

ASNR AMERICAN SOCIETY OF NEUROREHABILITATION

ASNR Annual Meeting  
November 13, 2014  
Hyatt Regency Washington on Capitol Hill  
The Annual Meeting will be held in conjunction with the Society for Neuroscience meeting.

## Barriers to multi-site collaborations

### A case for common data elements (CDE)

#### Who Needs Common Data Elements?

Carolee J. Winstein, PhD, PT, FAPTA  
Director, Motor Behavior and Neurorehabilitation Laboratory  
Division Biokinesiology & Physical Therapy  
University of Southern California

## Clinical Research Panel

- ▣ 4:40 - 4:46 Introduction: Who needs CDEs? Winstein
- ▣ 4:47 - 4:53 CDE databases-What's out there? Plummer
- ▣ 4:54 - 5:00 Developing a database-The Cornell experience. Dohle
- ▣ 5:01 - 5:07 A Neuropsychological perspective on CDE's. Lazar
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NIH U.S. National Library of Medicine

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### NIH Common Data Element (CDE) Resource Portal

Home | Resource Summaries | Glossary

#### Home

NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records. This portal provides access to NIH-supported CDE initiatives and other tools and resources that can assist investigators developing protocols for data collection. [What is a CDE?](#)

#### NIH CDE Initiatives

Collections of CDEs that have been identified for use in particular NIH-supported research projects or registries after a formal evaluation and selection processes.

[Summary Table](#) [Subject Areas](#)

#### NIH CDE Tools and Resources

Databases and repositories of data elements and case report forms that may assist investigators in identifying and selecting data elements for use in their projects.

[Summary Table](#) [Subject Areas](#)

The CDE Resource Portal also includes [Other CDE Resources and Relevant Standards](#). Descriptions of all four groups can be found in the [Glossary](#).

The CDE Working Group of the [Trans-NIH BioMedical Informatics Coordinating Committee \(BMIC\)](#) developed this Portal to improve the coordination of CDEs. BMIC encourages researchers to use CDEs from the Resources in this Portal where applicable, and to consider existing CDE initiatives before starting additional initiatives.

Are we missing a CDE Resource? [Contact us](#).

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Last reviewed: 03 January 2013  
Last updated: 03 January 2013  
First published: 18 June 2012  
Metadata: Permanence: Inspec; Permanence: Dynamic Content

## Definition: Common Data Elements

▣ **Common Data Element (CDE)** - A data element that is common to multiple data sets across different studies or clinics. Commonality may be intentional or unintentional; those who need/use them, place emphasis on the intentional use of CDEs to improve data quality and promote **data sharing**.

## Types of CDEs

- ❑ **Universal** - CDEs that may be used in studies, regardless of the specific disease or condition of interest.
- ❑ **Domain-specific** - CDEs that are designed and intended for use in studies of a particular topic, disease or condition, body system, or other classification. (e.g., ICF domain)
- ❑ **Required** - CDEs that are required or expected, as a matter of institutional policy (e.g., research funder or performer), to be collected for all subjects in studies of a particular type.
- ❑ **Core** - CDEs that are required or expected to be collected in particular classes of studies, e.g., any study of neurological disease or cancer, any genome-wide association study.

## CDEs can be used to promote data sharing

- ❑ **Across multi-site collaborations (funded or not)**
  - ❑ Retrospective chart reviews (clinical practice)
  - ❑ Prospective projects (funded research or clinical practice)

## Framework for choosing CDEs

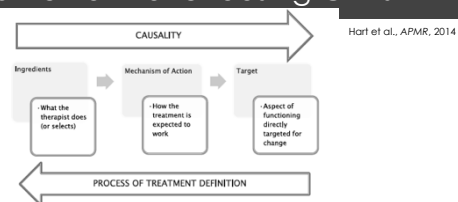


Fig 1 Casual and temporal aspects of the tripartite structure of treatment theory.

