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Research Data Stewardship Community of Practice

*The ABCs of CDEs: How Common Data Elements
Support Interoperability in Research*

October 24, 2024

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Agenda

- I. Announcements
- II. Presentations
 - a. Brief introduction to CDEs - Megan Chenoweth
 - b. Researchers' experiences with CDEs
 - i. Dr. David Williams
 - ii. Dr. James McNally
- III. Q & A



Announcements

- RDSI MCommunity email lists:
 - [RDSI Updates](#) [existing] - occasional emails from RDSI working group
 - [RDSI Community of Practice](#) [newer!] - preferred communication method from the survey. A more active email group for sharing data-related questions, news, and events.
 - Want to join the new CoP group? [Sign up](#) on MCommunity.
 - To email the new CoP group: ResearchDataCoP@umich.edu
- Other announcements?



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Introduction to Common Data Elements (CDEs)

Megan Chenoweth



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Introduction and Background



SBE CCC Social, Behavioral, & Economic COVID Coordinating Center

Home COVID-19 Research Support for Researchers About Us Contact Us

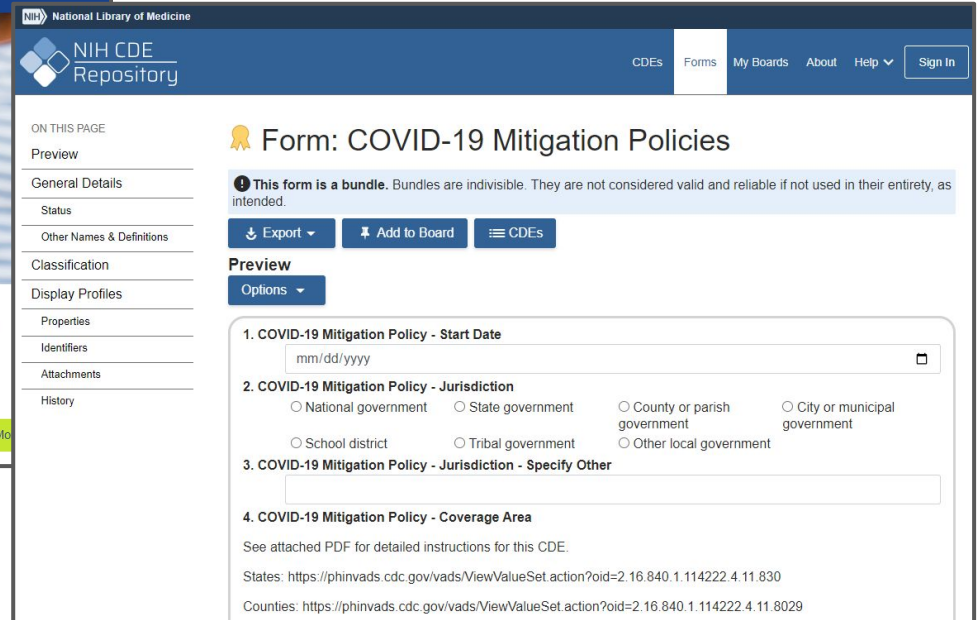
LOG IN / CREATE ACCOUNT



Social, Behavioral, & Economic COVID Coordinating Center

A nexus of communication and collaboration among NIH-funded projects undertaking social, behavioral, and economic research on COVID-19. We promote an innovative, cross-disciplinary approach to COVID-19 research across the behavioral and social science community, multiple NIH award recipients, and the public.

[Read More](#)



NIH National Library of Medicine

NIH CDE Repository

CDEs Forms My Boards About Help Sign In

Form: COVID-19 Mitigation Policies

This form is a bundle. Bundles are indivisible. They are not considered valid and reliable if not used in their entirety, as intended.

