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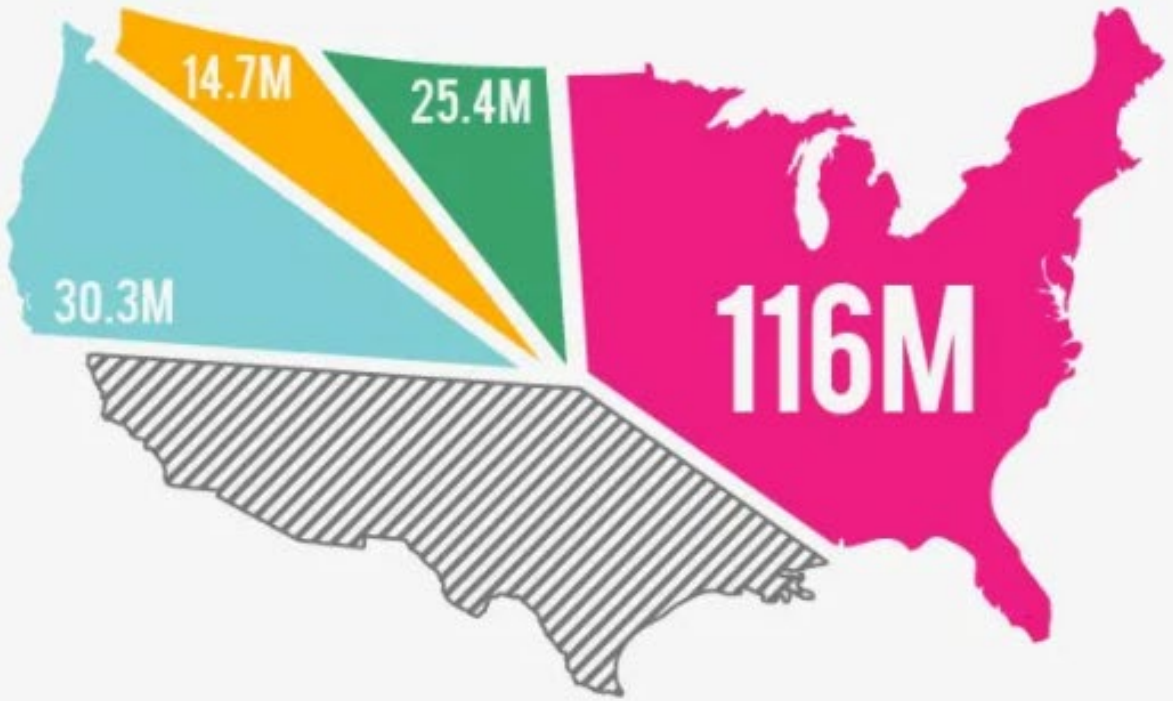
https://www.nih.gov/heal

HEAL Pain
Strategic Research Priorities

David Shurtleff, PhD
Acting Director, NCCIH
April 13, 2026

PAIN IN AMERICA



More than 30% of Americans are living with some form of chronic or severe pain.

