

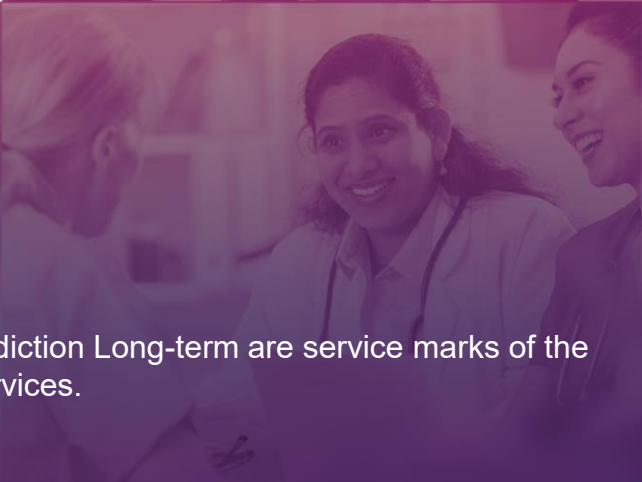


**NIH
HEAL
INITIATIVE**

Helping to End Addiction Long-term

Rebecca G. Baker, PhD
Director, HEAL Initiative, NIH OD

November 19, 2019



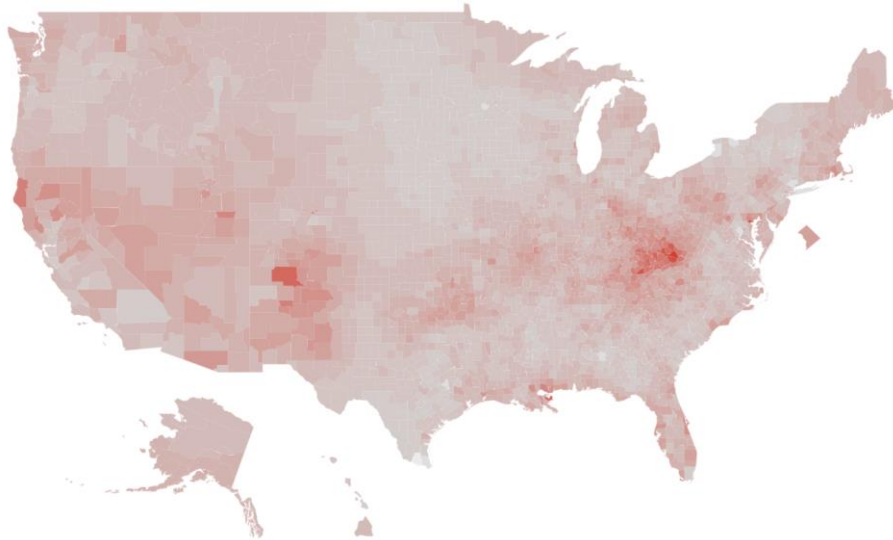
NIH National Institutes of Health
HEAL Initiative

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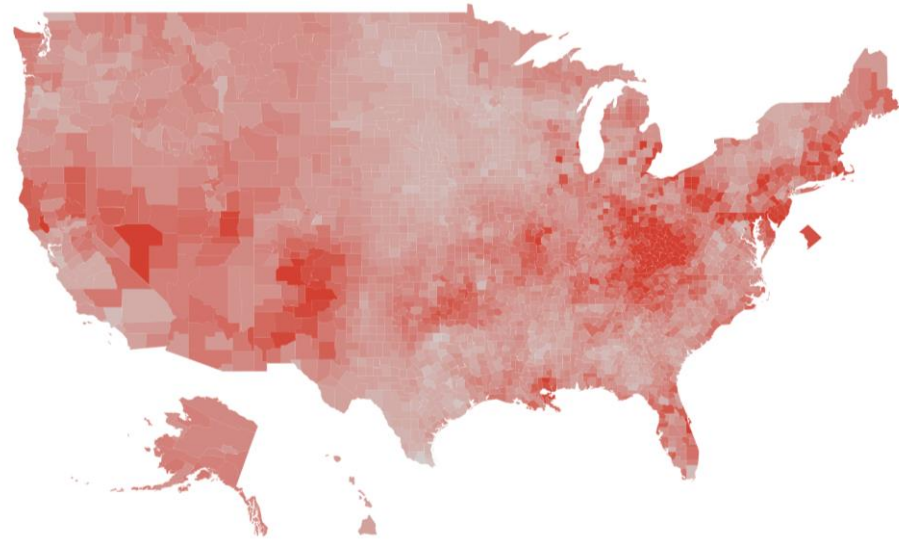
Crisis #1: National Overdose Deaths

