### NIH HEAL INITIATIVE

### National Institute of Nursing Research Council Meeting May 24, 2022

Rebecca Baker, Ph.D., Director, NIH 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.

### An Evolving Crisis of Opioid Misuse, Overdose, and Pain

widespread unbearable tiring expanding throbbing tight pins-and-needles deep bites pass-out-pain draining weird expletive crawling-sensation weird pulsing white-blinding-pain vice-like tension stinging pain vice-like tension stinging pain sudden anticipated arthritic shooting stiff primordial aching hot/cold background aches intense dull drilling-bone sharp pin-pricks

In 2022, pain is still a huge unmet need

- 50 million Americans have chronic pain
- 25 million have severe pain
- 20 million have high-impact chronic pain

NCHS Data Brief. 2020 Nov;(390):1-8. PMID: 33151145



## The Response: NIH HEAL Initiative

- Over \$2 billion in research
- More than 600 research projects
- 32 research programs
- Projects underway in all 50 states
- Released 50+ funding announcements since inception
  - 30+ released in FY22!

From prevention, basic and translational research, clinical trials, to implementation science

#### NIH HEAL INITIATIVE RESEARCH OVERVIEW





## **OPIOID MISUSE and OVERDOSE**

#### Novel Therapeutics Options \$363M to date

• 50+ compounds, 20 INDs filed with FDA

#### Enhanced Outcomes for Infants and Children \$83M to date

- Treatment for infants exposed to opioids
- Impact of opioid exposure across child development

#### New Prevention & Treatment Strategies \$226M to date

- Optimizing care and addressing mental health comorbidities
- Prevention in at-risk groups
- Tools to identify high risk opioid use patterns for early intervention

#### Translating Research into Practice \$611M to date

- Behavioral interventions to improve treatment outcomes
- Treatments in justice and community-based settings



**Research Spotlights** 



Re-envisioning How the Criminal Justice System Responds to the Opioid Crisis

**Research Spotlights** 





## PAIN MANAGEMENT

#### Preclinical and Translational Research in Pain Management \$335M to date

- Novel targets and devices
- Screening and testing platforms, tissue chips, and optimization research
- Team based research frameworks

#### Clinical Research in Pain Management \$351M to date

- Testing novel non-opioid medications and interventions
- Clinical trials of innovative pain therapies
- Management of chronic pain and opioid use disorder







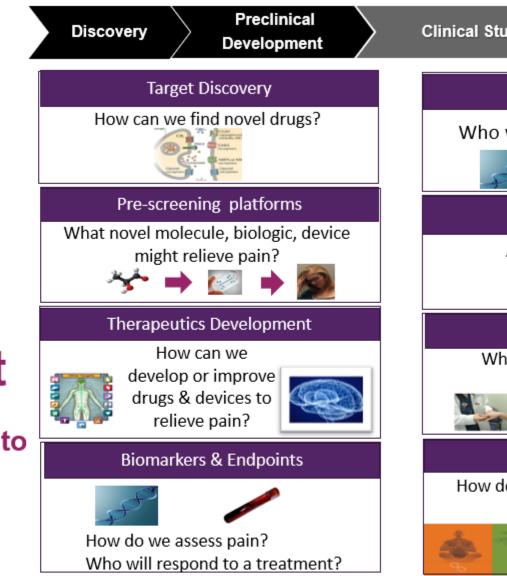
## **Progress This Past Year**





## HEAL Enhancing Pain Management

Accelerating Research to Improve Pain Care







### **Relevance of Nursing in HEAL Clinical Pain Research**

- Identify the most effective interventions and management strategies for pain while reducing reliance on opioids
- Improve functional and health outcomes
- Reduce pain across the continuum of acute to chronic pain associated with disease and pain presenting as disease itself
- Screen for chronic pain and opioid use disorder
- Address health inequities in pain and addiction
- Hear the voice of lived experience



