

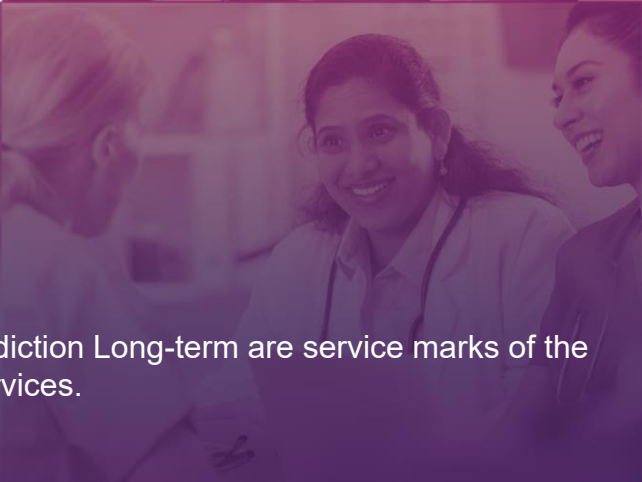


**NIH  
HEAL  
INITIATIVE**

## The HEAL Pain Common Data Elements (CDE) Program

**Laura Wandner, PhD  
Program Director  
OPPP, NINDS**

5/22/24



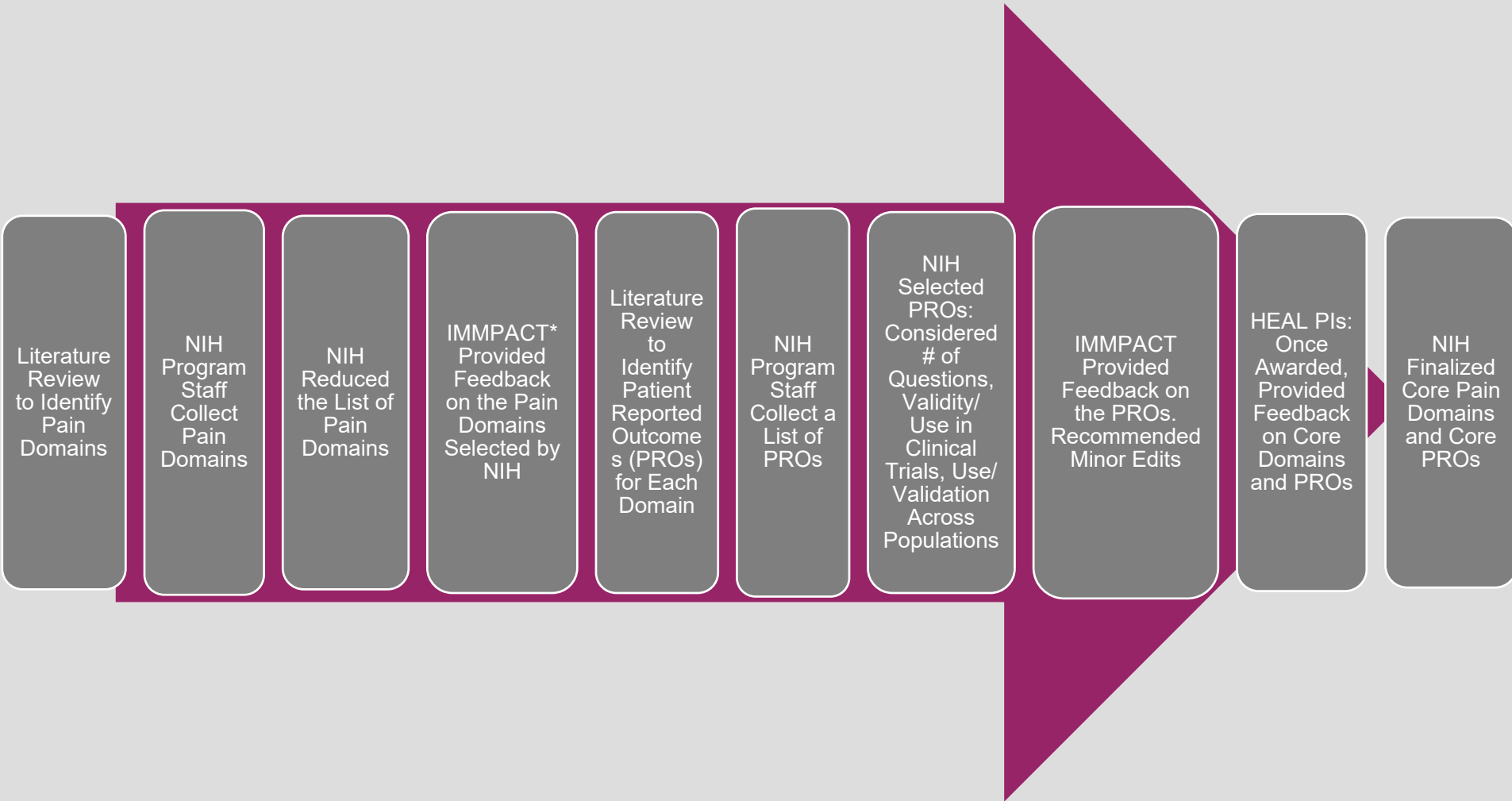
**NIH** National Institutes of Health  
HEAL Initiative

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

# Rationale for the HEAL Pain CDE Program

- Facilitate cross-study **comparisons** and improve the **interpretability** of findings for patient-reported outcome measures
- Opportunity for pain research community to **access quality data** across pain **conditions**, in diverse **populations**, and multiple **interventions**
- Ability to **compare results** across trials to quantify the impact of interventions

# Overview of the HEAL Pain CDE Process



\*Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

# CORE CDEs

- **Core CDEs:** a minimal and defined set of patient reported outcome screening tools for each pain domain that all HEAL pain clinical trials are required to collect.
- Core CDEs were released on 1/14/20
  - Your team is **REQUIRED** to use the HEAL CDE Details -- variable names, coding, etc.
- Core Demographics were re-released on 3/16/20
  - Demographics were made CDISC compliant.
  - New Demographic question (RUCA Code) was added in Aug. 2022
- Core Spanish case report forms (CRFs) were released on 9/10/21

# Core Domains and Questionnaires

## Adult – Chronic Pain

Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	MME	Demographics
PEG		PROMIS Physical Functioning Short Form 6B	WHO (2 Qs)	PROMIS Sleep Disturbance 6A + Sleep Duration Question	PCS-6 or PCS-13	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	TAPS1	Components of MME + total MME	Adult demographics + SDOH (1 Q)

## Adult – Acute Pain

Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	MME	Demographics
PEG		PROMIS Physical Functioning Short Form 6B	WHO (2 Qs)	PROMIS Sleep Disturbance 6A + Sleep Duration Question	PCS-6 or PCS-13	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	TAPS1	Components of MME + total MME	Adult demographics + SDOH (1 Q)