In **2018**, there were **67,367** overdose deaths – dramatically higher than in 2003

2003



2018



Model-based Death Rate



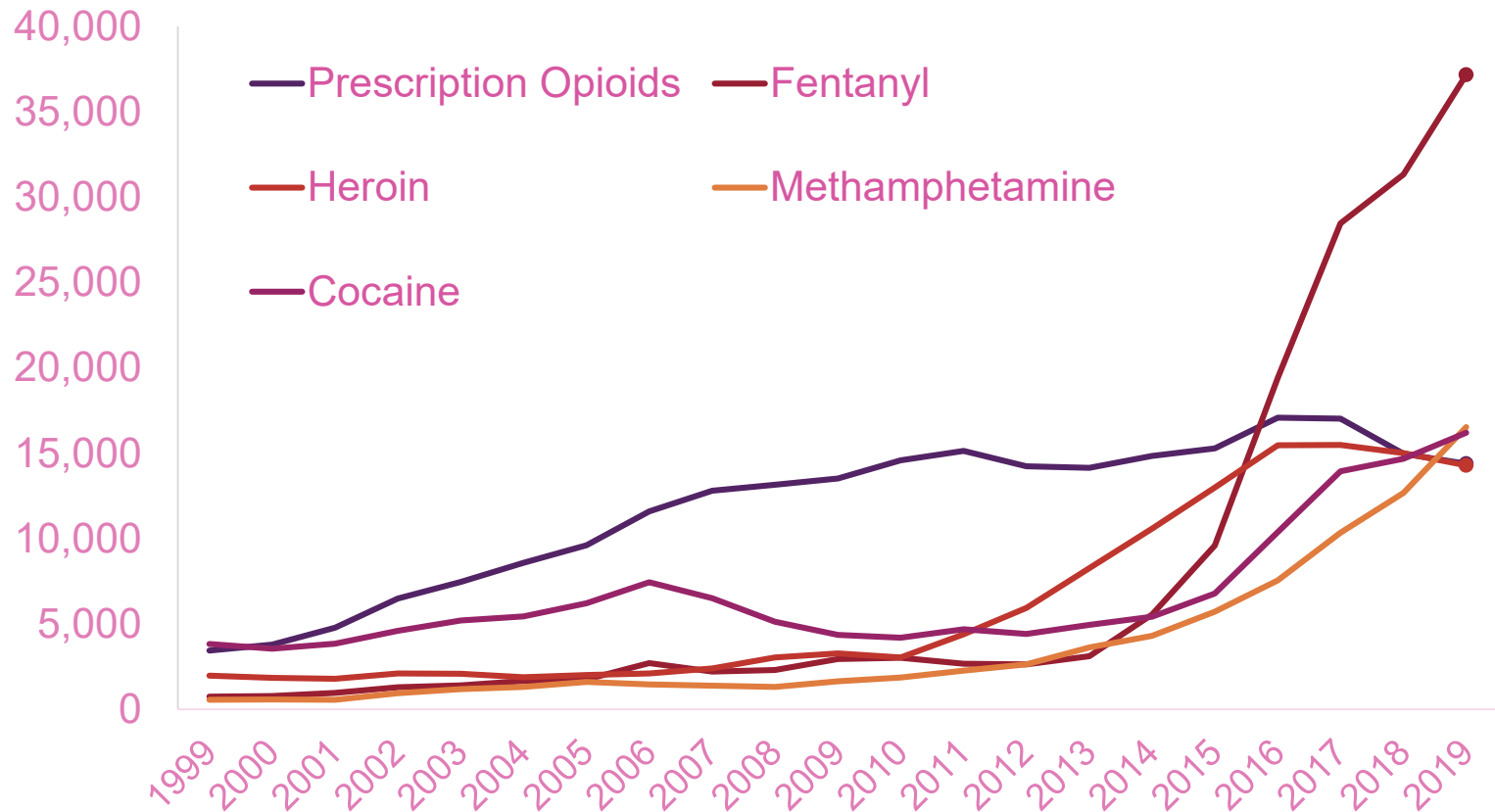
Age-adjusted death rate (per 100,000 population)

