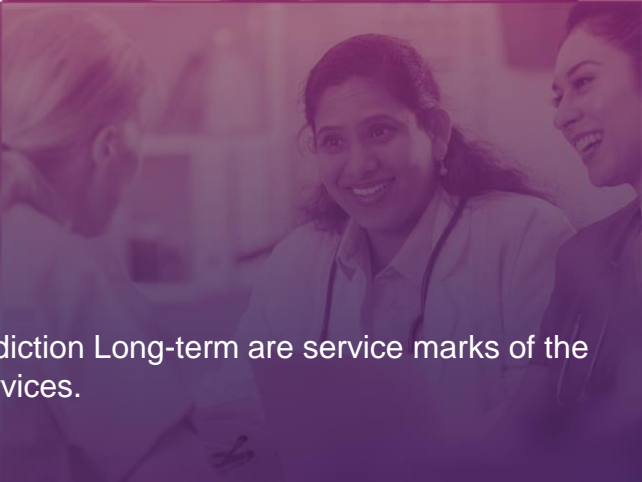
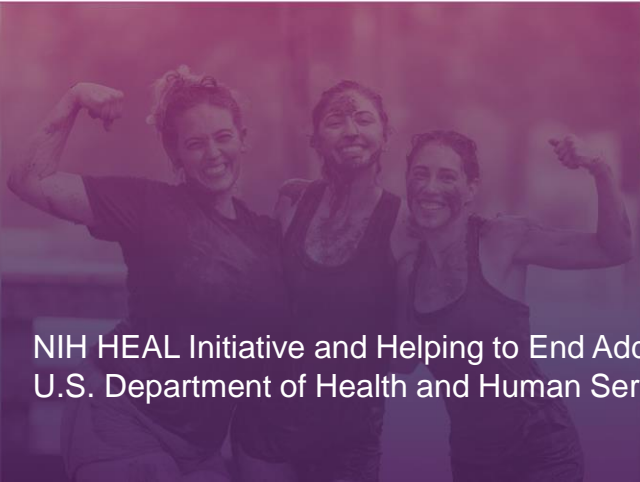




**NIH
HEAL
INITIATIVE**

Virtual Workshop: Engaging Patients in the Research Process

August 26, 2020



NIH 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.

Welcome to the workshop on Engaging Patients in the Research Process!

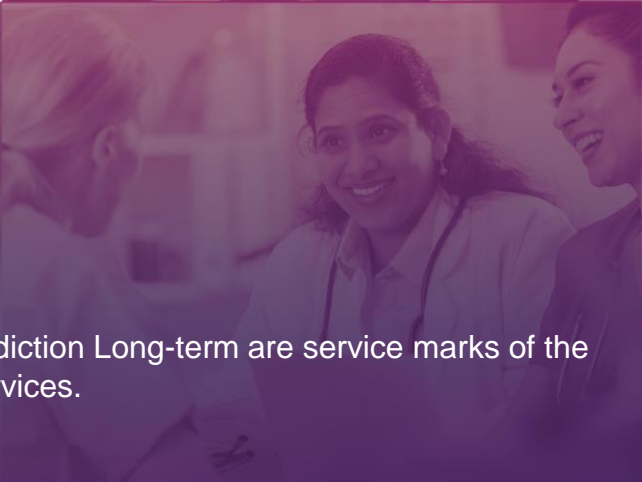
- This Zoom Webinar will be recorded. If you do not wish to be part of this recording, we ask that you disconnect.
- Attendees:
 - Will automatically be muted upon joining the webinar.
 - Should submit questions in the Q&A box (located at the bottom of the Zoom Webinar window).
 - Do not utilize the “hand raise” function.



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Welcome, Objectives and HEAL Initiative Overview

*Dr. Rebecca Baker, Director, Helping to
End Addiction Long-term (HEAL)
Initiative, NIH*



**NIH
HEAL
INITIATIVE**

Welcome and Overview

August 26, 2020

Rebecca Baker, Ph.D, Director, Helping to End Addiction Long-term (HEAL) Initiative, NIH



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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 ...