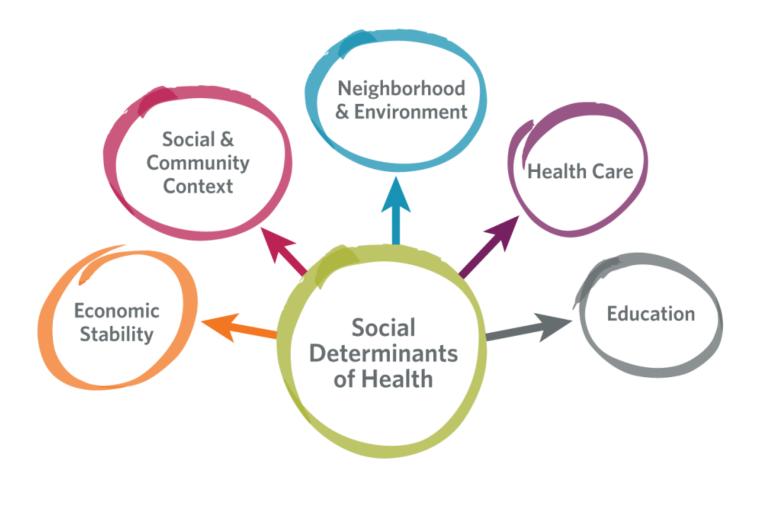
## HEAL Research Addresses Pain Across the Lifespan

- Back Pain Consortium
- Pain Management Effectiveness Research Network
- Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing
- Hemodialysis Opioid Prescription Effort consortium
- Integrative Management of chronic Pain and OUD for Whole Recovery



### Advancing Health Equity in HEAL Research

- Advancing Health Equity in Pain Management
- Preventing Opioid Misuse and Co-Occurring Conditions by Intervening on Social Determinants Advancing Health Equity in Pain and Comorbidities
- Coordinated Pain Care in Health Care Systems



## NIH Pain Training Opportunities

- National consortium of mentors, institutions, and promising scholars
- Postdoc to-independent career transition awards in pain, SUD research
- Translational Science Training for Early and Mid-career Investigators
- HEAL Innovator Awards
- Illuminating novel targets for pain therapeutics
- Coordinated approaches to pain care in health care systems



### **New HEAL Research Aligns with HHS Overdose Prevention Strategy:**

Evidence-Based Treatment + Prevention + Harm Reduction + Recovery Support

| Care Coordination and<br>Collaboration   | Health Equity  | Data-Driven Research  |  |
|--|--|---|--|
| <ul> <li>Research Adoption<br/>Partnerships</li> <li>Mental Health, OUD and<br/>Comorbidities</li> </ul> | <ul> <li>Sickle Cell Disease</li> <li>Social Determinants</li> <li>Pain and Comorbidities</li> </ul> | <ul> <li>Real World Healthcare Data</li> <li>Secondary Data Analysis</li> <li>Data2Action Partnerships</li> </ul> |  |
|  |  |   |  |
| Harm Reduction   | Evidence-Based<br>Treatments   | Preventing Overdose   |  |

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### **Open Funding Opportunities**



| FOA #             | FOA Title  | Research Focus Area   | Earliest Submission Date | Expiration Date | Posted Date     |
|-------------------|--|---|--------------------------|-----------------|-----------------|
| NOT-DA-22-<br>056 | Notice of Special Interest<br>(NOSI): Developing Digital<br>Therapeutics for Substance Use<br>Disorders  | Novel Medication Options for<br>Opioid Use Disorder and<br>Overdose | Wed, 04/06/2022          | Thu, 12/07/2023 | Fri, 02/18/2022 |
| RFA-NS-22-<br>050 | HEAL Initiative: Discovery of<br>Biomarkers and Biomarker<br>Signatures to Facilitate Clinical<br>Trials for Pain Therapeutics<br>(UG3/UH3 Clinical Trial<br>Optional) | Preclinical and Translational<br>Research in Pain Management        | Fri, 02/11/2022          | Fri, 02/24/2023 | Tue, 02/08/2022 |
| NOT-NS-22-<br>066 | HEAL Initiative: Notice of<br>Special Interest (NOSI)<br>regarding the Availability of   | Clinical Research in Pain<br>Management                             | Fri, 04/29/2022          | Sat, 04/30/2022 | Tue, 02/08/2022 |



## **New Research Directions for HEAL in 2023**

#### Care Coordination and Collaboration

- Pain Management in Rural Communities
- Multilevel Interventions for Patients on Long-term Opioid Therapy

#### **Health Equity**

- Medications for OUD in Diverse Groups
- Social Determinants of Addiction and Behavioral Health

#### **Data-Driven Research**

- Longitudinal Tracking of Opioid Exposures and Health Outcomes
- Piloting the HEAL Data Ecosystem

