



**NIH
HEAL
INITIATIVE**

**Multi-Disciplinary
Working Group
Spring Meeting**

March 1-2, 2022

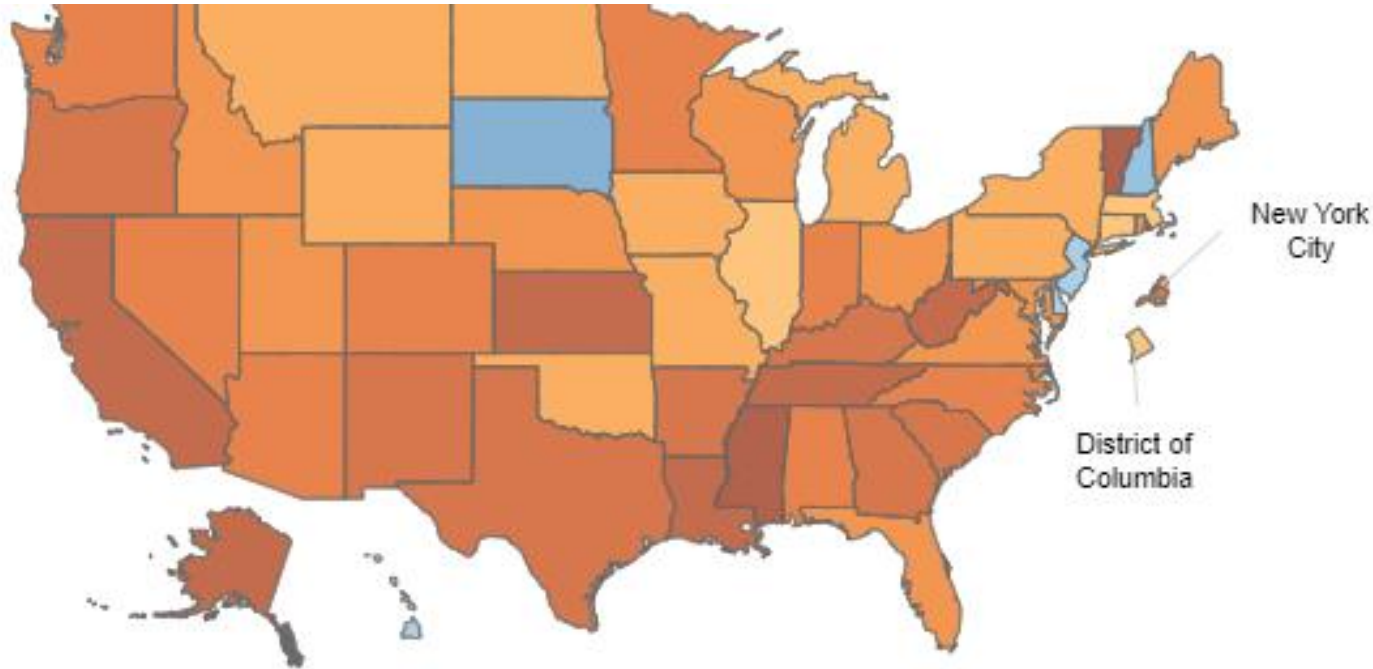




Helping to End Addiction Long-term Research Overview

Rebecca Baker, Director, NIH HEAL Initiative, Office of the Director, NIH

Crisis #1: National Overdose Deaths



21% increase in fatal drug overdoses in 12 months ending June 2021

Driven by powerful synthetic opioids like fentanyl and rising polysubstance use

10 Million Americans misuse opioids, at risk for OUD or overdose

Legend for Percent Change in Drug Overdose Deaths Between 12-Month Ending Periods



Over 100,000 Drug Overdose Deaths in last 12 months measured; National Public Health Emergency since 2017

Crisis #2: Pain in the United States

- 50 million adults affected by chronic pain
- 25 million report severe pain daily
- 20 million have high impact chronic pain
 - Risks associated with opioid medications
 - Challenges to high quality, multidisciplinary pain management

[CDC](#), Morbidity and Mortality Weekly Report, Sept. 2018



The Response: NIH HEAL Initiative

- Over \$2 billion in research
- More than 600 research projects
- 26 research programs
- Projects underway in all 50 States
- Released 50+ funding announcements since inception
 - **30+ open now!!**