[Export](#) [Add to Board](#) [CDEs](#)

Preview

[Options](#)

- COVID-19 Mitigation Policy - Start Date**
mm/dd/yyyy
- COVID-19 Mitigation Policy - Jurisdiction**
 National government State government County or parish government City or municipal government
 School district Tribal government Other local government
- COVID-19 Mitigation Policy - Jurisdiction - Specify Other**
- COVID-19 Mitigation Policy - Coverage Area**
See attached PDF for detailed instructions for this CDE.
States: <https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.830>
Counties: <https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.8029>



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Defining Common Data Elements

- Standardized questions, variables, or measures
- Specific sets of allowable responses
- Used across multiple studies to ensure consistent data collection

NIH CDE Repository

CDEs Forms My Boards About Help Sign In

Use of CDEs Supports the NIH Data Management and Sharing Policy

Common data elements (CDEs) help researchers share and combine datasets, meet funding requirements, and save time. [Learn More...](#)

Search NIH-Endorsed CDEs Search All CDEs Search Forms

Search by topic, keyword, or organization

NIH-endorsed CDEs have been reviewed and approved by an expert panel, and meet established criteria. They are designated with a gold ribbon.

NIH CDE Repository: <https://cde.nlm.nih.gov>



Common Data Elements: An Example

Employment Status

 This CDE is part of a bundle. All CDEs within a bundle must be used together. [Go to bundle](#)

Question Text

We would like to know about what you do-are you working now, looking for work, retired, keeping house, a student, or what?

Definition

A textual description of a person's employment status.

Data Type: Value List

Steward: Project 5 (COVID-19)

Origin:

Data Type Details

Data Type: Value List

Permissible Value

PV Labels	PV Definitions	PV Concept Identifiers	PV Terminology Sources	Codes for PVs	PV C Sys
Working without pay	Exertion or effort directed to produce or accomplish something.; Used to indicate the absence or lack of something or someone.; Money or other benefits received in exchange for work. C74299:C25718:C180612	C74299:C25718:C180612	NCI Thesaurus		
Employed full-time	Employed for a standard number of hours of working time, at least 50% or 20 hours per week. C52658	C52658	NCI Thesaurus		
Employed part-time	Employment involving less than the standard or customary working time. C75562	C75562	NCI Thesaurus		



Use of Common Data Elements

- Incorporate CDEs into research design
- Often due to funding requirements or other mandates
- Most common in health sciences research, but growing support in the social sciences
- Exact prevalence is unknown, but growing

CDEs Benefits:

- Facilitate data aggregation and meta-analyses
- Simplify training and operations
- Improve efficiency
- Enhance quality of data collection

Sheehan J, Hirschfeld S, Foster E, Ghitza U, Goetz K, Karpinski J, Lang L, Moser RP, Odenkirchen J, Reeves D, Rubinstein Y, Werner E, Huerta M. Improving the value of clinical research through the use of Common Data Elements. Clin Trials. 2016 Dec;13(6):671-676. doi: 10.1177/1740774516653238. Epub 2016 Jun 15. PMID: 27311638; PMCID: PMC5133155.



Where Do CDEs Come From?

1. Originate in research studies
 - May be validated instruments or scales
 - May originate from other sources
2. Identified as possible CDEs via a consensus building process
 - Working groups
 - Revision and feedback
3. Submitted to and reviewed by the NIH CDE Governance Committee



CDEs and FAIR Data Principles

F



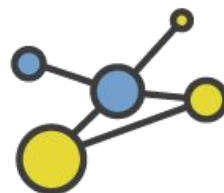
Findable

A



Accessible

I



Interoperable

R



Reusable



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CDEs: Learning and Resources

- NLM CDEs repository: [NIH Common Data Elements \(CDE\) Repository](#)
- Other repositories:
 - PhenX: [PhenX Toolkit](#)
 - RADx-UP: [NIH RADx-UP Common Data Elements](#)
 - NINDS: [NINDS Common Data Elements](#)
- On-demand training from NLM:
 - [Standardize Your Research Data with the NIH Common Data Element Repository – On Demand | NNLM](#)
 - [Common Data Elements: Standardizing Data Collection | NNLM](#)
- Article: Sheehan et al (2016). Improving the value of clinical research through the use of Common Data Elements. <https://doi.org/10.1177/17407745166653238>



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The HEAL Common Data Elements

Dr. David Williams

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The HEAL Common Data Elements

RDSI Community of Practice Event: The ABCs of CDE's

Oct 24, 2024

David A. Williams, Ph.D.

