



NIH
HEAL
INITIATIVE

HEAL Pain Common Data Elements (CDE) Program

Laura Wandner, PhD
Program Director
OPPP, NINDS

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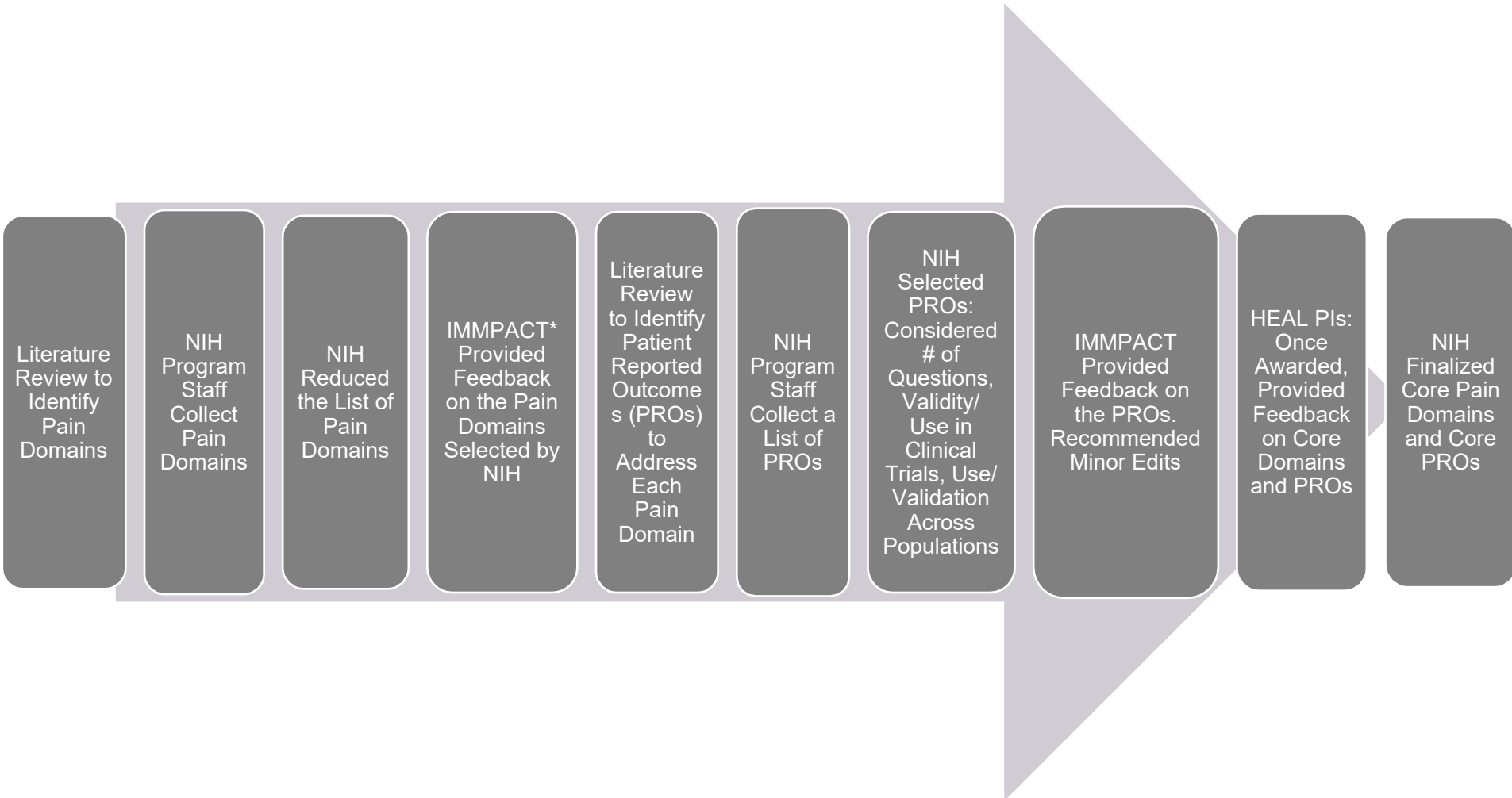
National Institutes of Health
HEAL Initiative

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.
- Unprecedented opportunity for the pain research community to access quality and meaningful 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 report 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 **WILL NEED** to use the HEAL CDE Details -- variable names, coding, etc.
- Core Demographics were re-released on 3/16/20
 - Demographics were made CDISC compliant.
- Core Spanish CRFS were released on 9/10/21

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		

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*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.

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

- **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 of the clinical pain programs and/or studies.
- 475 distinct supplemental questionnaires have been submitted to the NIH for this initiative.

Accessing the NIH CDE Box Account

- The Core and Supplemental Measures can be found on the NIH HEAL CDE Box account.
 - Studies will need to use the variable names and coding provided by the HEAL CDE program.
- Your HEL team will need to request access to the NIH HEAL CDE Box account
 - Contact:
Laura.Wandner@nih.gov

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HEAL CDE Reference

- The HEAL pain CDE program has a website:
 - <https://heal.nih.gov/data/common-data-elements>
- The NIH has written a journal article 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.

Questions?



Please feel free to contact me: Laura.Wandner@nih.gov