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

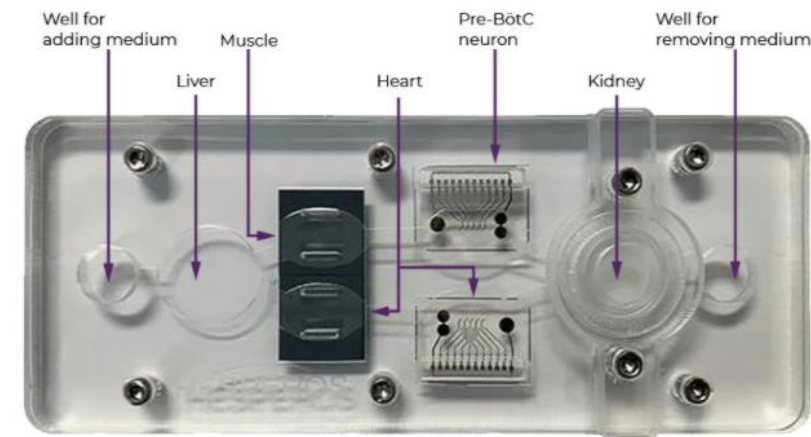
NIH HEAL INITIATIVE RESEARCH OVERVIEW



Preclinical and Translational Research in Pain Management

\$335M to date; non-addictive analgesic development programs

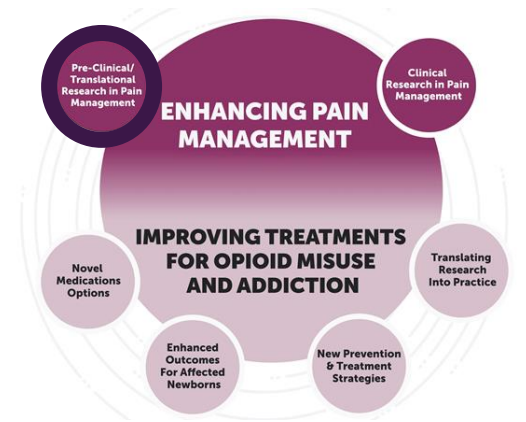
- Discovery and validation of novel targets for safe and effective pain treatment
 - 2 patents for small molecule modulators of pain receptors-chronic pain and migraine
 - Investigational New Drug (IND) for a first-in-class non-addictive drug candidate for the treatment of chronic pain
- Screening and testing platforms, tissue chips, and optimization research
- Devices to treat pain
 - Portable thermoelectric device to inhibit pain signals in two different peripheral nerves
- Team based research framework



Preclinical and Translational Research in Pain Management

\$335M to date; non-addictive therapeutic development programs

- **Launched in 2021:**
 - Expanded analgesic therapeutics development program- planning studies and phased awards
- **Planned for 2022:**
 - Devices for pain relief
 - Studying pain in human genes & cells
 - Restoring joint health and function (REJOIN)
 - HEAL Innovator awards



Clinical Research in Pain Management

\$351M to date; supports research to evaluate and compare pain management approaches

- Early Phase Preclinical Investigation Network (EPPIC Net)
 - New treatment for pain from knee osteoarthritis and diabetic neuropathy
- Back Pain Consortium (BACPAC)
 - Iterative model - precision medicine for chronic low back pain
- Hemodialysis Opioid Prescription Effort (HOPE)
 - Multidisciplinary pain management for people on kidney dialysis
- Pain Effectiveness Research Network (Pain ERN)
- Pragmatic and Implementation Studies for Management of Pain to reduce opioid prescribing (PRISM)
- Integrated Management of chronic pain and OUD (IMPOWR)



Data harmonization through core Common Data Elements

Clinical Research in Pain Management

\$351M to date; supports research to evaluate and compare pain management approaches

- **Launched in FY2021:**

- Integrated management of chronic pain and OUD (IMPOWR) program
- Focus on health equity in pain management: interventions to mitigate effects of bias, stigma and socioeconomic barriers to pain treatment

- **Planned for FY2022:**

- Quantitative imaging and biomarkers of myofascial tissues
- Enhancing the pain research workforce
- Secondary data analysis for acute and chronic pain