\*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 Domains and Questionnaires

## Pediatric – Acute and Chronic Pain

Respondent	Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	MME	Demographics
Child	BPI Pain Severity	BPI Pain Interference	PedsQL physical function (SF or LF)	PedsQL Version 4.0 (General or SF)	AWS + Sleep Duration	PCS for Children	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	NIDA Modified Assist Tool - 2		
Parent	N/A	N/A	N/a	PedsQL Version 4.0 (General or SF)	N/A	PCS for Parent	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	N/A	N/A	Components of MME + total MME	Child demographics + SDOH

\*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 Demographics (Adult and Pediatric)

- Date of Birth
- Age
- Sex at Birth
- Gender Identity
- Ethnicity, Race
- Zip Code
- Highest Level of Education
- Employment Status
- Relationship Status
- Annual Household Income
- Applied for Disability Insurance
- Pain Duration
- RUCA Code (based on Zip code)
- Social Determinates of Health

\*Demographics are, for the most part, CDISC compliant

# New Domain: Social Determinates of Health (SDoH)

- **SDoH** = The conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks
- Importance of including SDoH in research:
  - **Recruit and retain** diverse individuals
  - Impacts the **quality and completeness of data** collected
  - Impacts the **effectiveness of interventions** evaluated

## References:

1) Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved 04/02/2024, from

<https://health.gov/healthypeople/objectives-and-data/social-determinants-health>

2) Sonbol, W., (2023). How Social Determinants of Health Affect Clinical Trials and What eClinical Solutions Can Do to Help Level the Playing Field. ACRP. [https://acrpnet.org/2023/06/how-social-determinants-of-health-affect-clinical-trials-and-what-eclinical-solutions-can-do-to-help-level-the-playing-](https://acrpnet.org/2023/06/how-social-determinants-of-health-affect-clinical-trials-and-what-eclinical-solutions-can-do-to-help-level-the-playing-field/#:~:text=Data%20collection%3A%20SDOH%20can%20impact,the%20interpretation%20of%20clinical%20outcomes)

field/#:~:text=Data%20collection%3A%20SDOH%20can%20impact,the%20interpretation%20of%20clinical%20outcomes

# New Domain: Quality of Life (QoL)

- **Quality of Life** = individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns
- Importance of including QoL evaluation:
  - Emphasizes interventions, treatments, and personalized care that enhance **overall well-being** – important to patients
  - Informs **healthcare policy - resource allocation** for maximum impact on well-being

## References:

- 1) The World Health Organization Quality of Life assessment (WHOQOL): position paper from the World Health Organization. Soc Sci Med. 1995 Nov;41(10):1403-9. doi: 10.1016/0277-9536(95)00112-k. PMID: 8560308.
- 2) McGee, H. M. (2001). Chronic Illness: Quality of Life. In N. J. Smelser & P. B. Baltes (Eds.), International Encyclopedia of the Social & Behavioral Sciences (pp. 1779-1782). Pergamon. <https://doi.org/10.1016/B0-08-043076-7/03825-0>

# Morphine Milligram Equivalent (MME) Calculation

As of FY 23, the NIH HEAL Initiative requires that clinical pain studies monitor legitimate prescription opioid use reported in morphine milligram equivalents (MME).

Studies must report the following information:

- Name of opioid
- Dose of opioid
- Prescription duration
  - Total days exposed (if different from prescription duration)
  - Days elapsed during follow-up, hospital stay or enrollment (if different)
- MME conversion factor **pdf 83.69 kb**
  - If known: MME value
    - If MME value is provided, please indicate how it was calculated (i.e., Total Days Supply, On-therapy Days, Fixed Observation Window, or Maximum Daily Dose)

# 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, but the benefits include:

- **Compare** questionnaires being used between similar studies
- Coding and collecting data (in addition to the core CDEs) for the HEAL Data Ecosystem – **data harmonization**

# Public HEAL CDE Repository

The HEAL CDE program recently added a public HEAL CDE repository to make CDEs more accessible and foster data harmonization beyond HEAL.

- ~ 290 questionnaires and CDEs have been uploaded into this repository
- Link to the Public Repository:

<https://heal.nih.gov/data/common-data-elements-repository>

Enter Keywords  Search

[Download List](#)

► Selected 0 items  
 Select / deselect all results (all pages, 299 total)

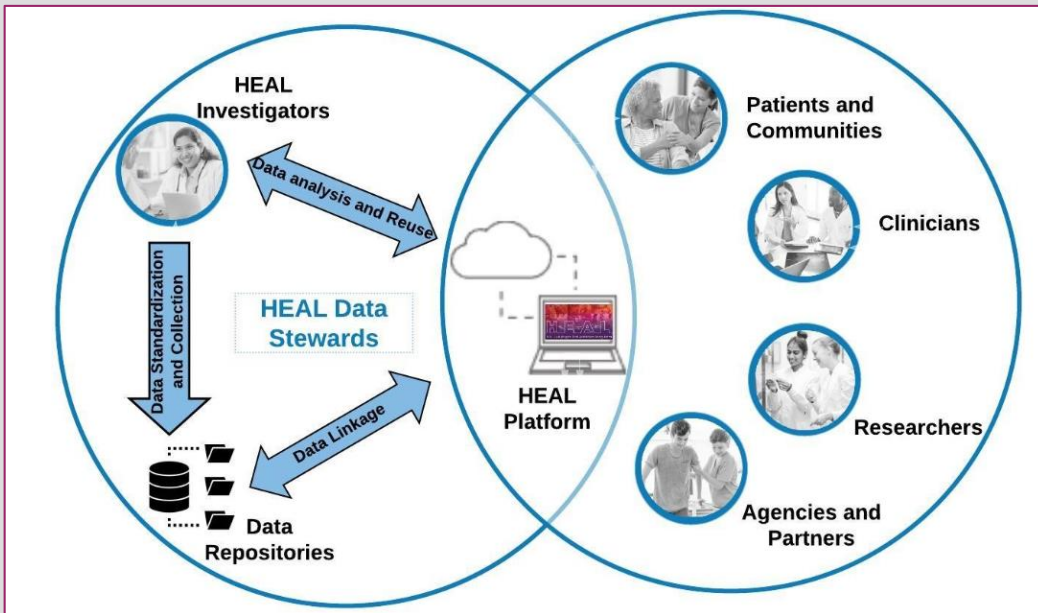
Select All	Description	File Name	Core or Supplemental	File Language
<input type="checkbox"/>	The Generalized Anxiety Disorder 2 (GAD-2) is an initial screening tool for generalized anxiety disorder.	<ul style="list-style-type: none"><li>gad2-crf (docx, 26.54 KB)</li><li>gad2-cdes (xlsx, 22.73 KB)</li></ul>	<ul style="list-style-type: none"><li>Adult Chronic</li><li>Adult Acute</li><li>Pediatrics</li></ul>	English
<input type="checkbox"/>	The Generalized Anxiety Disorder 2 (GAD-2) is an initial screening tool for generalized anxiety disorder.	<ul style="list-style-type: none"><li>gad2-crf-spanish (docx, 27.2 KB)</li><li>gad2-cdes (xlsx, 22.73 KB)</li></ul>	<ul style="list-style-type: none"><li>Adult Chronic</li><li>Adult Acute</li><li>Pediatrics</li></ul>	Spanish