- ❑ that describe your population cohort
- ❑ that capture the target of the intervention
- ❑ that capture the mechanism of action
- ❑ that capture/describe the ingredients

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## CDE Databases:

What's out there?  
(for neurorehab)

Prudence Plummer, PhD  
Department of Allied Health Sciences  
Division of Physical Therapy  
University of North Carolina, Chapel Hill

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## NIH CDE Initiatives

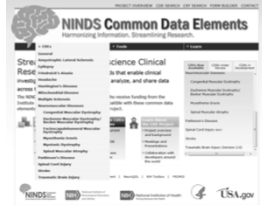
- █ Collections of CDEs identified for use in particular NIH-supported research projects
  - █ Minimum or core set of data elements to be collected in all studies of a particular type
- █ Resources are free to use
  - █ May require registration for access

### NIH CDE Initiatives: Summary Table

Link to Homepage	Link to CDEs	Brief Summary	Subject Area	Number of Elements	CDE Resource Contact
Early Detection Research Program	EDRP	CDEs for use in describing samples and data collected as part of cancer biomarker research. <a href="#">More...</a>	Cancer. <a href="#">More...</a>	1,600	NCI
National Ophthalmic Disease Genebank	eyeGENE	As part of eyeGENE, common data elements have been developed for collecting phenotypic data associated with more than 30 inherited ophthalmic diseases. <a href="#">More...</a>	Ophthalmology. <a href="#">More...</a>	300+	NEI
Global Rare Diseases Patient Registry and Data Repository	GRDR	CDEs to facilitate standardized data collection into the GRDR and to assist organizations in establishing rare disease registries that contribute information to GRDR. <a href="#">More...</a>	Rare diseases. <a href="#">More...</a>	70	ORIP
Quality of Life Outcomes in Neurological Disorders	Neuro-QOL	A core set of quality-of-life questions that address chronic neurologic disorders, plus sets of supplemental questions specific to targeted diseases or subgroups of patients. <a href="#">More...</a>	Neurological disorders. <a href="#">More...</a>	500	NINDS
NIDA Substance Abuse Electronic Health Record Data Elements	NIDA EHR	A set of brief screening and initial assessment tools for substance use disorders (SUDs) for use in general medical settings. <a href="#">More...</a>	Substance Use Disorders. <a href="#">More...</a>	45	NIDA
NIH Toolkit for Assessment of Neurological and Behavioral Function	NIH Toolbox	An integrated set of tools for measuring cognitive, emotional, motor and sensory function. <a href="#">More...</a>	Cognitive, emotional, motor, and sensory function. <a href="#">More...</a>	4 batteries of tests, each with 5-24 tests	NIH
NINDS Common Data Elements	NINDS CDEs	A core set of data elements for use in NINDS-funded studies, including core and supplementary sets of data elements for use in disease-specific studies. <a href="#">More...</a>	Neurological disorders. <a href="#">More...</a>	7,000+ variables, 1000 of instruments	NINDS
Consensus Measures for Phenotypes and Exposures	PhenX	Standard measures related to complex diseases, phenotypic traits and environmental exposures for inclusion in genome-wide association studies (GWAS) and other large-scale genomic and epidemiologic research efforts. <a href="#">More...</a>	Genome-wide association studies. <a href="#">More...</a>	15,000+ variables, 428 protocols	NIH/NIH
Patient Reported Outcomes Measurement Information System	PROMS	A system of item banks measuring patient-reported health status for various domains of physical, mental, and social health across clinical populations (i.e. not disease-specific). <a href="#">More...</a>	Physical, mental, and social health. <a href="#">More...</a>	50 item banks	NAMS


## NINDS Common Data Elements

- █ To streamline sharing of clinical research data
  - █ through systematic collection and analysis of data
- █ Core set for each disease-specific area ("gold standard" measures for that disease)
- █ NINDS-funded researchers encouraged to use CDEs



[www.commondataelements.ninds.nih.gov](http://www.commondataelements.ninds.nih.gov)

## NIH Toolbox




- NIA
- Standard set of measures
- Monitors neurological and behavioral function
  - Cognitive, emotional, motor, sensory
- 4 batteries of tests (5-24 measures each)
- NIA encourages use of all 4 batteries in funded studies

[www.nihtoolbox.org](http://www.nihtoolbox.org)

## PROMIS Patient-Reported Outcomes Measurement Information System


- A system of item banks measuring patient reported health status
- Paper, web-based short forms, web-based CAT
- Physical, mental, social health, global health
  - Not disease-specific



[www.nihpromis.org](http://www.nihpromis.org)


## Non-NIH Initiatives: APTA EDGE Task Force

- Evaluation Database to Guide Effectiveness
- Identification of a core set of tests/measures for each practice area
- To enable pooling of data
  - To help accumulate evidence on effectiveness of treatments
- Published sets of recommended outcome measures



[www.neuropt.org/professional-resources/neurology-section-outcome-measures-recommendations](http://www.neuropt.org/professional-resources/neurology-section-outcome-measures-recommendations)