Source: <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/index.htm>

National Public Health Emergency declared in 2017

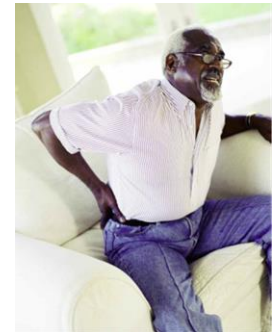
Overdose Deaths Increased by 4.6% in 2019

Number of Deaths



Crisis #2: Chronic Pain in the U.S.

- 50 million adults are affected by chronic pain
- 25 million report severe pain on a daily basis
- 20 million have high impact chronic pain



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

The Response: \$500 million/year Sustained Research Investment

**25+ HEAL Research
Programs**

**Prevention – Basic &
Translational Research –
Clinical Trials –
Implementation Science**

12 NIH ICs leading studies

Trans-NIH governance structure

Partnerships across government,
communities, and the private sector

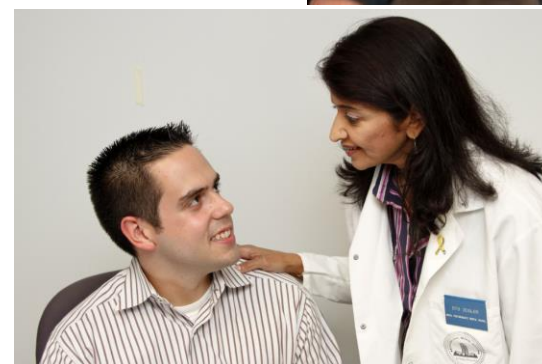


NIH HEAL INITIATIVE RESEARCH OVERVIEW



Problem: Many people with opioid use disorder do not receive appropriate treatment

- **HEAL Research:** Develop new interventions and test integration into community, justice and emergency settings where people come seeking help



Problem: Many patients do not stay on medication-based treatment long enough to achieve long-term recovery

- **HEAL Research:** Develop novel, longer-lasting and innovative treatments
 - Immunotherapies to prevent relapse and overdose
 - Extended-release formulations
 - Medications to reduce drug cravings



Problem: No national standard for care of infants born exposed to opioids

- **HEAL Research:** Determine best assessment and treatments
 - Inform screening protocols and treatment guidelines for infants exposed to opioids
 - Track effects of prenatal opioid exposure on brain growth and development

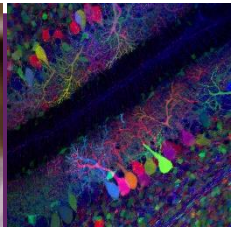


Problem: Need for pain control is in balance with the risks of long-term opioid therapy

- **HEAL Research:** Test non-addictive medications for pain and new models of care in real world settings
 - Phase 2 testing of novel therapeutics for multiple different pain conditions
 - Trial of acupuncture for chronic low back pain in older adults, in collaboration with CMS
 - Effectiveness studies for nonpharmacological pain management strategies

Enhancing Pain Management

- Pre-Clinical and Translational Research in Pain Management
 - Discovery and validation of novel targets for safe and effective pain treatment
 - Biomarkers, signatures and endpoints for pain
 - Translating discoveries into effective devices for pain treatment
 - Engineering preclinical screening platforms + novel drug development
- Clinical Research in Pain Management
 - Test novel treatments in a new clinical trials network: (EPPIC Net)
 - Back Pain Research Consortium
 - Pain Management Effectiveness Research Network
 - Integrated approach to pain and opioid use in hemodialysis patients
 - Pragmatic and Implementation Studies for the Management of Pain



Early Phase Pain Investigation Clinical Network (EPPIC-Net)

- Accelerate the early phase testing of promising non-addictive therapeutics and devices for pain
 - Develop infrastructure for the rigorous early phase testing of promising pain treatments (small molecules, biologics, devices) from academia and industry.
- Incorporate biomarkers of target engagement or proof-of-principle into clinical trial design



Back Pain Research Consortium: BACPAC

A patient-centric, translational research program

- BASIC: Integrated model of Low Back Pain through improved understanding of mechanisms
- TRANSLATIONAL: Clinical trials, integrating new therapies into multimodal interventions, combined with deep phenotyping and patient-reported symptoms and outcomes
- CLINICAL: Algorithms to match patients to best treatments based on phenotype and psychosocial context