# HEAL CDE Reference

- The HEAL pain CDE program website:
  - <https://heal.nih.gov/data/common-data-elements>
- NIH paper summarizing the HEAL CDE program. Please use the reference in future journal articles.
  - Wandner, LD, Domenichiello, A.F., Beierlein, J., Pororzala, L., Aquino, G., Siddons, A., Porter, L., Atkinson, J., and NIH Pain Consortium Representatives. (2022). NIH's Helping to End Addiction Long-term Initiative (NIH HEAL Initiative) Clinical Pain Management Common Data Element Program. *Journal of Pain*, 23(3), 370-378.

# HEAL Data Ecosystem

- **Goal:** Share HEAL-generated data among researchers, healthcare providers, community leaders, policymakers, stakeholders who can learn from results of research
- **How:** investigators upload data to repositories, data is made available on the Data Ecosystem (virtual, annotated, searchable catalog), datasets and findings from different studies can be analyzed, compared, and combined



## NIH HEAL Semantic Search

Enter a term to search for related concepts and studies

pain intensity

Search

### Dig Deeper into HEAL Data with Semantic Search

Recognizing the urgency and difficulty of addressing the pain and opioid public health crises, the **NIH HEAL Initiative**® has funded more than 1000 research studies to speed solutions. This wealth of information provides unprecedented opportunities for new discoveries in the pain and addiction research landscape, enabling novel treatment development. However, searching for relationships across HEAL studies is challenging due to the diverse research methods and data types.

HEAL Semantic Search provides a smart way to explore the HEAL research landscape by incorporating concept knowledge, synonyms, and relationships. Users do not need specific keywords or access to actual datasets to:

- Discover related biomedical concepts, studies, and variables.
- Identify datasets and variables for further analysis.

# Roadmap to Sharing HEAL Data: Expectations

## Step by Step Guide for HEAL-Compliant Data

This roadmap guides HEAL-funded investigators in complying with the [HEAL Public Access and Data Sharing Policy](#). Regardless of when you received your HEAL award, please start at the beginning, as the steps are generally in chronological order.



### Award Received

Congratulations on your HEAL award! This roadmap will guide you through the steps to complying with the [HEAL Public Access and Data Sharing Policy](#).

#### Related Links

- [Guidance for complying with the HEAL Data Sharing Policy](#)
- [NIH Policy for Data Management and Sharing, going into effect January 2023](#)

CONTINUE



Provide your Data Management and Sharing Plan to the HEAL Stewards

Clinical  
Trials.gov

Register your Study on ClinicalTrials.gov



Register your Study with the HEAL Data Platform



Complete your Study-level Metadata Form



Select a Repository



Use HEAL Common Data Elements to Collect Your Data



Submit Data and Metadata to a Repository



Report your Research Publication

# HEAL Data Ecosystem Registration

Please review HEAL's data sharing requirements.

- Select a HEAL compliant repository for long-term data storage:  
<https://www.healdatafair.org/resources/guidance/selection>
- Register your HEAL study in the HEAL Data Platform:  
<https://heal.github.io/platform-documentation/study-registration/>
- Submit metadata to the HEAL Data Platform:  
[https://heal.github.io/platform-documentation/slmd\\_submission/](https://heal.github.io/platform-documentation/slmd_submission/)

For more information, see: <https://www.healdatafair.org/>

# Questions?



Please feel free to contact: [Laura.Wandner@nih.gov](mailto:Laura.Wandner@nih.gov) OR  
[HEAL\\_CDE@hsc.Utah.edu](mailto:HEAL_CDE@hsc.Utah.edu)

# CDE DEVELOPMENT PROCESS

**Katherine Sward, PhD, RN, FAAN**

Professor, College of Nursing & Department of Biomedical Informatics  
MPI, HEAL-ERN Data Coordinating Resource Center



# METADATA

- “Data about data”
- Summarizes basic information - can make tracking and working with specific data easier
- Examples: author, date created
- Optimally, both machine and human readable
- CDE are a type of metadata
- HEAL data ecosystem uses CDE as part of their search infrastructure
- Helps make the study “Findable”, “Interoperable”, and “Reusable” (FAIR criteria)
- HEAL data ecosystem has “study level” metadata (information about the study) and “variable level” metadata (information about the variables collected).

# NIH CDE REPOSITORY

NIH National Library of Medicine



CDEs Forms My Boards About Help KSWARD

## 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 All CDEs

 Search NIH-Endorsed CDEs

Search Forms

Search by topic, keyword, or organization



*CDEs in the Repository have been submitted by NIH recognized bodies.*

# HEAL CDE REPOSITORY

The screenshot shows the top portion of a web browser displaying the URL <https://heal.nih.gov/data/common-data-elements-repository>. The header includes the U.S. Department of Health & Human Services and National Institutes of Health logos. The NIH HEAL Initiative logo is prominent, followed by a search bar with a 'Search' button. A navigation menu contains links for 'About', 'Research', 'Data', 'Funding', 'News & Events', and 'Resources', each with an upward-pointing arrow. Below the menu is a breadcrumb trail: 'Home / Data / Common Data Elements (CDE...'.

## Common Data Elements (CDEs) Repository

The NIH HEAL Initiative's [Common Data Elements \(CDEs\) program](#) aims to harmonize the data collected by the initiative's studies, enhancing the comparability of various data sets generated by HEAL research.

HEAL researchers and potential applicants conducting research with human participants should also prioritize using the HEAL CDEs. Researchers outside the HEAL Initiative conducting pain research may also be interested in using validated and structured questionnaires.

The “core” questionnaires in ten domains, demographic information, and opioid usage are required for the clinical pain HEAL grants and are organized depending on the type of pain and population being studied.