## Non-NIH Initiatives: Stroke Rehab Outcome Measures Tool Box



- Outcome measures selected by expert panel on stroke rehab outcomes
- Tool-specific resources
  - Overview of selected outcome measurement tools
  - StrokEngine
    - Provides evidence about stroke assessments
- Evidence-based review of stroke rehabilitation

[www.heartandstroke.on.ca](http://www.heartandstroke.on.ca)  
[www.ebrsr.com](http://www.ebrsr.com)

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## Developing a CDE database- The Cornell Experience

Carolyn Dohle, MD  
cdohle@burke.org

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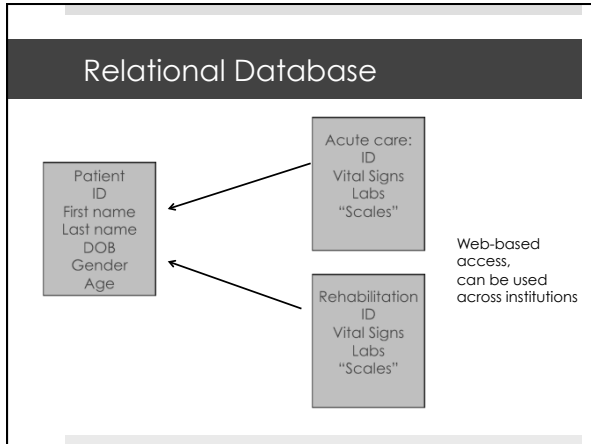
## The Cornell Project: "Choosing and Implementing Standardized Assessments in Inpatient Stroke Rehabilitation"

REDCap™

Research Electronic Data Capture

Clinical & Translational Research Center

- **Secure**, web-based application for custom-building databases and surveys
- *Fast and flexible*: no programming or database building experience is required, can build database in less than a day
  - Ad hoc reporting tools, easily run queries
  - Data export SPSS, SAS, Excel.....
- *Safe*: Data housed at Cornell Server, access audit trail, restricted access for users; HIPAA compliant



- ### Advantages of Relational Databases
- ❑ Patient demographics are entered once
  - ❑ All measurements, lab tests etc. are linked to one patient entry
  - ❑ Removes redundancies and risk for data entry errors



Project status:  Development Completed steps 1 of 9

**Main project settings**

Use longitudinal data collection with repeating forms? [?]

Use surveys in this project? [?] [VIDEO: How to create and manage a survey](#)

**Design your data collection instruments & enable your surveys**

Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method), in which you may use either method or both. You may then enable your instruments to be used as surveys in the Online Designer. Quick links: [Download PDF of all data collection instruments](#) OR [Download the current Data Dictionary](#)

Go to [Online Designer](#) or [Data Dictionary](#)

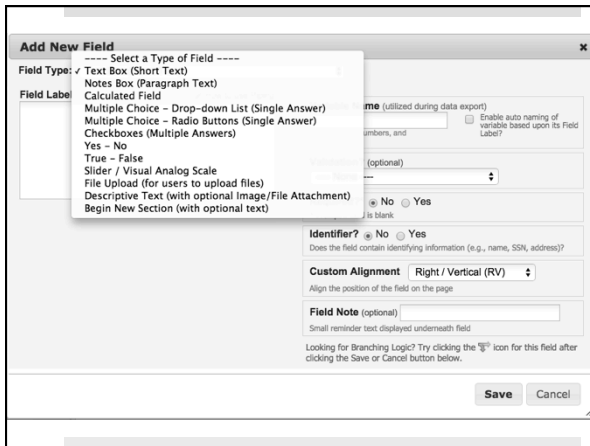
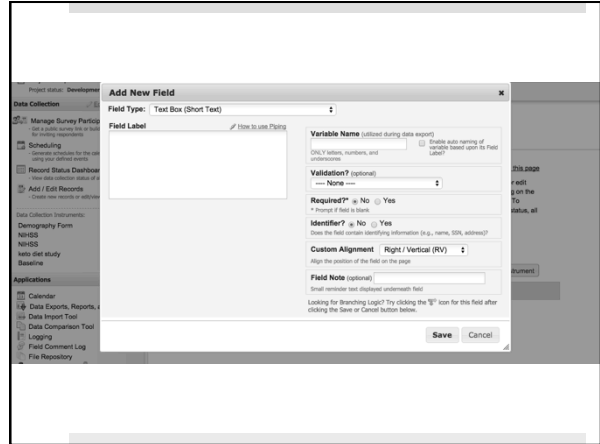
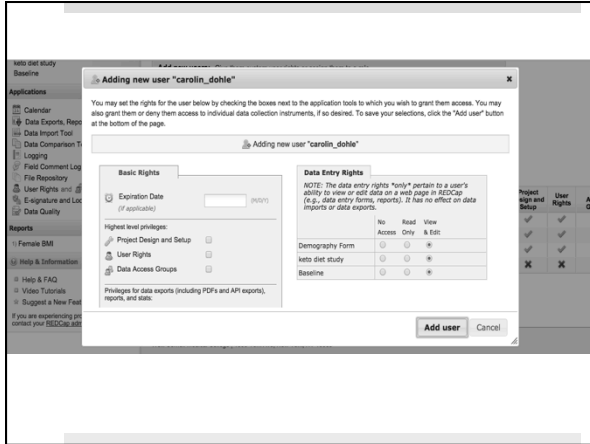
You may also browse for pre-built data collection instruments in the [REDCap Shared Library](#)