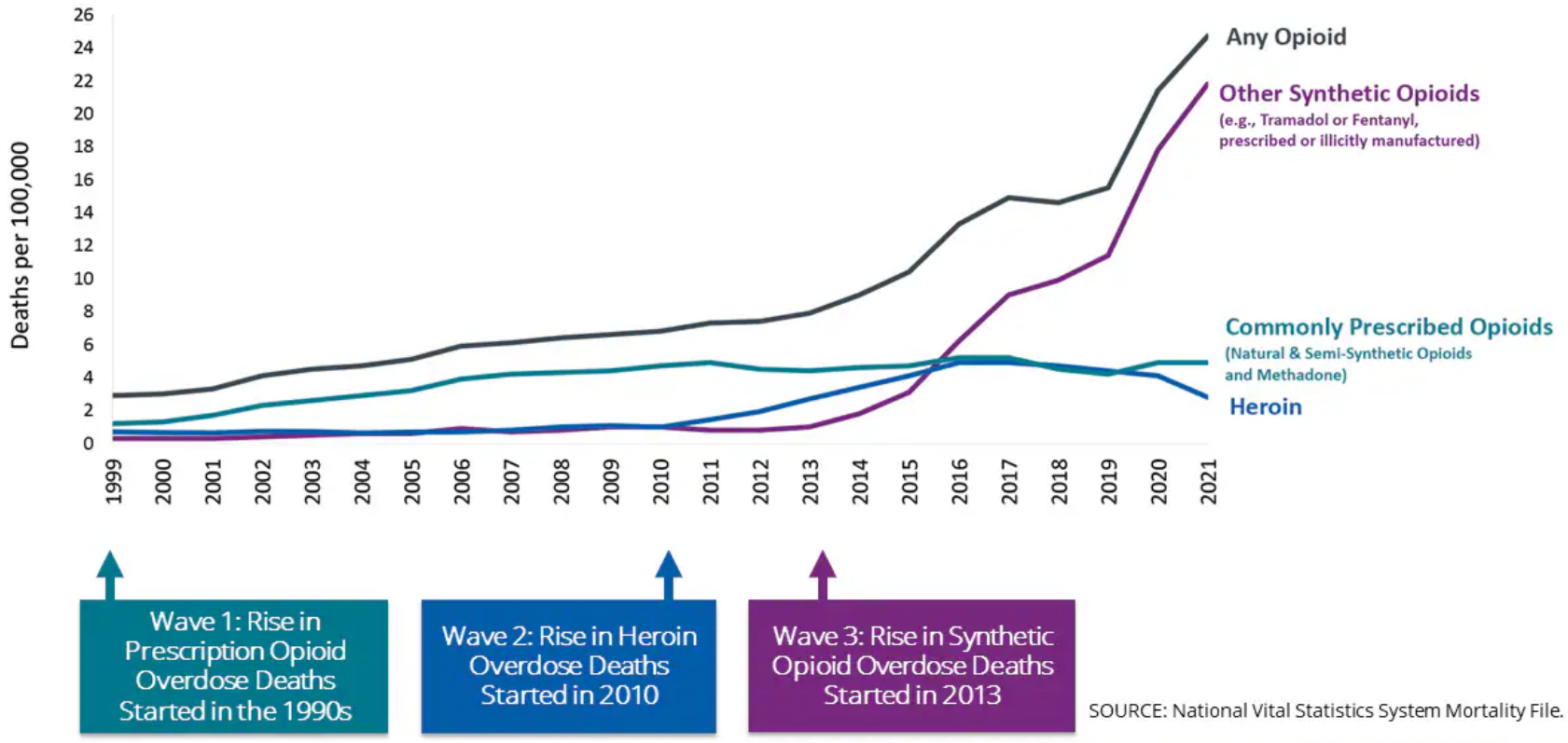
MORE PEOPLE LIVE WITH CHRONIC PAIN THAN CANCER, HEART DISEASE, AND DIABETES, COMBINED.

- Chronic pain: 116M
- Diabetes: 30.3M
- Heart disease: 25.4M
- Cancer: 14.7M

Sources: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Institute of Medicine

The NIH Helping to End Addiction Long-term® (HEAL) Initiative: How we got here

Three Waves of Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

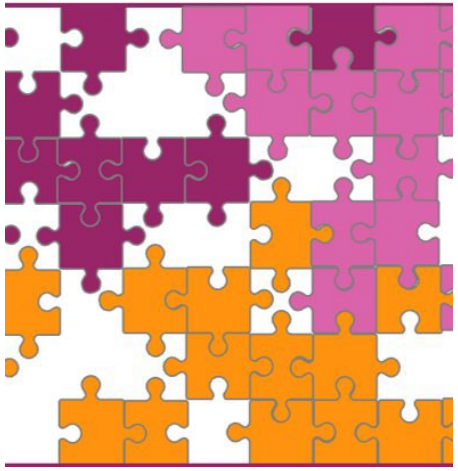
- In 2017 HHS declared the opioid crisis a public health emergency
- In 2018, with support from Congress, NIH Helping to End Addiction Long-term® Initiative, (HEAL Initiative®), was launched to accelerate scientific solutions for opioid use disorder, overdose, and management of pain.

HEAL…at the beginning

- HEAL launched in April 2018 after Congress added $500m to the annual base appropriation to NIH "for a new initiative to research opioid addiction, development of opioids alternatives, pain management, and addiction treatment."
- Early investments were guided by:
  - 2017 Federal Pain Research Strategy
  - 2017 Series of "Cutting Edge Science Meetings to End the Opioid Crisis"
    - Develop safe and effective pain treatments
    - Understand pain mechanisms
    - Preventing and treating OUD
  - Informed the "HEAL Research Strategy" (JAMA)
- From 2018-2023, led by NIH Office of the Director