### + Using the CDEs Repository

Enter Keywords

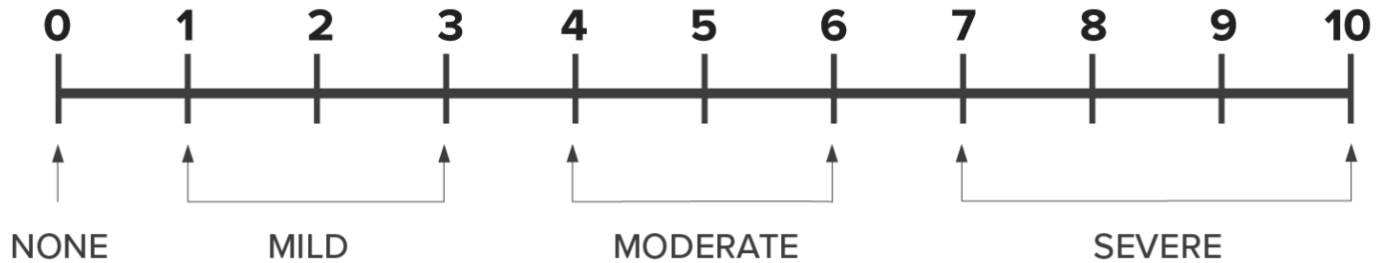
# WHY CDE?

## DATA SHARING & RE-USE

### Example: Pain Scales

Let's look at an example of data gathering from healthcare. These are two pain scales.

#### 0 - 10 Numeric Pain Rating Scale



#### Categorical Scale



# WHAT IS A CDE

- A common data element (CDE) is a standardized, **precisely defined question ...**
- paired with a set of **specific allowable responses**
- Multiple CDE may be grouped together as an instrument (e.g., a specific questionnaire)

Common data elements are developed so that data can be collected in the same way across multiple research studies

Help you to understand what the data actually represent, in a study dataset.

# HEAL CDE PROCESS

## NEW INSTRUMENTS (SUPPLEMENTAL – “BEYOND THE CORE”)

- Initial efforts – started in the HEAL “pain” arm. Opioid arm is beginning development.
- CDE development process starts with the questionnaires and CRF that are planned for use, for human-scale HEAL research

### Steps of CDE development

#### Step 1. Identify the need

- Studies submit questionnaire or form.
- CDE project managers check if the questionnaire already exists (or if a similar questionnaire exists)

# HEAL CDE PROCESS

## 1. IDENTIFY THE NEED

- Compare submitted instrument to published version (or if already in HEAL – compare to the current HEAL version).
  - Instrument “drift” is common
- Search information about the questionnaire – is it a validated instrument, is the instrument protected by copyright, etc.
- Locate scoring instructions, if any

# HEAL CDE PROCESS

## STEP 2. PLANNING

- Analyze instrument. Not always clear what is the best way to represent the data (e.g., for a log or repeated question with unspecified number of repeats; or for deeply embedded skip logic

- Assign to CDE developer
- Track progress

HEAL Common Data Elements  
Kanban board

QUICK FILTERS: Non-PM Tasks PM Tasks Only My Issues Recently Updated

Board

You can enable your Kanban backlog later at Board configuration - Columns

TO DO 21

- Tableau Changes - March batch
- HEALCDE-461 RUCA Updates
- HEALCDE-365 New studies confirmation
- HEALCDE-436 REDCap Data Dictionary FAQ
- HEALCDE-480 Match networks on master list to REDCap

IN PROGRESS 9

- HEALCDE-315 Initiating OUD Project
- HEALCDE-367 OUD Tableau
- HEALCDE-484 Quality check for OUD/ SUD data
- HEALCDE-386 Status for MD Anderson Lic...
- HEALCDE-462 BPI Verification and Send to PI
- HEALCDE-376 Obtain MapiTrust Copyright ...
- HEALCDE-465 PCS Verification and Send to PI

UTAH REVIEW 13

- Status for MD Anderson Licenses pdf's
- HEALCDE-376 Obtain MapiTrust Copyright WO
- HEALCDE-448 Cognitive Emotional Regulation Questionnaire-CERQ
- HEALCDE-418 Penn Online Evaluation of Migraine
- HEALCDE-421 PhenXToolkit Demographic

NIND REVIEW 1 OF 23

FINALIZED 3 OF 359

- Existing Studies Confirmation

We're only showing recently modified issues.  
Looking for an older issue?

<https://www.section508.gov/>

# HEAL CDE PROCESS

## STEP 3. DEVELOP CASE REPORT FORM

*Brief Pain Inventory Pain Severity*

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

1) Please rate your pain by marking the number that best describes your pain at its worst in the last 24 hours.

\_0 \_1 \_2 \_3 \_4 \_5 \_6 \_7 \_8 \_9 \_10

No pain Pain as bad as  
you can imagine

2) Please rate your pain by marking the number that best describes your pain at its least in the last 24 hours.

\_0 \_1 \_2 \_3 \_4 \_5 \_6 \_7 \_8 \_9 \_10

No pain Pain as bad as  
you can imagine

3) Please rate your pain by marking the number that describes your pain on average in the last 24 hours.

\_0 \_1 \_2 \_3 \_4 \_5 \_6 \_7 \_8 \_9 \_10

No pain Pain as bad as  
you can imagine

4) Please rate your pain by marking the number that tells how much pain you have right now.

\_0 \_1 \_2 \_3 \_4 \_5 \_6 \_7 \_8 \_9 \_10

No pain Pain as bad as  
you can imagine

- Step 3. “508-compliant” Case Report Form
- 508-compliance is about digital accessibility – making the form readable by a screen reader

<https://www.section508.gov/>

# HEAL CDE PROCESS

## STEP 4. CDE DETAIL FILE

- Step 4. Develop the CDE detail
- Assign variable names
- Develop definitions
- A challenge – “choose all that apply” questions

CDE Name	Variable Name	Definition
Brief Pain Inventory (BPI) - worst pain rating scale	BPIWorstPainRatingScl	Scale indicating the rating of the worst pain, as part of the Brief Pain Inventory (BPI) form.
Brief Pain Inventory (BPI) - least pain rating scale	BPILeastPainRatingScl	Scale indicating the rating of the least pain experienced by the subject, as part of the Brief Pain Inventory (BPI) form.

# HEAL CDE PROCESS

- Define allowable values

Additional Notes (Question Text)	Permissible Values	PV Description	Data Type
Please rate your pain by marking the number that best describes your pain at its worst in the last 24 hours.	0;1;2;3;4;5;6;7;8;9;10	0 = No pain;.....;10 = Pain as bad as you can imagine	Numeric Values
Please rate your pain by marking the number that best describes your pain at its least in the last 24 hours.	0;1;2;3;4;5;6;7;8;9;10	0 = No pain;.....;10 = Pain as bad as you can imagine	Numeric Values

# HEAL CDE PROCESS

Then...

- Review/validate
- Publish (make the CDE available)



# HEAL CDE

## CALL TO ACTION

- Call to action – use CDE when possible, in planning your study data collection.
- CDE makes it easier for data to be combined across studies, or re-used for secondary analyses.