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been flagged?

**Define your events and designate instruments for them**


Create events for re-using data collection instruments and/or set up scheduling.

Go to [Define My Events](#) or [Designate Instruments for My Events](#)



Need to determine....

- What?
- How often?
- By Whom?



- Accessible through CTSC partner institutions



-> point person affiliated with CTSC partner could submit application on behalf of the consortium

## Potential Challenges

- IRB approval? How do IRBs feel about sharing data across institutions?
  - If no own IRB, can check with Cornell
- (De-)identified data? What about patients moving between institutions?
- Data input point person?

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### BARRIERS TO MULTI-SITE COLLABORATIONS: A Case for Common Data Elements

### Neurocognitive Outcomes

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**Ronald M Lazar, PhD, FAHA, FAAN, FANA**  
Division of Stroke and Cerebrovascular Disease  
Tanenbaum Stroke Center, Neurological Institute  
New York Presbyterian Hospital/Columbia University Medical Center



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### Three Critical Points

- ◆ Cognition is not a single skill
- ◆ Tests should match brain mechanism
- ◆ Keep it simple!

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### Rule 1: Cognition is not a single skill

- Language
- Perception
- Attention and Concentration
- Memory
- Organization
- Calculation
- Abstraction
- Insight and Judgment
- Decision-Making

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### Common Causes of Cognitive Impairment in a Rehabilitation Setting

- Stroke (Ischemic or Hemorrhagic)
- Trauma
- Infectious Disease
- Neoplasm and its Treatment
- Neurodegenerative Disease (AD, Parkinson's)
- Demyelinating Disease (MS)
- Anoxia (Cardiac Arrest, Asphyxia)
- Congenital Injury

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### Design of the Cognitive Assessment Battery - 1

- NIH Common Data Elements Encompass any Cognitive Outcome
- Not all cognitive functions are assessed on any one test
- No one cause affects all cognitive functions

Rule 2: Battery = Brain Mechanism

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## Design of the Cognitive Assessment Battery – 2

### Other Considerations

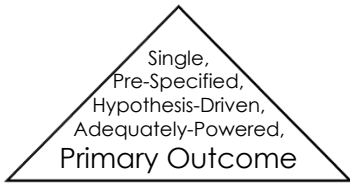
- **Goal: Impairment vs Function?**
- **Acute inpatients or outpatients?**
- **Patient Burden vs Comprehensiveness**
- **Physical Limitations**
- **Concomitant Medications**
- **Depression**
- **Language and Culture**
- **Support System**

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## Rule 3: Keep It Simple!



Single,  
Pre-Specified,  
Hypothesis-Driven,  
Adequately-Powered,  
Primary Outcome

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## Clinical Research Opportunities

- ASNR Clinical Research Network Application (ASNR Website)

**ASNR Clinical Research Network**  
This is a great opportunity for junior and senior investigators to collaborate and develop research skills, while at the same time, advance the field of Neurorehabilitation. Learn more!

- NINDS StrokeNet (see nihstrokenet.org)

NIH StrokeNet aims to maximize efficiencies to develop, promote and conduct high-quality, multi-site clinical trials focused on key interventions in stroke prevention, treatment and recovery.

If there is an intervention that appears promising in initial studies, please consider a submission to this network (PAR-14-220).

Steve Cramer  
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**See** [nihstrokenet.org/](http://nihstrokenet.org/)