#### Evidence-Based Treatments

- Addressing Polysubstance Use
- Medication Development

#### **Preventing Overdose**

- Integrated Basic and Clinical Research
- High-throughput Tech
- Innovative Devices to Treat Pain

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#### https://heal.nih.gov/funding/research-concepts



Home / Funding / Research Concepts

### **Research Concepts**

A Research Concept describes the basic purpose, scope, and objectives of a potential solicitation of grants or contracts. Current concepts under development are listed below to alert researchers to areas of NIH HEAL Initiative research interest and to give researchers maximal lead time to plan projects. Past concepts that have converted to funding opportunities (FOAs) can be found at the bottom of the page. Please note that not every concept will lead to a FOA. The NIH HEAL Initiative bases this determination on scientific and programmatic priorities and the availability of funds, and a FOA may also differ in certain details from its originating concept. Please visit this page often for updates, subscribe to the HEAL Digest for updates, and view current (open) and past (closed) HEAL FOAs.

#### **Research Concepts on this page**:

- Translation of Research to Practice for the Treatment of Opioid Addiction
- New Strategies to Prevent and Treat Opioid Addiction
- Enhanced Outcomes for Infants and Children Exposed to Opioids
- Novel Medication Options for Opioid Use Disorder and Overdose
- Clinical Research in Pain Management
- Preclinical and Translational Research in Pain Management
- Past Concepts

Emerging Data Will Inform Practice

- Will acute pain turn chronic post-surgery?
- Who will respond to nonpharmacological treatments?
- How to identify risk for prevention beyond primary care?
- How to expand use of electronic health records
  - Tool for reducing provider bias
  - Capture patient preferences
- Diverse data: patient self-report, imaging, sensory testing, psychosocial assessments, more



## **HEAL Data Ecosystem**

#### Make HEAL data accessible (near-term)

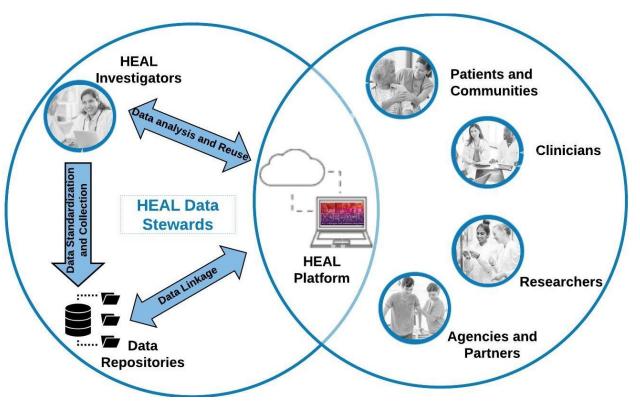
- HEAL-generated data indexed and searchable, with clear routes to access
- Data management & sharing support
- User-friendly search & interface

#### Build the community (ongoing)

- HEAL PI engagement and consensus-building, foster crossawareness of research projects and drive collaborations
- Broad researcher, stakeholder & user engagement

## Provide the 'sandbox' (near-term and building with time)

- Secure cloud computing
- Analytical tools
- Diverse, representative datasets
- Key overdose & pain datasets
- Data harmonization and reuse to address critical research questions





## **Cross Cutting Themes**

- Integrating pain and OUD research
- Health equity research, enhanced participant diversity
- Partnership with people with lived experience
- Research dissemination and the HEAL Data Ecosystem
- Adapting Research Interventions for COVID-19
- And much more ...

### JAMA

August 26, 2021

#### The Helping to End Addiction Long-term (HEAL) Initiative of the National Institutes of Health

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Nutional Institutes of Health HEAL Initiative

REPORT

ONLINE FIRST FREE

The Helping to End Addiction Long-term (HEAL) initia 2018 to provide scientific solutions to the evolve dedicated support from Congress, the HEAL initiative h than 500 projects nationwide, and plans to expand reserve efforts to develop more effective therapies for managin fective pain management strategies that limit addiction variety of settings.<sup>1</sup> The HEAL initiative joins the power an urgent public health need (see Table for selected reserve)

### Research in Action





### Voices of Lived Experience - HEAL Community Partner Committee







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Jessica Hulsey Nickel







- Patients, advocates, liaisons, and family members
- Input on key issues faced by individuals affected by pain and addiction
- Identify, refine, and prioritize engagement activities and links to HEAL science



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