Professor of Anesthesiology, Medicine, Psychiatry and Psychology
Associate Director, Chronic Pain and Fatigue Research Center

Co-Director, Research Development, Michigan Institute for Clinical Health Research (MICHR)

Director, Network-based Research Unit, MICHR

University of Michigan Medical Center

Ann Arbor, Michigan

NIH HEAL INITIATIVE RESEARCH OVERVIEW



HEAL Research to Enhance Pain Management Across the Scientific Spectrum

Basic Science	Preclinical	Clinical	Implementation/ Dissemination
Drug Discovery		Preventing Chronic Pain	
New targets for non-opioid medications		Identify risk for developing chronic pain	
Pre-Screening Platforms		Clinical Studies	
Novel molecules, biologics, devices to relieve pain		Determine safety and efficacy of new treatments	
Therapeutics Development		Effectiveness Trials	
Develop or improve drugs & devices to relieve pain		Define and measure effectiveness for various populations and settings	
Biomarkers & Endpoints		Pragmatic Trials	
<ul style="list-style-type: none"> - Accurate pain measurement - Patient-centered outcomes 		Integrating treatments into real-world clinic practice	

HEAL CDEs

USASP

US ASSOCIATION FOR THE STUDY OF PAIN

PUBLISHED BY



ELSEVIER

The Journal of Pain, Vol 23, No 3 (March), 2022: pp 370–378
Available online at www.jpain.org and www.sciencedirect.com

Focus Article

NIH's Helping to End Addiction Long-termSM Initiative (NIH HEAL Initiative) Clinical Pain Management Common Data Element Program



Laura Dover Wandner,^{*} Anthony F. Domenichiello,[†] Jennifer Beierlein,^{*} Leah Pogorzala,^{*}
Guadalupe Aquino,[‡] Andrew Siddons,^{*} Linda Porter,^{*} and Jane Atkinson[‡]
NIH Pain Consortium Institute and Center Representatives

Core – Adult CDEs

Adult Acute Pain*

Pain Intensity	Pain Interference	Physical Functioning/ QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
BPI Pain Severity	BPI Pain Interference	PROMIS Physical Functioning Short Form 6b	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Pain Catastrophizing Scale – Short Form 6	PHQ-2	GAD-2	PGIC	TAPS 1

Adult Chronic Pain*

Pain Intensity	Pain Interference	Physical Functioning/ QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
PEG		PROMIS Physical Functioning Short Form 6b	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Pain Catastrophizing Scale – Short Form 6	PHQ-2	GAD-2	PGIC	TAPS 1

*Questions are required to be asked at two time points

*Monitoring opioid use will be required by HEAL, however, the method by which it will be assessed is still pending. PIs will be asked to monitor opioid use (including dosage) by appropriate PRO, EHR, or other measures.

Core – Pediatric CDEs

Pediatric Acute and Chronic Pain*

	Pain Intensity	Pain Interference	Physical Functioning / QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
Child	BPI Pain Severity	BPI Pain Interference	PedsQL Inventory	AWS + Sleep Duration Items	Pain Catastrophizing Scale for Children	PHQ-2	GAD-2	PGIC	NIDA Modified Assist Tool - 2
Parent					Pain Catastrophizing	PHQ-2	GAD-2		

Re-released* The Core Demographics (Adult and Pediatric) - Domains

- Date of Birth
- Age
- Sex at Birth
- Gender Identity
- Ethnicity, Race
- Highest Level of Education
- Employment Status
- Relationship Status
- Annual Household Income
- Applied for Disability Insurance
- Pain Duration

*Demographics are, for the most part, CDISC compliant

Supplemental Questionnaires

What are supplemental CDEs?