# THANK YOU

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[heal\\_cde@hsc.utah.edu](mailto:heal_cde@hsc.utah.edu)



Common Data Elements: Experiences from the NIH  
HEAL Initiative, the Effectiveness Research Network,  
the IMPOWR Network,  
and the Harm Reduction Research Network



# Co-Creating the Harm Reduction Research Network Common Data Elements



Lissette M. Saavedra, Ph.D.  
RTI International

Presented at the 45<sup>th</sup> Annual Meeting of the Society for Clinical Trials,  
May 22, 2024

# Disclosures

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- No financial support from for-profit businesses
- Funding from NIDA R24DA057611

Work reported in this presentation was supported by the National Institute on Drug Abuse of the National Institutes of Health under award number R24DA057611 (MPI: Oga and Cance).

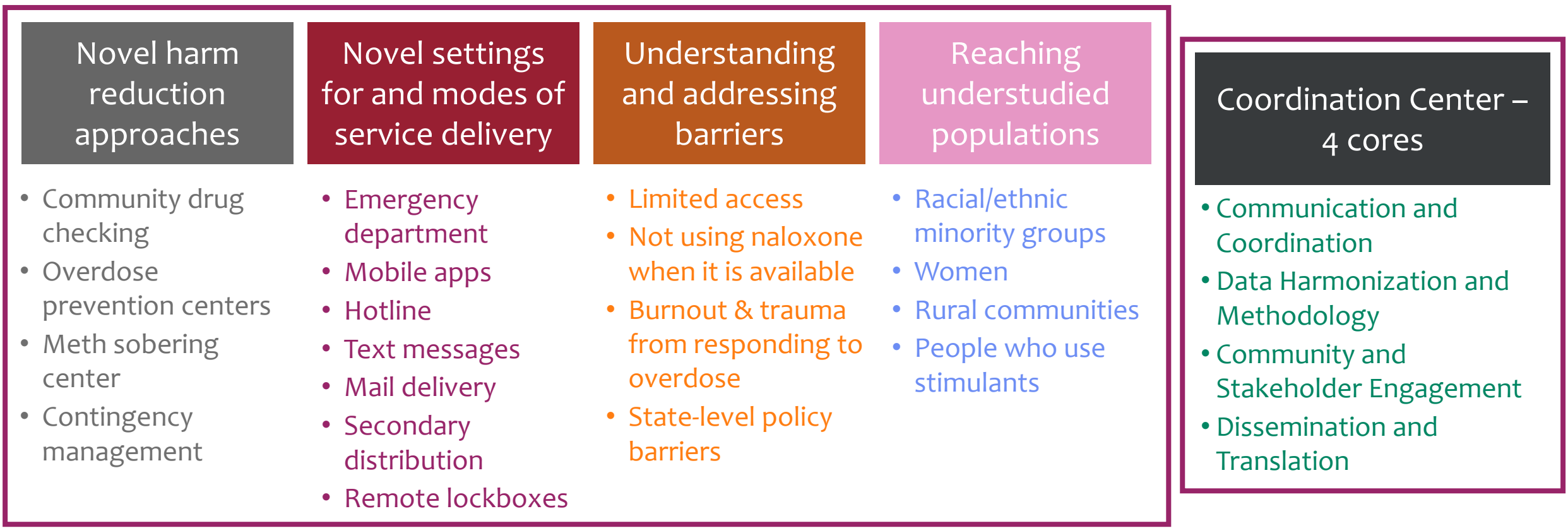
The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

# Harm Reduction Research Network – Purpose & Goals

- **Purpose:** Increase our understanding of the effectiveness, implementation, and impact of existing and new harm reduction strategies
- **Priority Goals:**
  - *Conducting high-quality research to answer critical research questions*
  - *Providing a space to share ideas and collaborate*
  - *Working with, learning from, and disseminating findings to community members and other stakeholders*
  - *Preventing overdose and saving lives*

Adapted from Zur (2022)

# Harm Reduction Research Network (10 R01s, 1 R24)



***\*All have a CAB and/or PWLE in paid positions; the RTI CC also convenes a quarterly CEC***

# Harm Reduction Research Network – PIs

- **Emmanuel Oga & Jessica Cance** (*RTI International*)
- **Czarina Behrends** (Weill Medical College of Cornell University)
- **Magdalena Cerdá** (NYU Grossman School of Medicine) & **Brandon Marshall** (Brown University)
- **Ayana Jordan** (NYU Grossman School of Medicine)
- **Alex Kral** (RTI International)
- **Todd Korthuis** (Oregon Health and Science University)
- **Mai Tuyet Pho** (University of Chicago) & **Mary Ellen Mackesy-Amiti** (University of Illinois-Chicago)
- **Susan Sherman** (Johns Hopkins University)
- **Karla Wagner** (University of Nevada-Reno)
- **Ryan Westergaard** (University of Wisconsin-Madison) & **David Seal** (Tulane University)
- **Deanna Wilson** (University of Pennsylvania)



