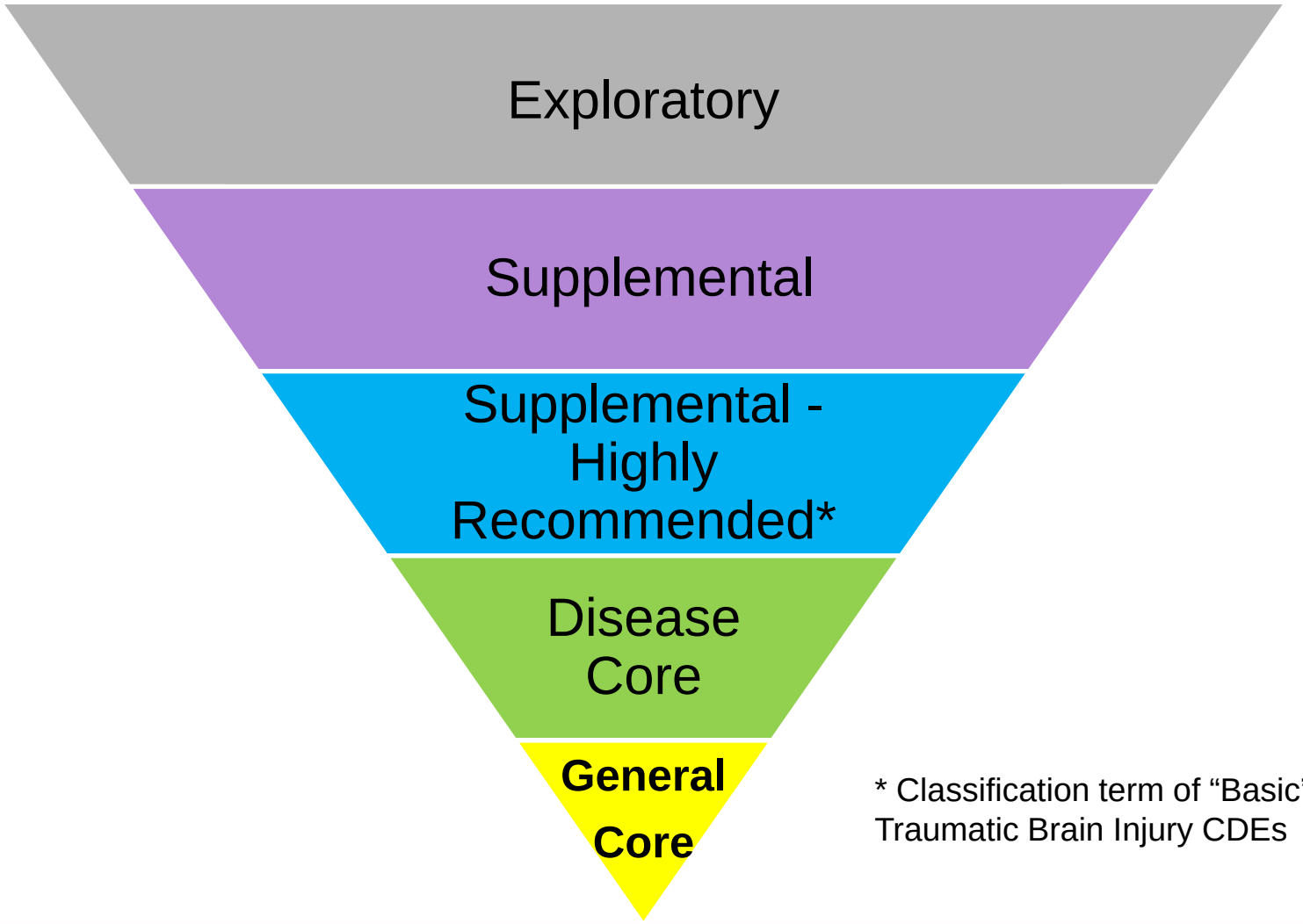
Stroke CDE Working Groups

1. Stroke Presentation
2. Medical History and Prior Health Status
3. Stroke Types and Subtypes
4. Laboratory Tests and Vital Signs
5. Hospital Course and Acute Therapies
6. Long Term Therapies
7. Outcomes and Endpoints
8. Imaging
9. Biospecimens/ Biomarkers

Stroke Oversight Committee Roster

- Jeffrey Saver, MD - **Co-Chair**
- Steven Warach, MD, PhD - **Co-Chair**
- Catherine Amlie-Lefond, MD
- Joseph Broderick, MD
- Colin Derdeyn, MD
- Mitchell Elkind, MD
- Michael Hill, MD, MSPH
- Virginia Howard, PhD
- Pooja Khatri, MD
- Kennedy Lees, MD
- David Levy, MD
- Prof. Bo Norrving
- Yuko Palesch, PhD
- Lee Schwamm, MD
- *William Dunn Jr., MD*
- *Lawrence Fine, MD*
- *Mary G. George, MD, MSPH*
- *Scott Janis, PhD*
- *Salina Waddy, MD*
- *Joanne Odenkirchen, MPH*

CDE Terminology – Classifications



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

Revising the Core Stroke CDEs

- The formal definition of " Supplemental Highly Recommended" CDEs is as follows:

  A data element which is almost always useful based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Revising the Core Stroke CDEs

Study Design: Randomized Clinical Trial	**Disease Type**		
Disease Stage:	SAH	ICH	Ischemic
Acute			
Recovery			
Prevention (primary)			
Prevention (secondary)			
Study Design: Observational/Epi	**Disease Type**		
Disease Stage:	SAH	ICH	Ischemic
Acute			
Recovery			
Prevention (primary)			
Prevention (secondary)			

Are there other categories or study designs that we should think about? biomarkers, imaging , etc. that would be different and are we there yet with the information we have to bin the CDEs differently?

Revising the Core Stroke CDEs

- Instruments also asked to be reclassified as whole:

Instrument	Prior Classification	New Classification for Clinical Trial Acute ICH (Supplemental or Supplemental - Highly Recommended)
Center for Epidemiologic Studies Depression Scale (CES-D)	Core	
Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Test Parts A&B	Core	
EuroQoL-5 Dimension Questionnaire	Core	
Modified Rankin Scale (mRS)	Core	
Montreal Cognitive Assessment (MoCA)	Core	
National Institutes of Health Stroke Scale (NIHSS)	Core	
Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) - Child Version (Children Aged 2 Year and Older)	Core	
Pediatric Stroke Outcome Measure Short Neuro Exam (PSOM-SNE) - Infant Version (Infants Term Birth to Two Years)	Core	
Walking Speed	Core	

Why is this Important to StrokeNet?

- NINDS' expects StrokeNet to provide the most input/data from large multicenter trials as to the changes that need to be made to the NINDS Stroke CDEs.
- Data from observational studies, phase I/II trials, SBIR/STTR, and phase III trials not conducted in StrokeNet will also help guide future StrokeNet studies. And information from these studies, like the studies in StrokeNet, will help to guide future revisions of the NINDS Stroke CDEs.
- NINDS sees the Stroke CDEs as tool available to the public, developed by an unbias international group of Stroke experts.

Future Plans:

- Limited General Core CDEs (7 across all diseases)
- Disease CDEs
  - We do not want to revise the CDEs UNTIL we have data and input from researchers that can guide us as to what should/could be changed
- Lessons learned from other CDE projects
- Continue to work with Stroke OC, StrokeNet and other networks/grantees/groups to ensure we are not working in silos
- Meta analysis of data

Questions?

http://www.commondataelements.ninds.nih.gov/stroke.aspx#tab=Data_Standards

Joanne Odenkirchen, MPH

jo2x@nih.gov