Collins, Koroshetz, Volkow; JAMA; 2018

HEAL…Now



- Since Fall 2023, Led by Drs. Volkow (NIDA) and Koroshetz/Adams (NINDS) as HEAL co-Scientific Directors
  - **HEAL Pain Portfolio** overseen by the NINDS Director, Dr. Adam and two rotating co-chairs from ICOs—currently Drs. Shurtleff (NCCIH) and Mazzucco (NIAMS) **~$285M (FY26)**
  - HEAL OUD overseen by Dr. Volkow (NIDA) **~$355M (FY26)**
- Since 2018, **>2,200** research projects in **all 50 states**, totaling over **$3.9 billion**
- Collaboration across **19** NIH Institutes, Centers, and Offices
- **>40** FDA approvals for investigational new drugs or devices, **300+** clinical trials under way
- Many of the **initial projects** launched in the first couple of years are wrapping up or at a transition point
- The HEAL MDWG **recommended developing a strategic plan** to guide future HEAL investments
  - Collaborative, multidisciplinary nature of pain research → deliberative process guided by an external Working Group to recommend strategic research priorities for HEAL Pain

Research Priority Subcommittees & Focus Areas

Co-chairs

Robert Gereau, PhD

Kathleen Sluka, PT, PhD, FAPTA

Lived Experience advisor

Michael Falcon, OTD, OTR/L, MHA

Health equity & pain across the life course

Tamara Baker, PhD

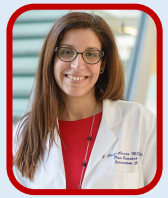
Susmita Kashikar-Zuck, PhD

Non-addictive therapeutics development

John Markman, MD

Theodore (Ted) Price, PhD

Pain biomarkers and predictors



Yenisel Cruz-Almeida, MSPH, PhD

Vivianne Tawfik, MD, PhD

Optimization of interventions to improve pain

John T. Farrar, MD, PhD

Claudia Campbell, PhD

Implementation and health services

Lynn DeBar, PhD, MPH

Steven George, PT, PhD, FAPTA

Intersection of pain and substance use disorder

Jessica S. Merlin, MD, PhD, MBA

Joanna Starrels, MD, MS

Pain research workforce and training

Cheryl L. Stucky, PhD

Jennifer Haythornthwaite, PhD

Proposed Core Principles

- **Involvement of People with Lived Experience in NIH HEAL research**
  - Training of investigators
  - Inclusion in basic and clinical research
  - Inclusion from design through data analysis
- **Education of Public and Providers**
  - Research dissemination of findings
  - Community Engagement for Clinical Trials and Implementation
  - Public campaign
- **Methodological principles for preclinical and clinical trial research**
  - Reporting of sex, longer term outcomes, life span, co-occurring conditions
  - Influence of social factors
  - Integrating implementation principles
- **Interdisciplinary teams should be employed to capitalize on unique skills and methodologies**
  - Development of interdisciplinary teams
- **Secondary analysis of existing data and biological samples, can also yield insights into the genesis and maintenance of chronic pain.**

Proposed Scientific Research Priorities

- Support development of diverse, highly effective mechanistic pain therapeutics.
- Invest in discovery research focused on human biology to develop novel therapeutics.
- Develop strategies across the lifespan to prevent chronic pain.
- Develop biomarkers to predict treatment response, safety, target engagement, and surrogate endpoints in clinical trials.
- Evaluate individualized, tailored, mechanism-based treatments to improve outcomes. ★
- Develop and test evidence-based guidance on initial pain therapy, sequencing and timing of multimodal care, and nonspecific effects to maximize benefit and minimize risk for each patient. ★
- Prioritize embedded, real-world research- including hybrid implementation-effectiveness studies and pragmatic trials- to enhance impact, scalability, and sustainability. ★
- Identify populations disproportionately affected by pain and substance use, understand underlying mechanisms, and develop and test targeted interventions. ★
- Support research on non-drug approaches to treat and prevent chronic pain, including in patients with co-occurring SUD. ★

NCCIH-led, HEAL-supported Pragmatic, Dissemination and Implementation Pain Research Programs

NIH HEAL Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM)