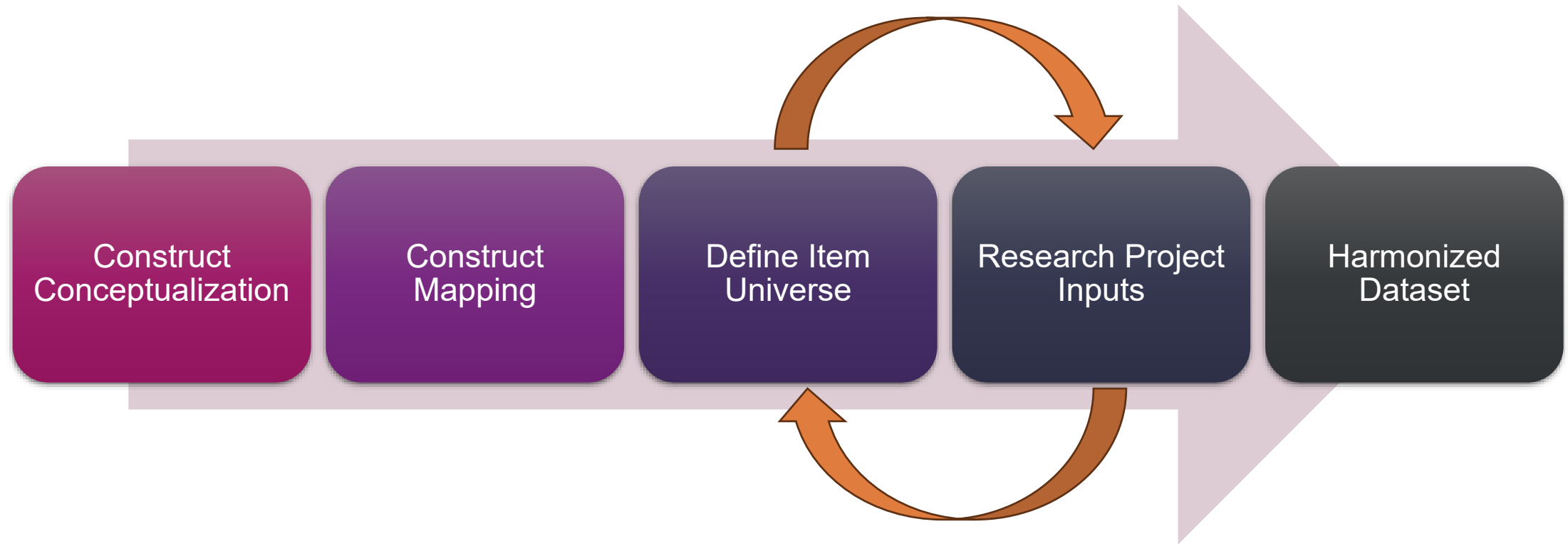
# Harm Reduction Core Concepts

- Offers a non-judgmental, non-coercive provision of services and resources for people who use drugs and the communities in which they live to assist them in reducing attendant harm.
- Establishes quality of individual and community life and well being - not necessarily cessation of all substance use - as the criteria for successful interventions and policies.
- Ensures that people who use drugs, and those with a history of substance use, have a real voice in the creation of programs and policies designed to serve them.

Adapted from the National Harm Reduction Coalition (<https://harmreduction.org/about-us/principles-of-harm-reduction/>)

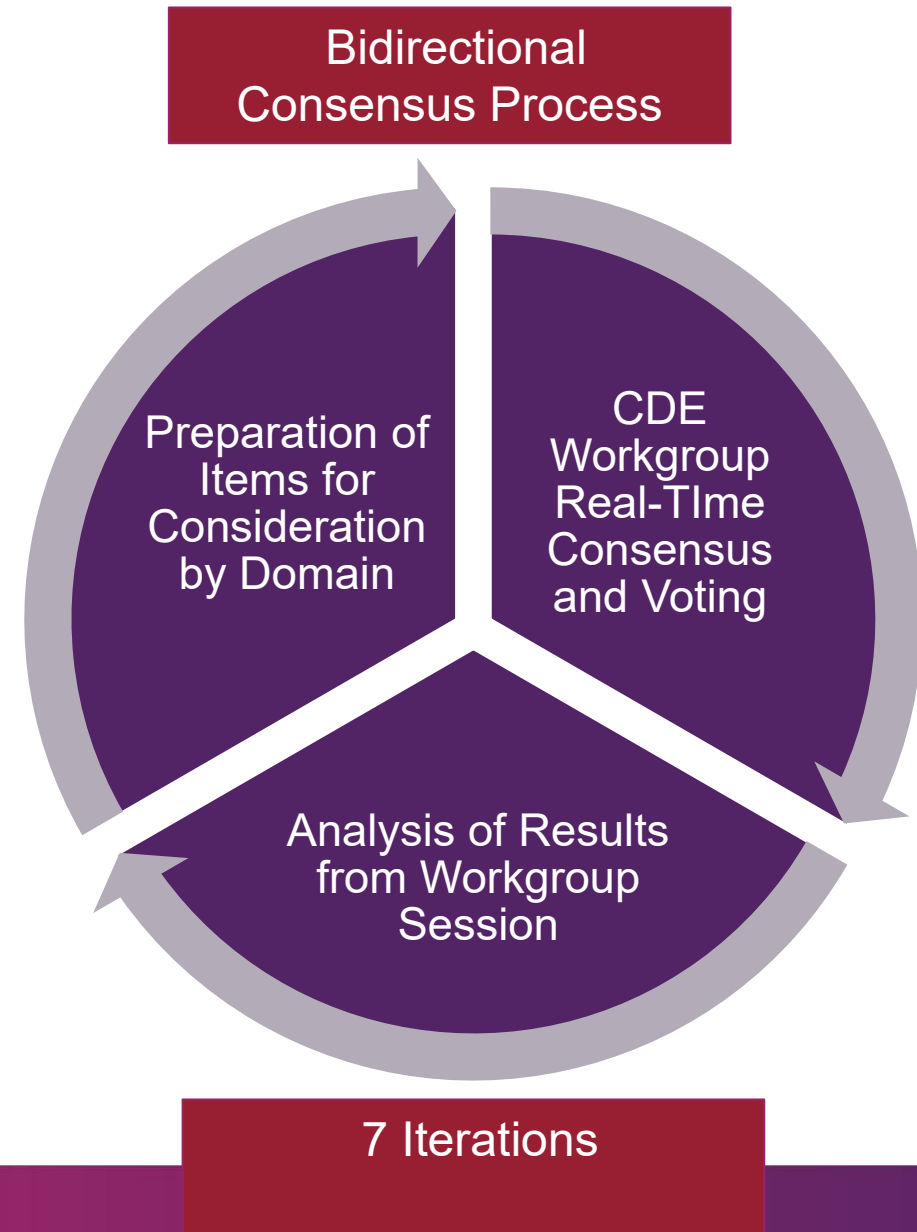
# Establishing Common Data Elements

*Standardized, uniform data collection terms and definitions used consistently across different studies and research projects*



# Process: Delphi Model

- The Delphi model is a methodological approach used to reach consensus that leverages expert input via iterative rounds of anonymous questionnaires.
- The Delphi method is often employed in the development of common data elements (CDEs).