New Prevention & Treatment Strategies for Opioid Use Disorder

\$226M to date; develop new or improved prevention and treatment strategies

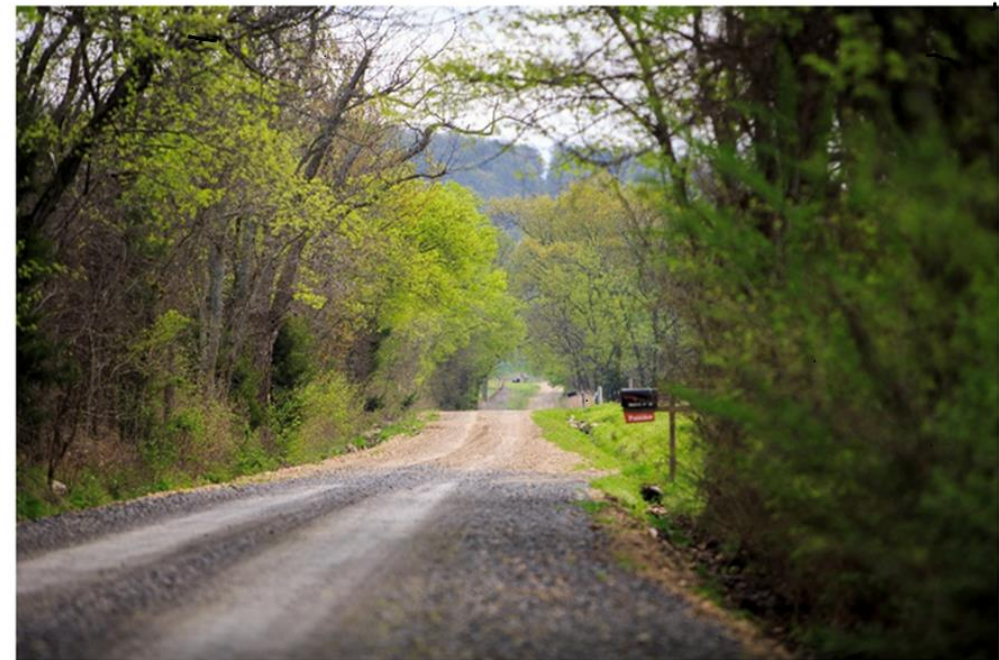
- Optimizing care for people with opioid use disorder and mental health conditions
- Preventing opioid use disorder in at-risk groups
 - Adolescents transitioning to adulthood, homeless, American Indian/Alaskan native (AI/AN)
- The role of sleep in opioid use disorder
- Tools for pharmacists to identify high risk opioid use patterns for early intervention



New Prevention & Treatment Strategies for Opioid Use Disorder

\$226M to date; develop new or improved prevention and treatment strategies

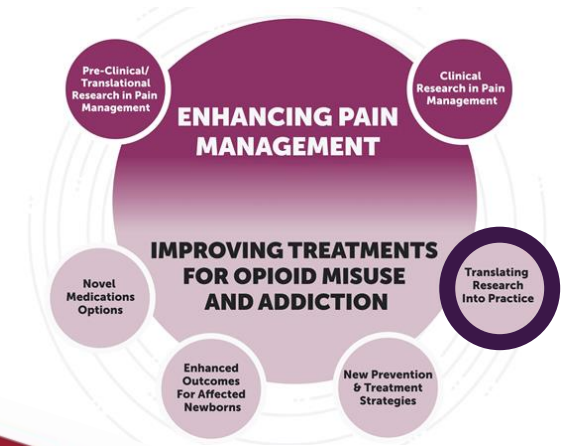
- **Launched in 2021:**
 - Research to optimize multi-component service delivery interventions for OUD and mental health conditions
- **Planned for 2022:**
 - Management of polysubstance use through the NIDA Clinical Trials Network
 - Screening for OUD
 - Preventing opioid misuse by intervening on social determinants of health



Translation of Research into Practice for Effective Treatments for OUD

\$611M to date; suite of implementation science efforts

- Behavioral Research to Enhance Medication-Based Treatment of OUD
- HEALing Communities Study
 - Communications campaign for community uptake of medications for OUD and naloxone
 - Real-time data tools to monitor overdose spikes
- Justice Community Opioid Innovation Network
 - Emerging best practices for criminal justice agencies on addressing OUD in the context of COVID-19

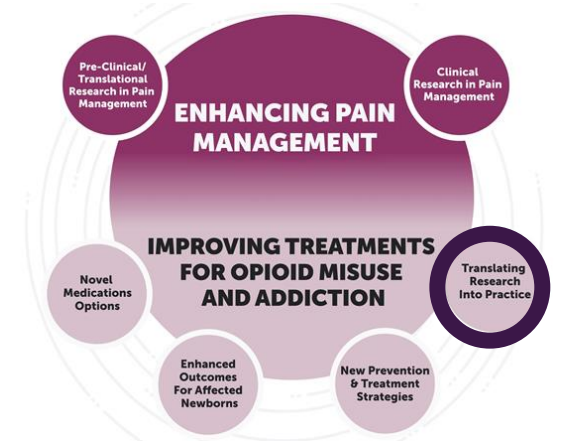


Translation of Research into Practice for Effective Treatments for OUD

\$611M to date; suite of implementation science efforts

- **Planned for 2022:**

- Recovery support services research
- Harm reduction strategies, including use of fentanyl test strips, in HCS
- Real-world application of existing data through *Data 2 Action*
 - Includes support centers for infrastructure, research adoption, and economic modeling