Pain Management Effectiveness Research Network (ERN)

- Evaluate the effectiveness of pharmacologic and nonpharmacologic therapies for a broad array of pain conditions
 - Leverage NCATS Trial Innovation Network
 - Phase 3 clinical trials to inform best practices in pain management and minimize risk of addiction
 - Coordination and harmonize data across studies

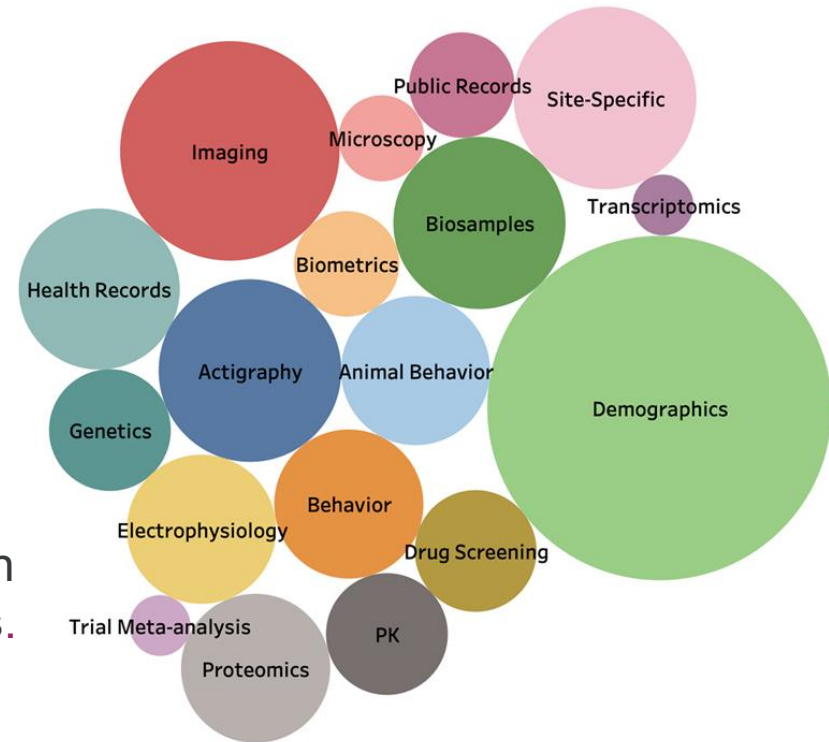


Cross-cutting HEAL themes

- Sharing and open access of data
 - HEAL Public Access and Data Sharing Policy
 - Secure infrastructure for making HEAL data FAIR
 - Harmonized measures established by HEAL teams
- Engagement of research participants, patients, and stakeholders
- Importance of partnerships, diversity and inclusion in HEAL research studies

Data Sharing and Harmonization Across HEAL

- HEAL to gather **diverse set of research data** drawing from an extraordinarily broad range of research domains in order to address the Opioid Crisis
 - Therapeutics, community-based treatment, pain neuroscience and detection, etc.
- The **HEAL Public Access and Data Sharing** plan provides a starting point.
- Potential to **further “open science”** through data management and data sharing policies.
- University of Chicago serving as platform



Call to action - NIH is committed to addressing racial and health disparities

BLACKS, DISCRIMINATION, TRAUMA, UNCONSCIOUS BIAS

NIH Director Message: Grieving For Loss and Confronting Social Injustice



June 5, 2020

By: Francis S. Collins, M.D., Ph.D.

The long history of discrimination against racial minorities in America bears directly on NIDA's mission to address addiction as a disease ...

Nora Volkow 2020, August 5. A Message from the Director on Racially Motivated Violence.



I am charged with striving to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.

Joshua Gordon, 2020, June 19. Racism and Mental Health Research: Steps Toward Equity.