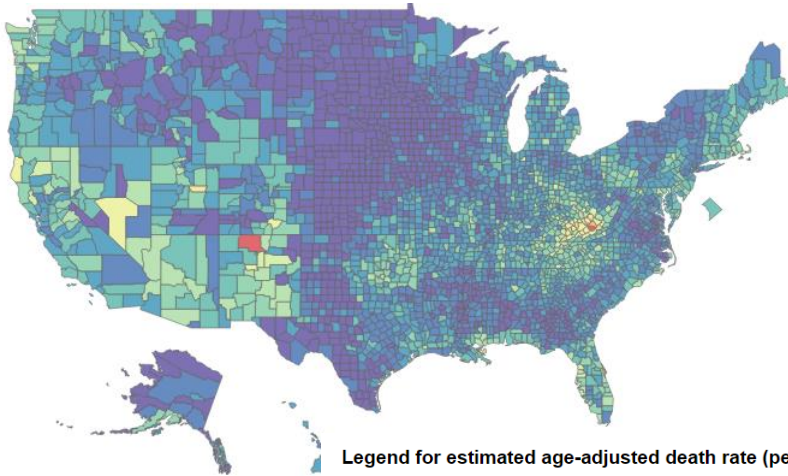
–Francis Collins, NIH Director



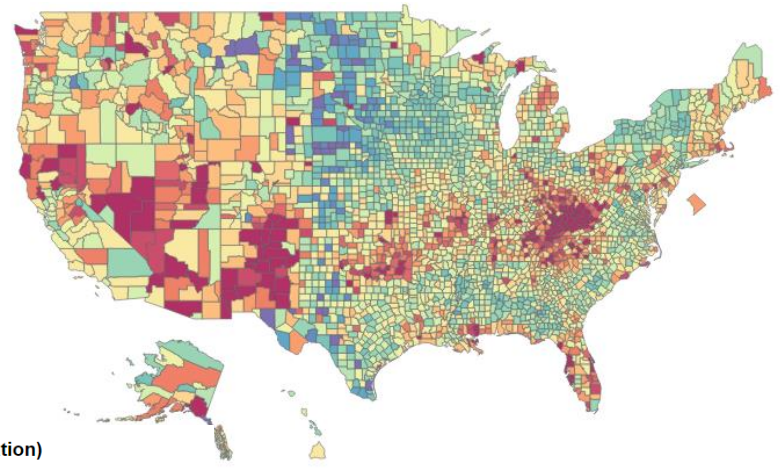
Crisis #1: National Overdose Death Rates

In 2017, there were 70,237 overdose deaths (9.6% higher than 2016)

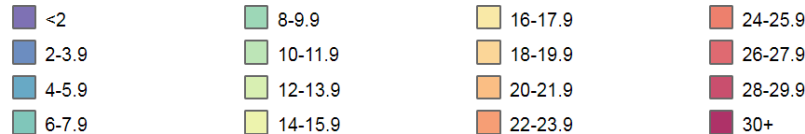
1999



2016



Legend for estimated age-adjusted death rate (per 100,000 population)