A comprehensive set of screening tools selected by HEAL PIs for use in their studies. They may be unique to the study; e.g., pain condition-specific or study-relevant measures.

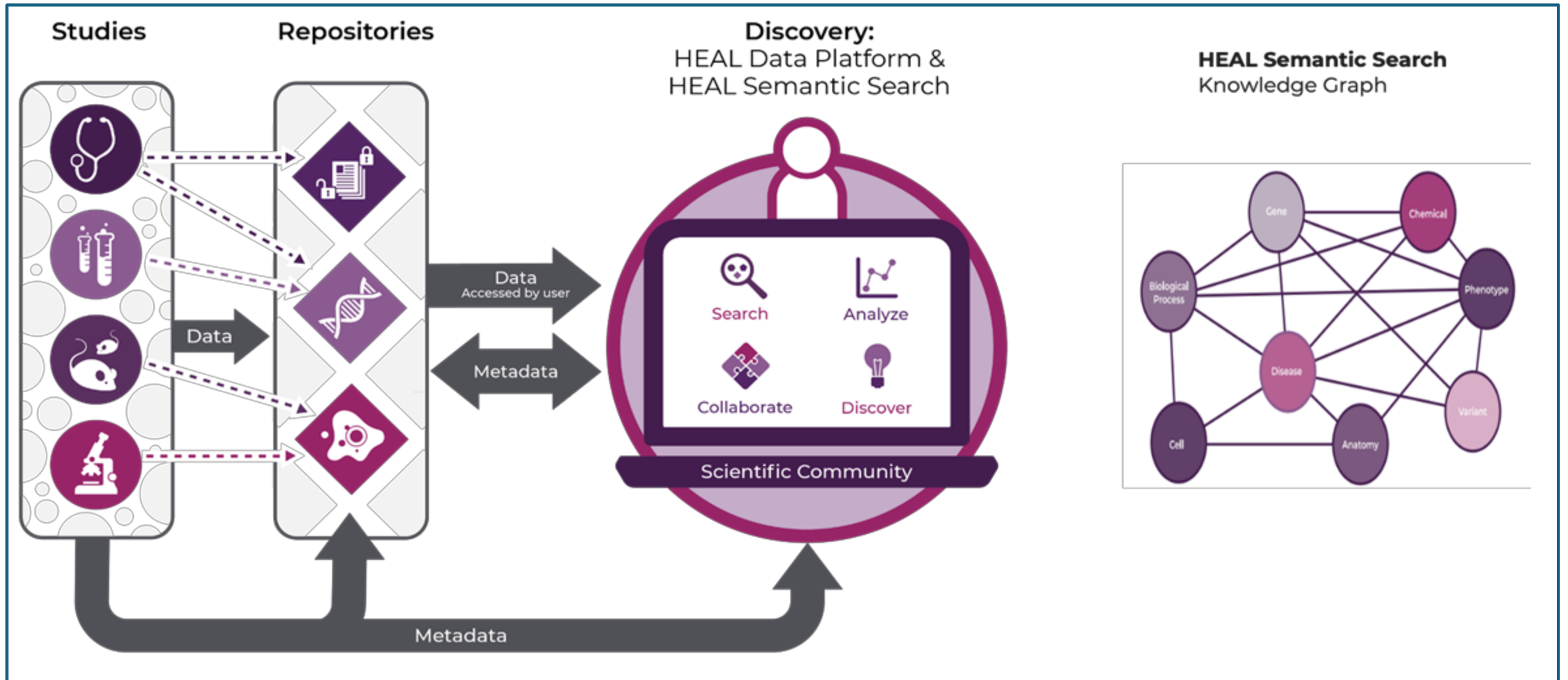
The NIH has collected supplemental questionnaires from all clinical pain programs and/or studies. ~600 distinct supplemental questionnaires have been accepted into the HEAL CDE program for this initiative.