The mission of NINDS is to generate knowledge to reduce the burden of neurological disorders, *for all people.*

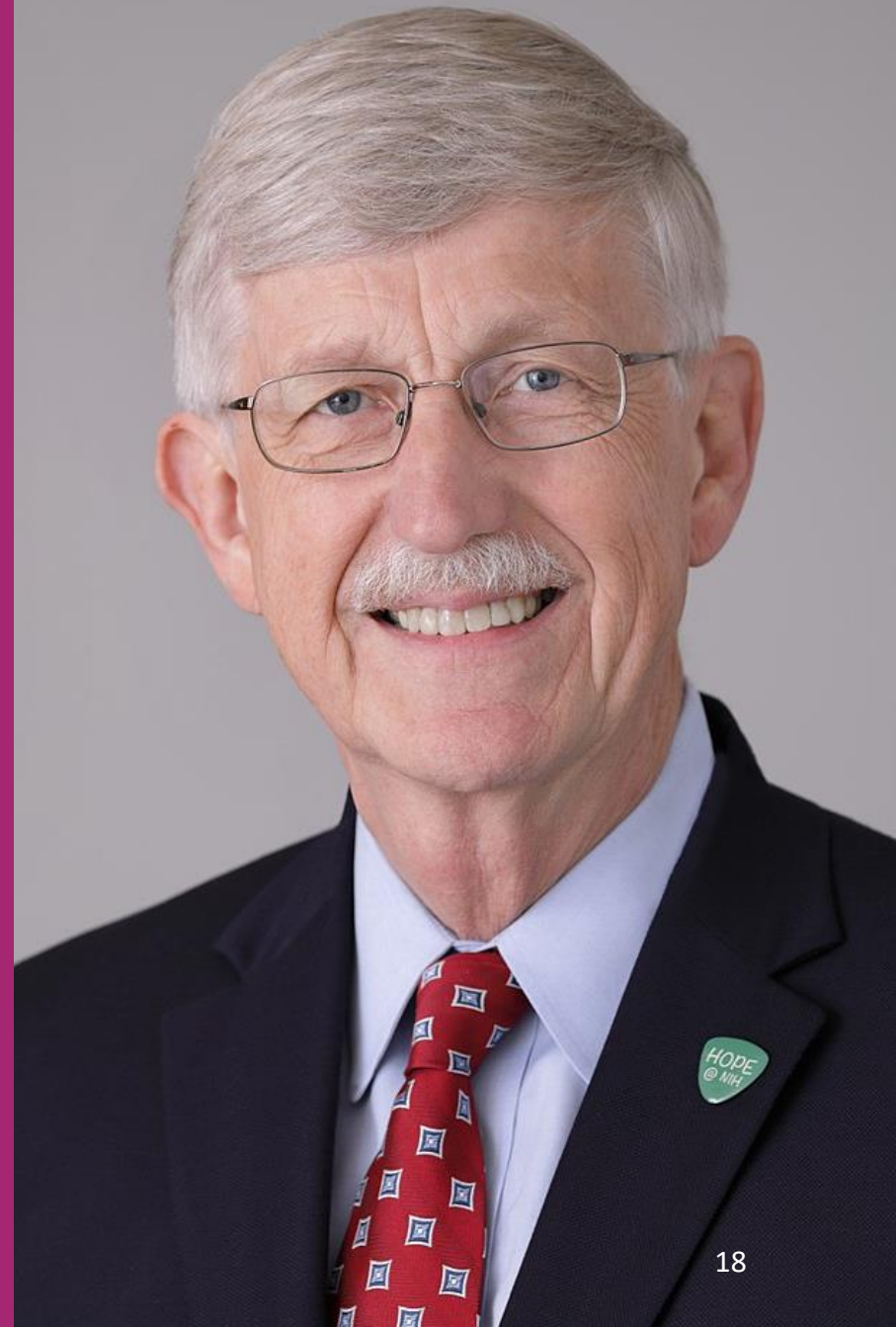
Walter Koroshetz 2020, June 19. A time for change: NINDS' commitment to diversity and eliminating racial bias.



