

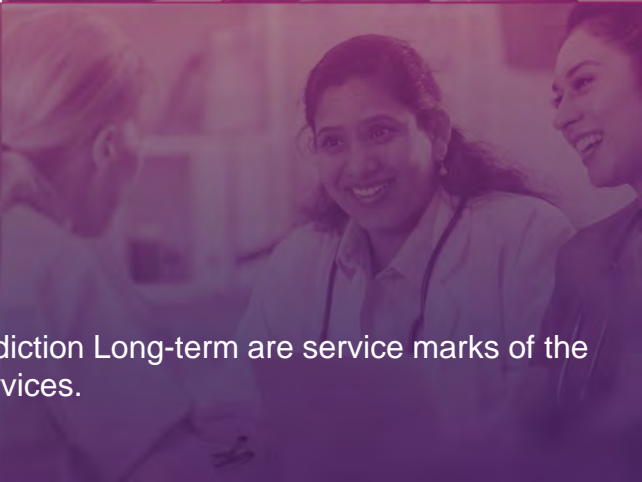
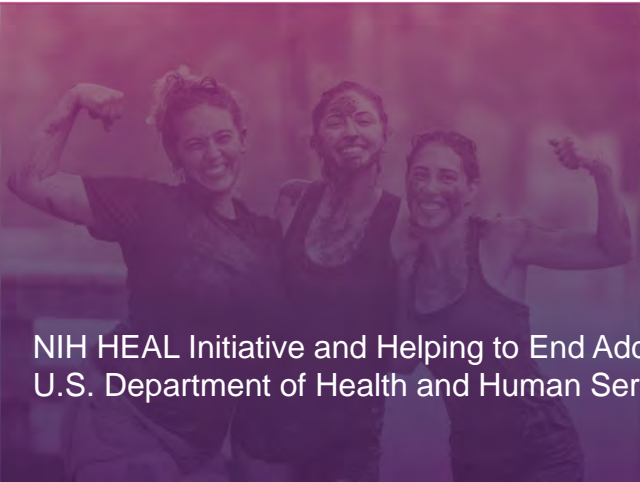


**NIH
HEAL
INITIATIVE**

Helping to End Addiction Long-term

December 2, 2019

Rebecca G. Baker, Ph.D.
Director, NIH HEAL Initiative



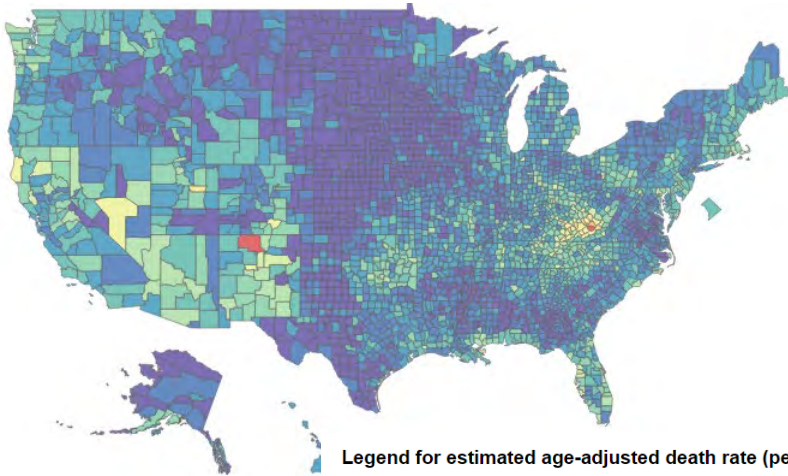
NIH National Institutes of Health
HEAL Initiative