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

- Public Health Emergency Declared in 2017

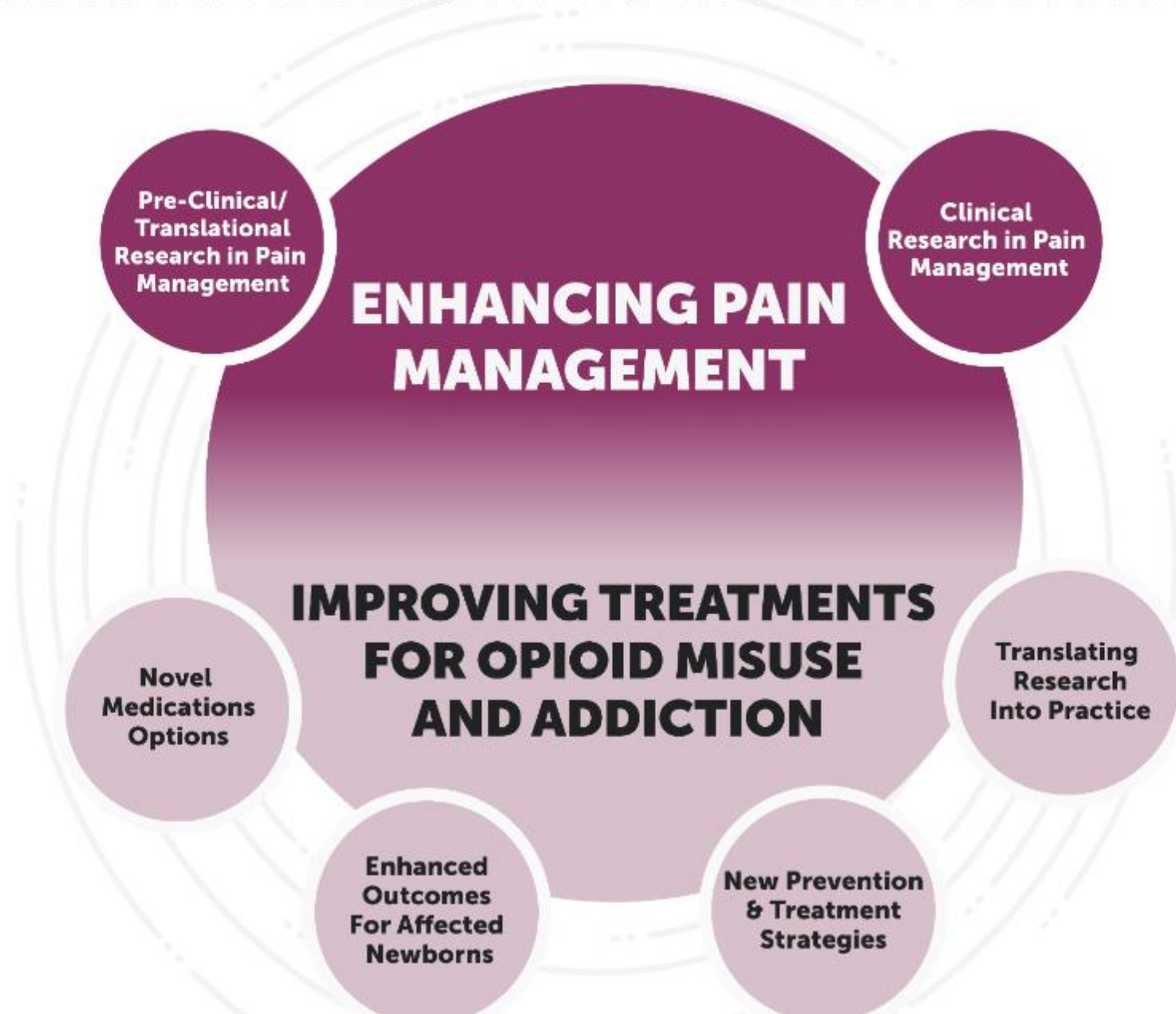
Crisis #2: Chronic Pain in the U.S.

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



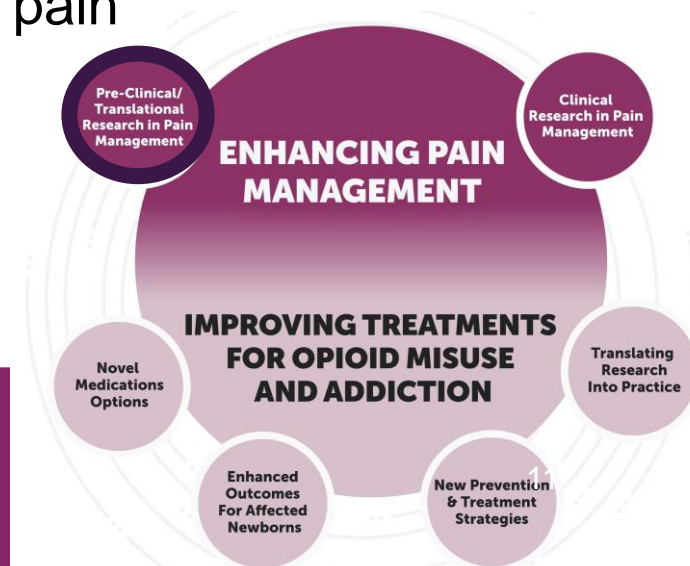
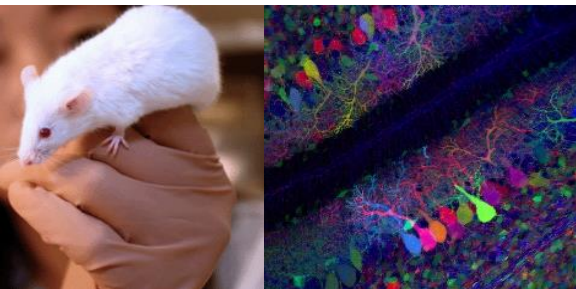
[CDC](#), Morbidity and Mortality Weekly Report, Sept. 2018