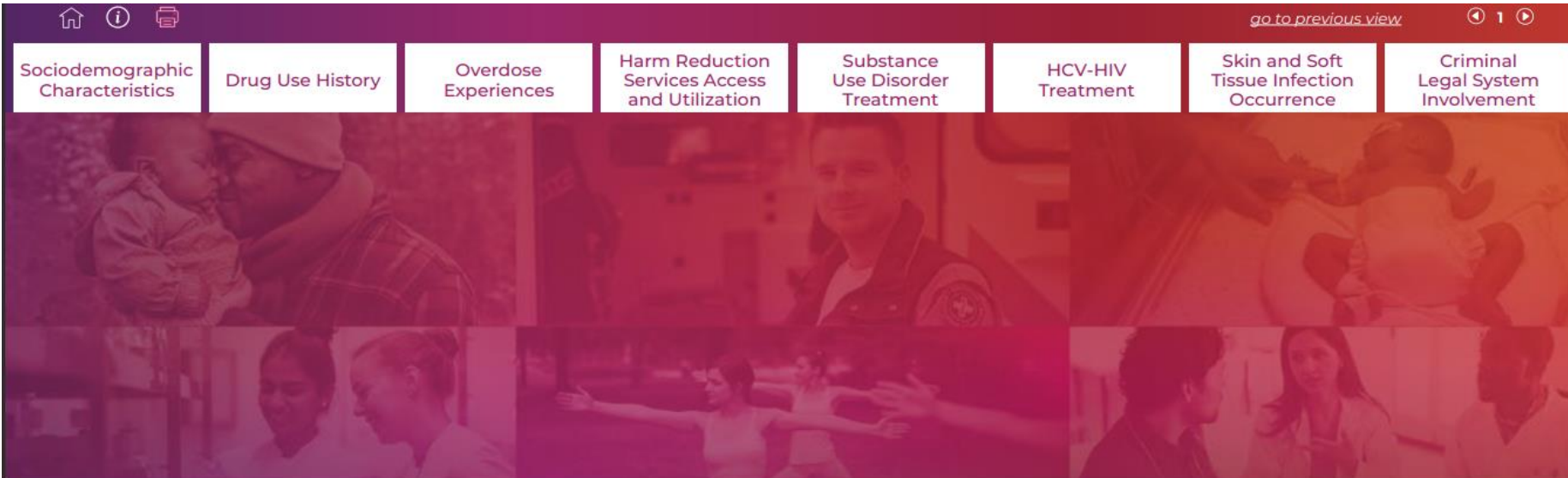


# HRRN Common Data Elements

- Constructs
  - Sociodemographic characteristics
  - Drug use history
  - Overdose experiences
  - Harm reduction services access and utilization
  - Substance use disorder treatment
  - Hepatitis C/HIV treatment
  - Skin and soft tissue infection occurrence
  - Criminal legal system involvement
- Tiers
  - Tier 1: Consensus
  - Tier 2: Overall commonality
  - Tier 3: Similar but variable

# Harm Reduction Research Network Outcomes

Outcomes	CU - Behrends	JHU - Sherman	NYU - Jordan	OHSU - Korthuis	Penn - Wilson	RTI - Kral	UC/UIC – Pho and Mackesy-Amiti	UNR - Wagner	UW/Tulane – Westergaard and Seal	NYU/Brown-Cerdá and Marshall
<b>Harm Reduction Service Utilization</b>	X	X	X	X	X	X	X	X	X	X
<b>OUD/SUD treatment (including Rx)</b>	X	X	X	X	X	X	X	X	X	X
<b>Drug use behaviors</b>	X	X	X	X	X	X	X	X	X	X
<b>Overdose</b>	X	X	X	X	X	X	X	X	X	X
<b>Social Determinants of Health</b>	X	X	X	X	X	X	X	X	X	X



**NIH  
HEAL  
INITIATIVE**

Harm Reduction  
Research Network

## HRRN Tier 1 Measures Common Data Elements Resource

2024

This document is an interactive PDF. For full functionality, download and save this file to your desktop. Use the tabs and arrow buttons at the top of the page to navigate between pages. Use "find" (<Ctrl> F) to search keywords.

» **SOCIODEMOGRAPHIC CHARACTERISTICS****1. How old are you?**

- a. \_\_\_\_ (in years)
- b. Don't know
- c. Prefer not to answer

**2. What is your gender?**

- a. Man
- b. Woman
- c. Gender-queer/Nonbinary
- d. Gender variant
- e. Questioning or unsure of my gender identity
- f. Something else: \_\_\_\_
- g. Don't know
- h. Prefer not to answer

**3. Do you identify as transgender?**

- a. Yes
- b. No
- c. Don't know
- d. Prefer not to answer

**4. Do you consider yourself to be Hispanic or Latino(a) or Latine/x?**

- a. Yes
- b. No
- c. Don't know
- d. Prefer not to answer

**5. If Q4 is Yes: Which ethnic group or groups do you identify as?  
(Select all that apply)**

- a. Mexican, Mexican American, Mexicano, or Chicano
- b. Puerto Rican
- c. Central or South American
- d. Cuban or Cuban American
- e. Dominican (from Dominican Republic)
- f. Spanish (from Spain)
- g. Something else: \_\_\_\_
- h. None of the above
- i. Don't know
- j. Prefer not to answer

# Value of Community Informed CDEs



Reflection on the broader impact of this prospective harmonization effort in advancing research methodologies



Recommendations for incorporating prospective data harmonization in upcoming projects



What HEAL harmonization can offer the field beyond the network



Encouragement for the research community to adopt similar practices in collaborative projects.

# Benefits of data sharing and harmonization

- Increased sample size in general
- Increased sample diversity
- Increased sample for rare events

# Methodological Challenges and Solutions

Measures/conceptualization vary across studies

- Time, age range, question wording and other contextual factors vary across studies
- Are differences across samples/studies real or are they just a result of the different settings, sampling processes, interventions etc.

Common Tier 1- same data element minor wording differences

- Maximize use of propensity score weighting
- Measurement invariance approaches local flexibility in capturing items

# Possibilities for Analytic Harmonization

- Network participation can allow creation of scores that account for measurement differences
- **Moderated Non-Linear Factor Analysis**
  - Creation of factors scores accounting for differential item functioning
    - Potential predictors: study, age, race/ethnicity, gender, site
- **Exploration of Measurement Non-invariance:**
  - Allow the Network to examine whether respondents from different groups interpret the same measure in a conceptually similar way

# Unique Challenges In Harm Reduction

- **Community centered:** Harm reduction hinges on its grassroots nature and its ability to adapt to the specific needs and dynamics of research projects within their communities.
- **Rapidly changing landscape:** the harm reduction landscape is constantly evolving in response to emerging trends, public health crises, and policy shifts. New substances, technologies, and socio-political factors impact the effectiveness and relevance of data collection methods.
- **Diversity of projects:** Each project has unique goals, target populations, and strategies, making it difficult to standardize data collection.

# Additional Strategies for Buy In

- **Capacity Building:** Provide training and technical assistance to project staff on data collection methodologies, ensuring consistency and quality.
- **Integration and Coordination:** Foster partnerships and networks to facilitate data sharing, integration, and coordination among projects and organizations.
- **Practical Guidance for PIs and their teams**
- **Ethical Guidelines:** Develop and adhere guidelines for data collection, storage, and sharing/archiving, prioritizing participant protection.