Supplemental CDEs are not required for the HEAL funded pain studies, but the benefits include:

- See questionnaires being used within similar studies
- Coding and collecting data (in addition to the core CDEs) for the HEAL Data Ecosystem

<p>The Migraine Disability Assessment (MIDAS) questionnaire assesses headache-related disability with the aim of improving migraine care.</p>	<ul style="list-style-type: none">• File midas-crf.docx (23.14 KB)• File midas-cde.xlsx (21 KB)	English	<ul style="list-style-type: none">• Supplemental	Headache/Migraine
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HEAL Data Ecosystem Strategy and Tools



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So You Made a CDE: Now What?

Dr. James McNally



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So you made a CDE: Now what?

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NACDA Program on Aging
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*RDSI Community of Practice
Event:
The ABCs of CDEs
October 24, 2024*

ABSTRACT

- Common Data Elements (CDEs) is a general term used to capture a wide array of constructs.
- CDE repositories are often a broad catalogue of variables that have been used to measure an outcome with little or no guidance.
- It may only be a search engine that lists related variables.
- The provenance of many CDEs is uncertain.
- Steps are being taken to bring more formality into the way CDEs are organized and presented.
- Much more work needs to be done.

IDEAL VARIABLE TRANSITION STAGES

Related Data Elements (RDEs)

```
graph TD; A[Related Data Elements (RDEs)] --> B[Common Data Elements (CDEs)]; B --> C[Normalized Data Elements (NDEs)]; C --> D[Required Data Elements (RDEs)];
```

Common Data Elements (CDEs)

Normalized Data Elements (NDEs)

Required Data Elements (RDEs)

Related Data Elements (RDEs)

- RDEs represent the majority of variables, including those maintained in a “CDE” repository. They are a centralized catalogue of variables.
- RDEs are connected by a general measurement structure that seek to identify specific outcomes or behaviors.
- They rarely share a One-to-One comparability.
- They may employ unrelated scales, collection metrics, definitions and variable ranges.
- Anyone can create a RDE and potentially add it to a CDE repository.
- There is no requirement that any specific measure be used.

RDE example in NIH CDE Repository

The screenshot shows the NIH CDE Repository interface. At the top, the logo and navigation menu are visible. The search bar contains the text 'depression', which is circled in red. Below the search bar, the 'ACTIVE CDE FILTERS' section shows 'depression' with a 'Clear all' button. The 'REFINE CDE RESULTS' section has a checkbox for 'NIH-Endorsed'. The 'Collections' section lists various categories with counts. The main content area is titled 'CDE Search Results' and includes buttons for 'Hide Filters', 'Table View', 'Summary View', 'Pin All', and 'Export All'. The search results are summarized as '521 results. Sorted by relevance.', which is also circled in red. Below this, a specific CDE entry for 'Depression' is shown with a pin icon. The entry includes a 'Qualified' label and a table with columns for 'Label', 'Code', and 'ConceptID'. The table contains two rows: the first row has '1' under 'Label' and '0' under 'Code'; the second row has '0' under 'Label' and '0' under 'Code'. The 'Steward' is listed as 'RADx-UP' and 'Used By' as 'RADx-UP'.

NIH CDE Repository

CDEs Forms My Boards About Help Sign In

All CDEs depression

ACTIVE CDE FILTERS
depression x Clear all x

REFINE CDE RESULTS
 NIH-Endorsed

Collections ^

- Women's CRN (1) >
- SchARe (2) >
- RADx-UP (1) >
- Project 5 (COVID-19) (6) >
- PhenX (29) >
- PROMIS / Neuro-QOL (46) >

CDE Search Results

Hide Filters Table View Summary View Pin All Export All

521 results. Sorted by relevance.