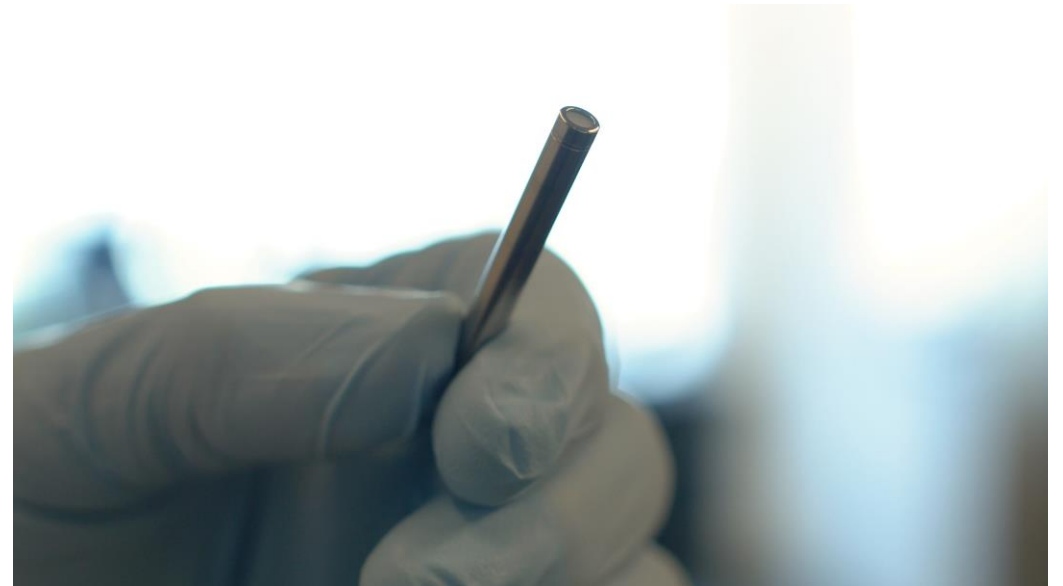


The banner features three portraits of individuals: a female EMT with a stethoscope, a male firefighter in full gear, and an older man with a beard. Below the portraits are three colored boxes with the text: "I'm a FIRST RESPONDER" (green), "I'm a FIRST RESPONDER" (blue), and "I am TOO" (red). To the left is a box of Narcan Nasal Spray. The NIH HEAL Initiative logo is in the bottom left. The main text on the right says: "Carry naloxone (Narcan®). Save a life. Recognize the signs of an opioid overdose. Learn where to get Narcan® and how to use it. HealTogetherKY.org/Franklin".

Novel Therapeutic Options for Opioid Use Disorder and Overdose:

\$363M to date; expand treatment options for all aspects of the opioid addiction cycle

- 50+ compounds being developed from early preclinical to late clinical phases
- 20 INDs filed with FDA
 - Exceeding HEAL Initiative goal of 15 INDs in 5 years
- *Biologics*: First study in humans of an opioid vaccine
- *Devices*: One IDE for Deep Brain Stimulation as a treatment for OUD



Novel Therapeutic Options for Opioid Use Disorder and Overdose:

\$363M to date; expand treatment options for all aspects of the opioid addiction cycle

Launched in 2021:

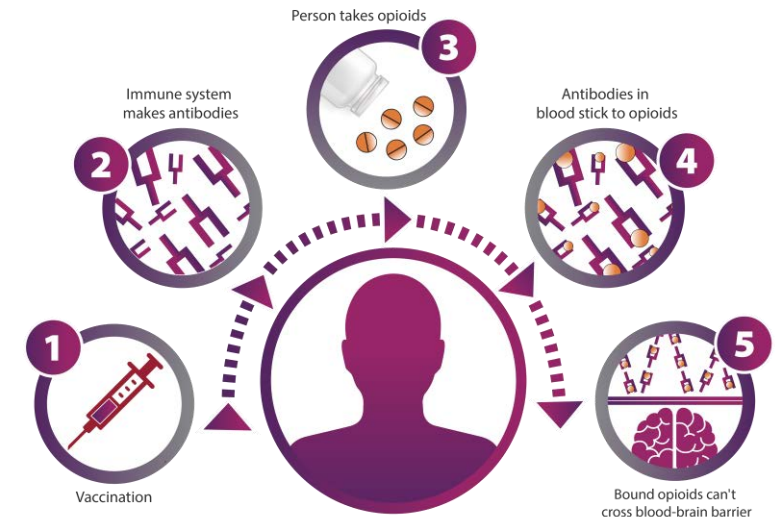
- Medications development for stimulant use disorder and polysubstance use