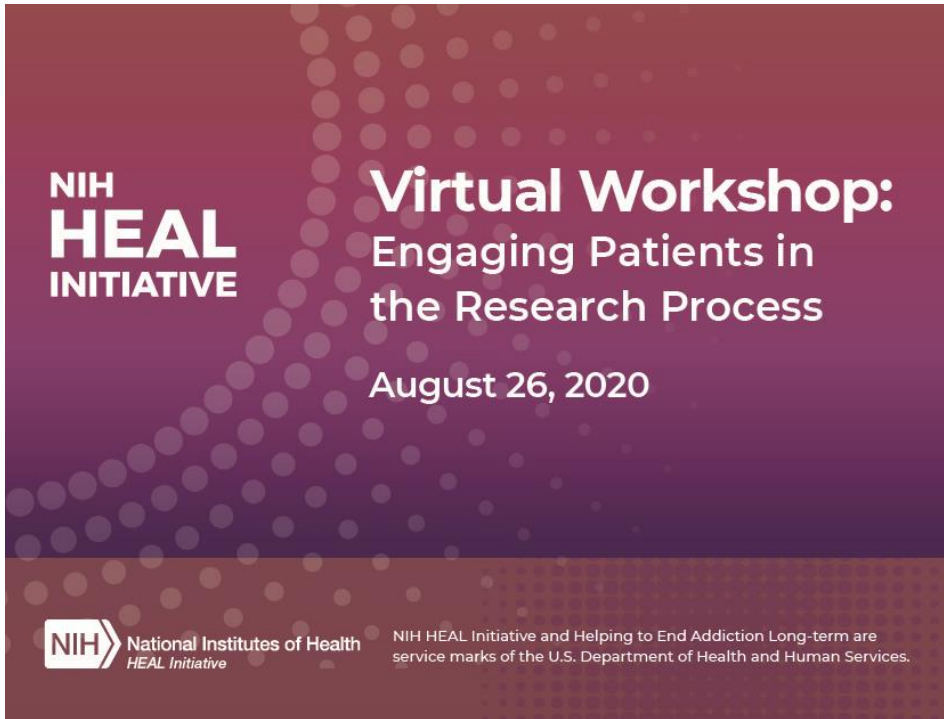
On Engagement

It's really important that everybody has a chance to participate in clinical trials. That's how we learn the differences and similarities and certainly underrepresented groups ought to be part of that. To make that more possible, we can do better outreach so people hear about these trials, we need to knock down barriers that might get in the way and we need to be sure we are getting people information back about themselves ...