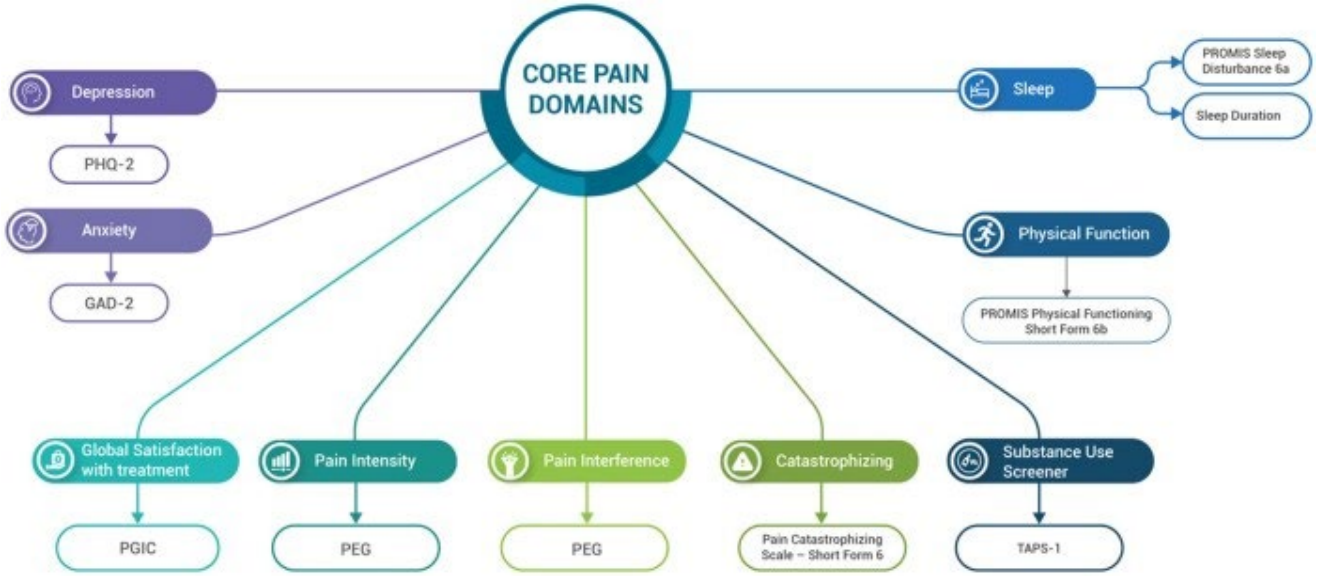
- Support multiple pragmatic trials embedded in health care systems
- Determine the **effectiveness of nonopioid interventions**
- Assess the impact of implementing interventions or guidelines on pain management and opioid use and pain.
- Supports trials from the NINR HEAL program on rural management of pain

pmc painmanagement collaboratory

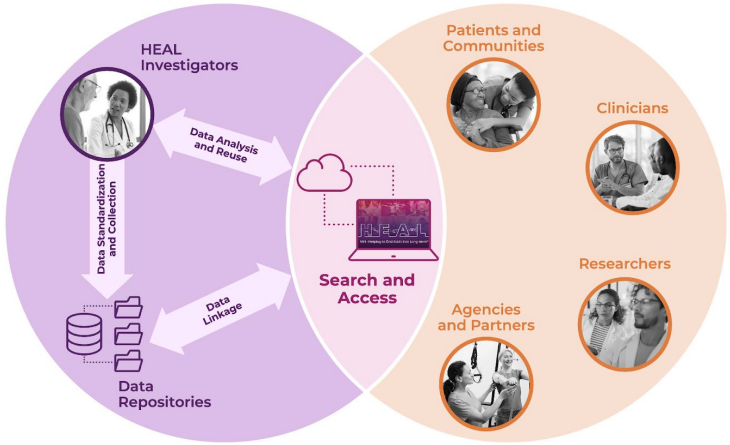
NIH-DOD-VA Pain Management Collaboratory (PMC)

- Addressing key scientific knowledge and clinical practice gaps in the delivery of high-quality pain care for military service members and veterans
- The PMC is addressing a critical gap between science and practice in pain management
- Focus on implementation and **evaluation of nonpharmacologic approaches for the** management of **pain and common co-occurring conditions in military and veterans health care systems**

Common Data Elements & Data Sharing



All human subjects studies must collect core CDEs—a defined set of PROs across ten key pain domains—plus demographics and prescription opioid use.



The HEAL Data Ecosystem enables open science by accelerating data sharing, promoting collaboration, and enhancing research impact.

Thoughts and Strategies for HEAL Pragmatic Trials

- Continue to use and require common data elements (CDEs)
- Expand the HEAL Data Ecosystem for harmonized data sharing
- Data Collect Once Use Numerous TimeS (FNIH-Data COUNTS) strategic effort to establish creating a secure, federated electronic health record (EHR) and health data architecture
- Increase alignment with NIH Care for Health™ (i.e., FQHCs; rural health)
- Test multi-component interventions to address pain co-morbidities (e.g., OUD, PTSD, depression)
- Head-to-head testing of multimodal, non-opioid, and integrative care pathways
- Focus on clinical decision points (e.g., first-line therapy, stepped-care approaches; escalation strategies)
- Outcomes centered on function, quality of life, and healthcare utilization
- Engage with CMS and payers for coverage-relevant evidence


THANK
YOU!