Planned for 2022:

- Novel targets for OUD and overdose
- Pharmacotherapies to reverse opioid induced respiratory depression without central opioid withdrawal
- Novel digital therapeutics for OUD



HOW THE OPIOID VACCINE WORKS



Enhanced Outcomes for Infants and Children

\$83M to date; addressing the long-term consequences of early opioid exposure

- **Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)**
 - 2 clinical trials –weaning and eat-sleep-console,
 - 1 longitudinal study
 - Early survey found significant site to site practice variation in treatment of infants with NOWS;
- **HEALthy Brain and Child Development Study (HBCD)**
 - Longitudinal study enrolling pregnant women across the US
 - Developing neuroimaging measures in infants and young children



Enhanced Outcomes for Infants and Children

\$83M to date; addressing the long-term consequences of early opioid exposure

- **Launched in 2021:**
 - Healthy Brain and Child Development Study
 - Consultation with NIH Bioethics Office--seeking an external bioethics consult
 - ACT NOW comparative-effectiveness trial
 - Goal to determine appropriate pharmacological treatment of infants with NOWS
- **Planned for 2022:**
 - Peer specialist support for HEAL studies



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...*

Viewpoint

ONLINE FIRST FREE

August 26, 2021

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

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[» Author Affiliations](#) | [Article Information](#)

JAMA. Published online August 26, 2021. doi:10.1001/jama.2021.13300

[Related Articles](#)

The Helping to End Addiction Long-term (HEAL) initiative was established in 2018 to provide scientific solutions to the evolving crisis of addiction. With dedicated support from Congress, the HEAL initiative has funded more than 500 projects nationwide, and plans to expand research in various efforts to develop more effective therapies for managing pain and addiction. The HEAL initiative joins the power of science to address an urgent public health need (see [Table](#) for selected research areas).



★ *2022 HEAL Annual Report coming soon!* ★

HEAL Current Activities and Future Directions

HEAL Budget: FY2022 and FY2023 Look-ahead

- President FY2022 budget proposed extra \$270M for HEAL research
 - Part of \$627M proposed increase in pain, opioid research across NIH, including increases directed to individual Institutes and Centers
- NIH considering plans in case budget increase becomes a reality
- Plan for similar fiscal level in FY2023

New Research Directions for HEAL Research in 2022 align with HHS Overdose Prevention Strategy

Care Coordination and Collaboration

- Pain Management in Systems of Care
- Research Adoption Partnerships
- Multicomponent Care for Mental Health, OUD and comorbidities

Health Equity

- Sickle Cell Disease Pain Management
- Social Determinants of Addiction and Behavioral Health
- Advancing Health Equity in Pain

Data Driven Research

- Real World Healthcare Data
- Secondary Data Analysis
- Data2Action Partnerships

Harm Reduction

- Policies, Practices and Modes of Delivery for Harm Reduction

Evidence Based Treatments

- Polysubstance Use
- Medication Development
- Recovery Support Services

Preventing Overdose Through Pain Management

- New Targets and Candidate Therapeutics for Pain
- Novel Pain Treatments
- Training and Innovator Awards

New Research Directions for HEAL in FY2023

Improve Care through Coordination, 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 Through Pain Management

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

Thanks! HEAL Scientific Teams and Leadership



Ivan Montoya,
NIDA



Alex Talkovsky,
NIMH



Jane Atkinson,
NCATS

Scientific team membership of 200+ program staff representing 20+ ICOs across NIH



Kentner Singleton,
NIAID



Geetha Subramaniam,
NIDA



Linda Porter,
NINDS



Wendy Weber,
NCCIH



Christine Colvis,
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Drew Bremer,
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Tisha Wiley,
NIDA



Michael Oshinsky,
NINDS



Michelle Freund,
NIDA



Thanks! *NIH Executive Committee*



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Thank You! Questions?