# Here is our Village

**NIDA:** Julia Zur

**RTI International:** Emmanuel Oga; Jessica Cance; Kayla Keys; Lissette Saavedra; Mia Christopher; Dora Illei; Bradley Ray

**Research Projects and Community Partners:** Czarina Navos Behrends; Aaron Fox; Catherine Tomko; Susan Sherman; Angela Lee-Winn; Ayana Jordan; Charla Nich; Leo Beletsky; Maria Khan; Sharifa Williams; Hira Hassan; Magdalena Cerda; Brandon Marshall; Alex Macmadu; Bennett Allen; Alexis Cooke; Erin Stack; Ryan Cook; Todd Korthuis; Cristina Murray-Krezan; J. Deanna Wilson; Alex Kral; Cari Megerian; Basmattee Boodram; Mai Tuyet Pho; Mary Ellen Mackesy-Amiti; Annick Borquez; Karla Wagner; Minggen Lu; David W Seal; Mikaela Becker; Ryan Westergaard; Carmella Brown

# Questions?





CDE Edition  
When data stops being  
polite and starts getting  
real

2024  
BOSTON

SCT | 45TH  
ANNUAL MEETING

**Megan Ghirolì**  
**Research Project Director**  
**Montefiore Medical Center/Albert Einstein**  
**College of Medicine**

# Disclosures

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- No relevant disclosures

# Real World Considerations for CDE Implementation

Community  
Engagement

Question order and  
design

Translation

Accurate collection  
of CDEs: Ongoing  
and real time QA to  
ensure

# Community Engagement General Principles

**Community engagement involves collaborating with stakeholders, including individuals, organizations, and groups, to develop common data elements.**

**Importance: Ensures that data elements are relevant, accepted, and effectively address the needs of all stakeholders.**

# Community Engagement



- **When developing CDEs/choosing which ones to use for your study/network and piloting them, reach out to your community members or community board for feedback.**
- **Be forthcoming with the community about what you are able to change and what you may not be able to change.**
- **Try to incorporate feedback as much as possible.**

# How many assessments are you asking?

- **How many CDEs are you required to ask? Pilot how long it takes to answer all questions.**
- **What other questions do you want to know for your study population?**
- **How long do these take to answer?**
- **Test your whole battery of assessments**
- **Try to avoid very long battery of assessments to avoid participant fatigue**



# How will your questions be answered?



Participants completing surveys or questionnaires on their own

Interview with research or clinical staff



# Data Reliability

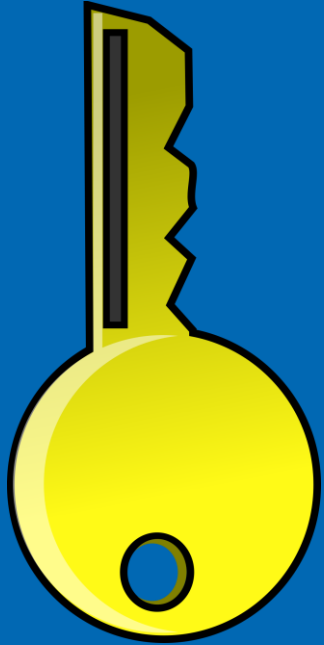
- Data reliability refers to the consistency, accuracy, and dependability of data over time, ensuring it is trustworthy and usable for decision-making.



[This Photo](#)

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# Key Aspects of Data Reliability



- Accuracy: Data correctly reflects the real-world values and conditions.
- **Consistency: Data remains uniform across different datasets and over time.**
- **Completeness: All necessary data is present without any omissions.**
- **Timeliness: Data is up-to-date and available when needed.**
- Validity: Data conforms to the required formats and standards.






# Changing wording of CDEs

- Should be strongly avoided, can affect the reliability of the measures you are looking at
- Are there any variations within the specific population being studied in your research that might necessitate adjustments for better understanding of specific language used, (translations)?
- Check in with Study Principal Investigators and/or network PIs or leadership prior to implementing your proposed changes to **any** of the questions.

# Design of CDEs in your data system






Reading each question to ensure clarity, especially for questions directly answered by participants

# Example of Participant facing question that would benefit from rewording

     Variable: moudbup\_lifemo Branching logic: [moudbup] = "1"



**Buprenorphine-naloxone or buprenorphine daily sublingual (e.g., Suboxone© film or tablet, generic films or tablets, or Subutex tablets) Lifetime months?**

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)






     Variable: moudbup\_6modays Branching logic: [moudbup\_lifemo] > 0

**Buprenorphine-naloxone or buprenorphine daily sublingual (e.g., Suboxone© film or tablet, generic films or tablets, or Subutex tablets) Past 6 months/since last assessment days used?**

# Reworded with the same spirit/intention of the question






[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

     Variable: moudbup\_lifemo Branching logic: [moud\_type(1)] = '1'

**How many months in your lifetime have you taken Buprenorphine-naloxone or buprenorphine daily sublingual (e.g., Suboxone© film or tablet, generic films or tablets, or Subutex tablets)?**

@C5209216

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

     Variable: moudbup\_6modays Branching logic: [moud\_type(1)] = '1'

**How many days in the past 6 months/since your last assessment have you used Buprenorphine-naloxone or buprenorphine daily sublingual (e.g., Suboxone© film or tablet, generic films or tablets, or Subutex tablets)?**

@C5209216

# Determining order of questionnaires

- How will the order of your questions help you build rapport?
- Grouping questionnaires by topic
- If you have the option, not starting the interview with emotionally heavy topics such as PTSD or suicidality questions

# Translation into other languages

**Promis Sf V10 Pain Interference 4a Heal** AAA

English

Please complete the survey below.

Thank you!

Por favor complete la encuesta a continuacion.

Gracias!

In the past 7 days,  
En los últimos 7 días,

	English	Little bit	Somewhat	Quite a bit	Very much
1) How much did pain interfere with your day to day activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) How much did pain interfere with work around the home?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) How much did pain interfere with your ability to participate in social activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) How much did pain interfere with your household chores?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Español

How many languages do you need your database in?

Are your CDEs already certified and available in the language you need?

What does your IRB require for a form to be translated? (e.g. there may be translation services or two bilingual staff members may be able to provide necessary requirements)?

# Translation into other languages



How many instruments do you have to translate?



What kind of other support do you need to complete translations (e.g financial, staff time)?



Option of starting in primary language first and adding second language as soon as you can.



What does your multilingual language model look like (some codes may not work with your multilingual model)?

# Quality Assurance

- You can create fields that track percentage of questions answered. This is particularly helpful for your questionnaires that are filled out directly by your participants.
- Also helpful for tracking your primary outcome responses

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#)

**Field Type:** Calculated Field

**Field Label:** Percent Questions Answered  Use the Rich Text Editor [?](#)

**Calculation Equation:** [How do I format the equation?](#) [Learn how to use](#) [Special Functions](#)

100 \* if([promisavgpainrtnp7dsc] <> "",1,0) / 1

Test calculation with a record: -- select record -- [Clear calculation](#)

**Action Tags / Field Annotation (optional):** @HIDDEN

# Quality Assurance

Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Percent Questions Answered pct_answ_fabqpa
Week 0			0
Week 0			100
Week 0			100
Week 0			100
Week 0			100
Week 0			100
Week 0			100
Week 0			100
Week 0			100
Week 0			100
Week 0			100

- Create similar reports to keep track of percent questions answered.
- Address missing questions in real time
- Helpful for long study visits with many questionnaires that are completed
- Participant direct entry questions

# Questions

Thank  
You!

Megan Ghioli

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