NIH HEAL INITIATIVE RESEARCH OVERVIEW



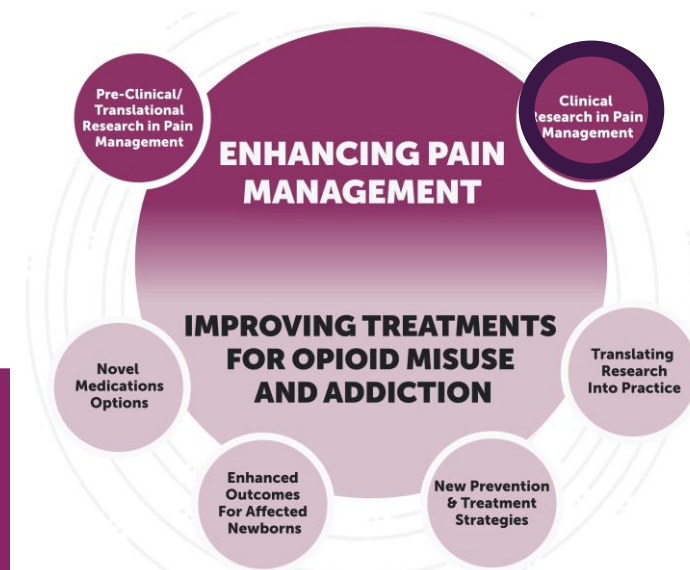
Pre-Clinical and Translational Research in Pain Management

- Discovery and validation of novel targets for safe and effective pain treatment
 - New target for migraine ___
 - 42 applications awards
- Translating discoveries into effective devices for pain treatment
- Engineering preclinical screening platforms + novel drug development
- Biomarkers, signatures and endpoints for pain



Clinical Research in Pain Management

- Test novel treatments in a new clinical trials network: (EPPIC Net)
- Back Pain Research Consortium
- Integrated approach to pain and opioid use in hemodialysis patients
- Pain Management Effectiveness Research Network
- Pragmatic and Implementation Studies for the Management of Pain



HEAL Funding Opportunities

Open Now... More to Come

U.S. Department of Health & Human Services National Institutes of Health



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FOA #	FOA Title	Research Focus Area	Earliest Submission Date	Expiration Date	Posted Date
NOT-OD-20-101	HEAL Initiative: Notice of Special Interest (NOSI) regarding the Availability of Administrative Supplements to Support Strategies to Reduce Stigma in Pain Management and Opioid Use Disorder (OUD) and Treatment	All	Fri, 05/29/2020	Sat, 05/30/2020	Thu, 04/23/2020
NOT-NS-20-044	Notice of Special Interest to Encourage Eligible NIH HEAL Initiative Awardees to Apply for Administrative Supplements to Promote Training in Clinical Research on Pain (Admin Supp – Clinical Trial Not Allowed)	Clinical Research in Pain Management	Fri, 05/15/2020	Fri, 07/31/2020	Fri, 04/10/2020
NOT-HL-20-746	Notice of Special Interest (NOSI): NHLBI and NIDA Announce Availability of Administrative Supplements for HEAL Awardees to Address Sleep Impairments in OUD Treatment Response and Recovery Outcomes	All	Mon, 06/01/2020	Tue, 06/02/2020	Fri, 03/27/2020
NOT-TR-20-008	Notice of Special Interest for HEAL Initiative: Request for Administrative Supplements to Existing Grants for Identification and Validation of New Pain and Opioid Use Disorder Targets within the Understudied Druggable Genome	Preclinical and Translational Research in Pain Management	Tue, 03/17/2020	Tue, 06/02/2020	Mon, 03/09/2020