Depression

Qualified

Label	Code	ConceptID
1	0	
0	0	

Steward: RADx-UP
Used By: RADx-UP

Common Data Elements (CDEs)

- CDEs represented a structured refinement of RDEs.
- CDEs share similar, if not identical, variable elements.
- CDEs lend themselves to harmonization across variables and studies.
- Content experts can validate their similarities in a systematic manner and emphasize their value as shared constructs.
- There is no requirement to use specific CDEs and they are often aggregated within larger RDE collections.
- CDEs need to be formally separated from RDEs to encourage use.

NIH-Endorsed CDEs: An example

The screenshot shows the NIH CDE Repository search results for 'Depression'. The search bar at the top contains 'NIH-Endorsed CDEs' and 'Depression'. The search results are displayed in 'Summary View' and show 8 results, sorted by relevance. The first result is 'COVID-19 Mental Health Symptom Type', which is highlighted with a red circle. The page also includes a sidebar with active filters and a table header for the results.

NIH National Library of Medicine

NIH CDE Repository

CDEs Forms My Boards About Help Sign In

NIH-Endorsed CDEs Depression

ACTIVE CDE FILTERS

NIH-Endorsed CDEs x

Depression x Clear all x

REFINE CDE RESULTS

NIH-Endorsed

Collections ^

- SCHARE (2) >
- Project 5 (COVID-19) (6) >

CDE Search Results

Hide Filters Table View Summary View Pin All Export All

8 results. Sorted by relevance.

COVID-19 Mental Health Symptom Type

A textual description of the psychological and emotional symptom such as being able to cope with everyday events, think clearly, be responsible, meet challenges, and have good relationships with other [...]

Qualified	Label	Code	ConceptID
-----------	-------	------	-----------

CDE Variable Comparisons – Match Types

Directly Comparable:

No manipulation of data needed for comparison.
Question phrasing and values match.

NSHAP	NHATS
CON_WEIGHT	CURRWEIGH
Weight (lbs) Actual weight in pounds	How much do you currently weigh? Actual weight in pounds

Need Harmonization:

Variables must be adjusted to be compared.
Questions more/less match, but values differ.

CON_GLASSES	GLASSESWR
Did respondent wear glasses to read chart?	Do you wear glasses or contacts to help you see things at a distance?
1 no	1 yes
2 no, but R usually wears glasses/contacts for distance	2 no
3 yes	

One to Many / Many to One:

Multiple variables in one series combine to match a single variable in another.

CON_GUPPROB_4	CANE	WALKER
Respondent uses a cane or walker.	Respondent used a cane.	Respondent used a walker.
0 no	1 yes	1 yes
1 yes	2 no	2 no

Related Concepts:

Subject matter is related, but variables do not precisely measure the same concept.

CON_GASP	PROBBREAT
Has anyone ever told you that you stop breathing or gasp for breath during sleep?	In the last month, did you have any breathing problems, including shortness of breath or difficulty breathing?
0 no	1 yes
1 yes	2 no

Normalized Data Elements (NDEs)

- NDEs represent a further refinement of the CDE construct.
- NDEs are variables whose use has achieved general consensus within a discipline as valid and generalizable to the broader population.
- Demography has many NDEs, ASDR, Index of Dissimilarity, Life Tables.
- Psychiatry also has many NDEs, Kessler 6, PHQ-9, CES-D.
- Gerontology also has NDEs, ADLs IADLs, Ecog, Barthel Scale.
- You use these NDEs the way they are presented.
- The PhenX Toolkit is an example of an emerging NDE system.

ADL and IADL Checklist

- ADL and IADL represent a generally agreed upon series of questions that capture function and independent living status.