–Francis Collins, NIH Director

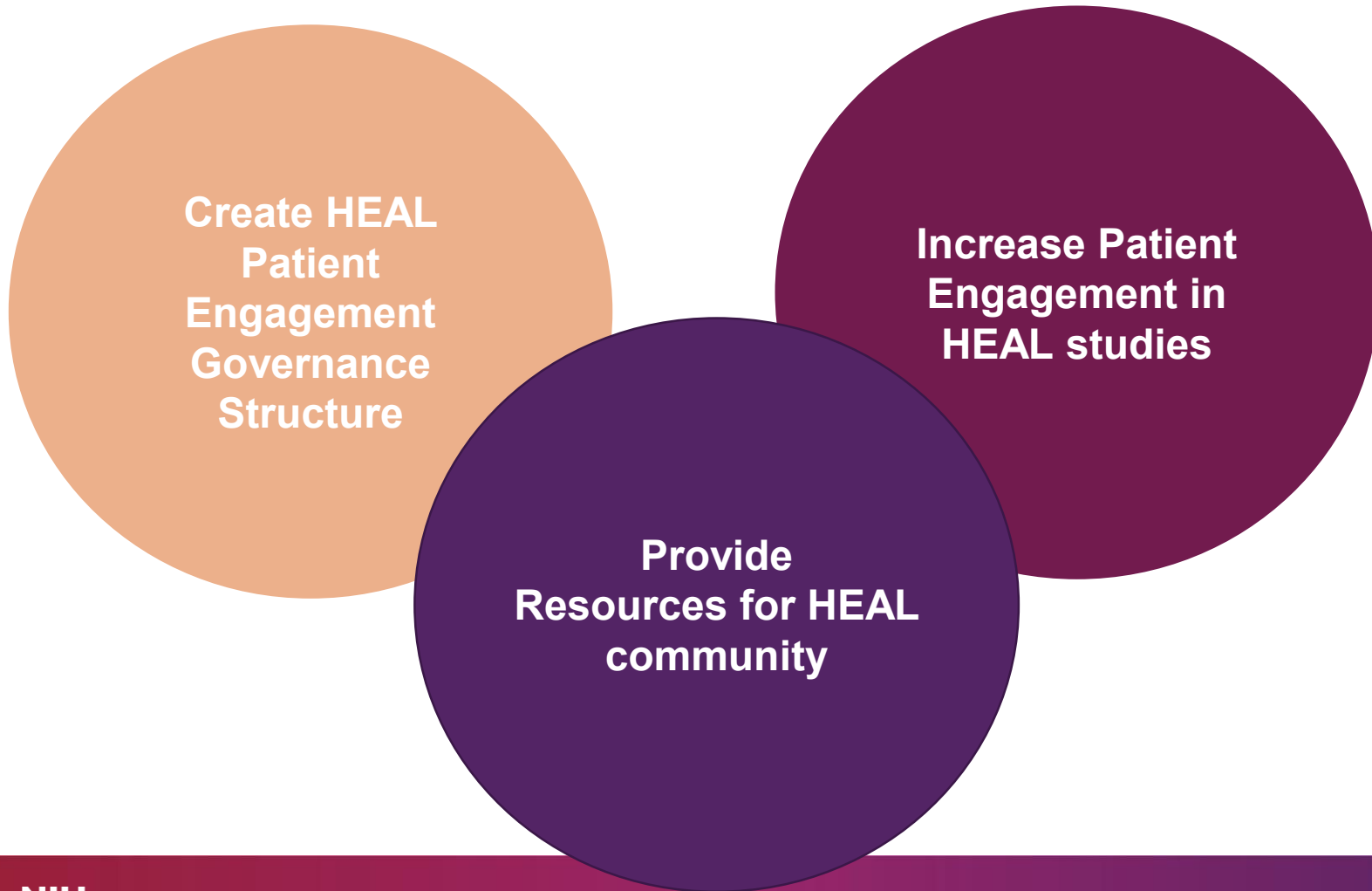


Engaging Patients In the Research Process



- Discussed opportunities, challenges, and benefits to incorporating patients and stakeholders in research
- Provided insights on engagement in the virtual environment
- Panelists:
 - Walter Koroshetz M.D.
 - CAP Robyn Bent (FDA)
 - Paul Kimmel M.D. (NIH)
 - Christin Veasley (CPR)
 - Dawn P. Edwards (HOPE)
- Discussants:
 - Lynn Debar, PhD
 - Mary Stroud, RN

Next Steps: The NIH HEAL Initiative Patient Engagement Workgroup Priorities



Engagement with HEAL Investigators and Research Dissemination

Investigators invited to continue to connect with one another as studies get underway

Ways to Engage:

- HEAL PI listserv
- Website functionalities
- Central engagement platform

Research Spotlights

Explore the projects helping to make a difference in the opioid crisis.



The Search for New, More Targeted Pain Treatments

From surgery and drugs to cell-based therapies, researchers will test innovative, non-addictive approaches for treating pain.

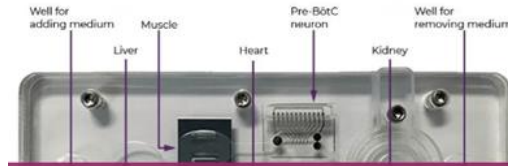
Discussion





Help for Babies Born Dependent on Opioids

Infant/Child Outcomes



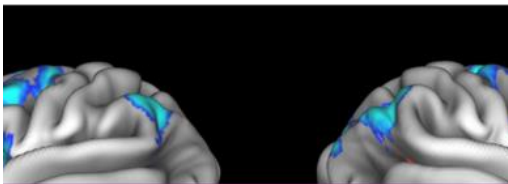
"Human-on-a-Chip" Models Effects of Opioid Overdose

Pain – Preclinical/Translational Research



The Search for New, More Targeted Pain Treatments

From surgery and drugs to cell-based therapies, researchers will test innovative, non-addictive approaches for treating pain.



Can Exposures Before Birth Predict Health Later in Life?

Infant/Child Outcomes



Is Lack of Sleep a Risk Factor for Relapse?

Preventing/Treating OUD



Next-gen Device Could Relieve Phantom Limb Pain

Pain – Preclinical/Translational Research

How do I manage my asthma, my acid reflux and my opioid use disorder.

Buprenorphine is a prescription medication that is used along with counseling and/or behavioral therapies to treat opioid use disorder.



Buprenorphine can be part of a comprehensive treatment plan for opioid use disorder.

Staying on the Road to Recovery

Preventing/Treating OUD • [Learn More](#)



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