#nihHEALInitiative

HEAL Patient Engagement Timeline



May 2019

Charged by HEAL Multidisciplinary Working Group and NIH Leadership to create patient engagement process



July–Oct. 2019

Performed environmental scan of patient engagement practices at NIH and PCORI



Nov. 2019

Recommendations for patient engagement considered by HEAL Senior Leadership



Feb-Apr. 2020

Established patient engagement workgroup



Aug- onward

Engagement Workshops, stakeholder identification, goal setting

Key Objectives of Today's Meeting

- Discuss opportunities, challenges, and benefits to incorporating patients in research
- Share best practices in community and patient engagement
- Address opportunities and challenges in engagement, recruitment and the new virtual environment
- Attendees will learn how patient engagement has transformed study processes and outcomes for the better
- Discuss engagement in the context of the HEAL initiative

HEAL Patient Engagement and Next Steps

- Use insights from this workshop to inform HEAL engagement framework and future meeting needs
- Work with NIH program scientists and investigators to understand engagement issues unique to populations in HEAL
- Gather input from community stakeholders, organizations and the HEAL community to guide best practice for engagement
- Develop a plan to promote representation in clinical trial participants



Lessons from the FDA Patient Focused Drug Development Program

*CAPT Robyn Bent, RN, MS, US Public
Health Service, Director, Patient Focused
Drug Development, FDA CDER*

FDA Slides

- The FDA Slides are in a separate link

Panel: Challenges, Opportunities, and Goals of Patient Engagement



Walter J. Koroshetz,
Director, National Institute of Neurological Disorders and Stroke , **Moderator**



CAPT Robyn Bent, RN,
MS, US Public Health
Service, Director, Patient
Focused Drug
Development, FDA
CDER



Dawn P. Edwards,
CEO of New York
State CKD
Champions, and
Wellness Ambassador,
The Rogosin Institute



Paul Kimmel, MD, MACP,
FASN, Senior Advisor, Program
Director HOPE, National
Institute of Diabetes and
Digestive and Kidney Diseases



Christin Veasley, Co-
founder & Director,
Chronic Pain Research
Alliance

Panel Discussion

- Begins at 29:00

Discussant Responses



Lynn Debar, PhD Senior Investigator, Kaiser Permanente Washington Health Research Institute, affiliate professor at the Department of Psychiatry, University of Washington



Mary Stroud RN, CCRP Project Manager Recruitment Innovation Center a part of The Trial Innovation Network, Vanderbilt Institute for Clinical and Translational Research

Discussant Responses

- Begin at 1:21

Question & Answer Session

Begins at 1:38

Questions Addressed

- How can we effectively engage patients in non-patient facing research (for example laboratory research, studies of clinician behavior, etc)?
- Is there some way to incorporate patient evals/surveys from prior studies into the new research protocol formulation process? Does all patient engagement need to be qualitative or can there be ways to incorporate quantitative data?
- What approach(es) are there for the inclusion of patients from underrepresented and minority backgrounds?

Questions Addressed

- How do we address patient engagement in a time of COVID-19 when the digital divide is further alienating large populations we need to connect with? I.e. older adults, rural communities, low income patients
- What are some of the tactics you use to mitigate the power differential between clinicians and the patient representative?
- For rare diseases, where there may be only very limited 'organized' patient groups - but many disparate unorganized groups across online forums etc (which actually represent 'more' patients) - how would you recommend establishing engagement for these groups?

Questions Addressed

- When do you choose to use the term 'patient' vs. 'participant' vs. something else?
- Can you please mention some specifics in engaging patients with active substance use? The role of stigma has been mentioned. I wonder, if little bit more info and sharing experiences would be possible.