ADL Checklist

ADL Function	Independent	Needs Help
Bathing		
Dressing		
Transferring, e.g., from bed to chair		
Toileting		
Grooming		
Feeding oneself		

IADL Checklist

ADL Function	Independent	Needs Help
Using the telephone		
Preparing meals		
Managing household finances		
Taking medications		
Doing laundry		
Doing housework		
Shopping		
Managing transportation		

Example of NDEs encouraged by NIH funding

The image shows a screenshot of the PhenX Toolkit website. The header is dark blue with the PhenX Toolkit logo on the left and navigation buttons for Register, Log in, and My Toolkit on the right. Below the header is a navigation menu with links for Home, Protocols, COVID-19, Search, Resources, News, Help, About, Cite PhenX, Contact, and a highlighted Tree link. A search bar is located below the navigation menu, with a placeholder text: "Search all protocols in the Toolkit using keywords (e.g. diabetes) or PhenX ID (e.g. 011502)". To the right of the search bar is an "Advanced Search" button. The main content area features a banner for "New Sickle Cell Disease Pregnancy Protocols - click here!". Below the banner are three main sections: "Designs benefit the PhenX" (with a water drop image), "PhenX Steering Recommendations" (with a list of bullet points), and "Research Domains" (with a tree diagram). A green button labeled "Browse Protocols Tree" is overlaid on the bottom right of the Research Domains section.

PhenX Toolkit

Register Log in My Toolkit

Home Protocols COVID-19 Search Resources News Help About Cite PhenX Contact **Tree**

Search: Search all protocols in the Toolkit using keywords (e.g. diabetes) or PhenX ID (e.g. 011502) Advanced Search

New Sickle Cell Disease Pregnancy Protocols - click here!

Designs benefit the PhenX

PhenX Steering Recommendations

- Use Social Determinants of Health (SDOH) Core collection for
- Review Investigator and participant information for conducting research with participants
- PhenX Citation

Research Domains

Browse Protocols Tree

Required Data Elements (RDEs)

- RDEs represent the most formalized and structured examples of variable classification.
- RDEs are comprehensive catalogs used as a navigational tool for healthcare professionals, researchers, and patients.
- RDEs are routinely reviewed by content experts and updated as science changes and formal definitions change.
- You use RDEs if you want to be published or paid.
- The International Classification of Disease (ICD) standardized codes and the Diagnostic and Statistical Manual of Mental Disorders (DSM) are examples of RDE systems.

The International Classification of Diseases (ICD) is first published in 1893 by the World Health Organization (WHO) as the ICD-1.

RDEs are not static but change is structured.

ICD-9	ICD-10
3-5 characters in length	3-7 characters in length
Approximately 13,000 codes	Approximately 68,000 available codes
First digit may be alpha (E or V) or numeric; digits 2-5 are numeric	Digit 1 is alpha; digits 2 and 3 are numeric; digits 4-7 are alpha or numeric (alpha digits are not case sensitive)
Limited space for adding new codes	Flexible for adding new codes
Lacks detail	Very specific
Lacks laterality	Has laterality (i.e., codes identifying right vs. left side of the body)
Use same code for every visit	Has possibility of identifying initial encounter, subsequent encounter; or sequela
Only 4 codes were reported on a claim form	Up to 12 codes can be reported on a claim form

Conclusions

- Our current system of CDEs is an unstructured mess.
- The use of specific variables is optional in all but the oldest, and most formalized variable systems.
- There is a structured framework we can use to think about “CDEs” in a more structured manner.
- Fitting a variable within this framework makes it possible to rigorously plan and identify metrics to encourage the use of one variable versus another variable.
- Its not a CDE if you are the only one using it, even if it is in a repository.

Thank you! Questions?

SCAN ME



Scan this QR Code to get to our LinkTree (<https://linktr.ee/nacdadata>):

- NACDA website
- NACDA Colectica Portal
- YouTube playlist (researcher interviews and presentation recordings)
- Newsletter signup
- NIH data sharing resources

• **jmcnally@umich.edu**



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Q & A



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Event evaluation

Please fill out our survey:

<https://myumi.ch/W5Z2D>



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Thank you for attending!

CoP co-chairs:

- Sara Samuel: henrysm@umich.edu
- Megan Chenoweth: mmchenow@umich.edu

Learn more about RDSI:

<https://research.umich.edu/research-data-stewardship/>



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