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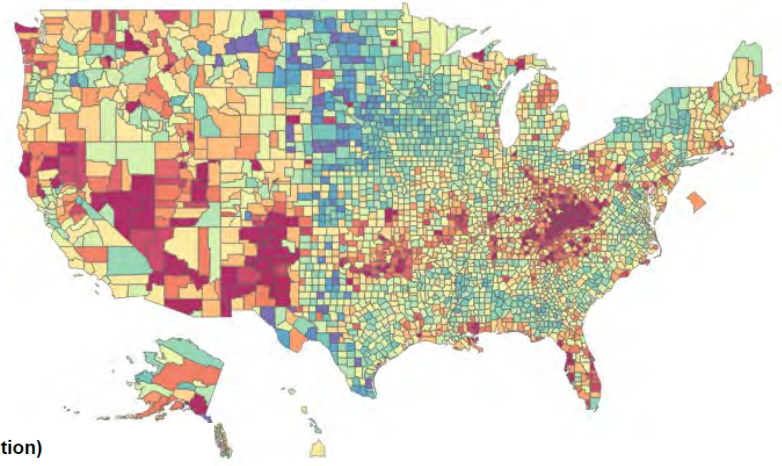
Crisis #1: National Overdose Death Rates

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

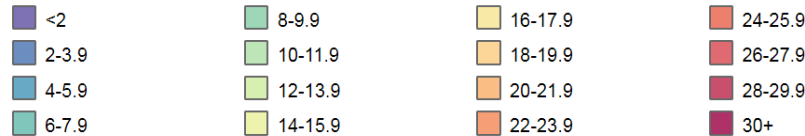
1999



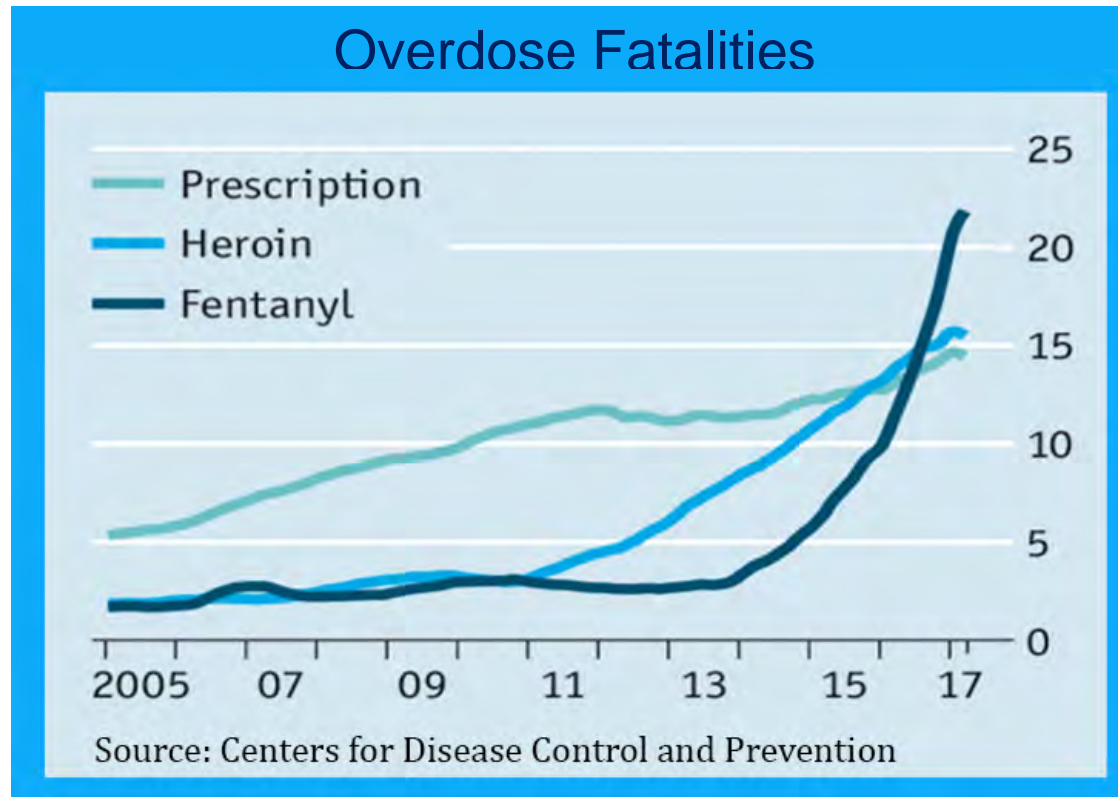
2016



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

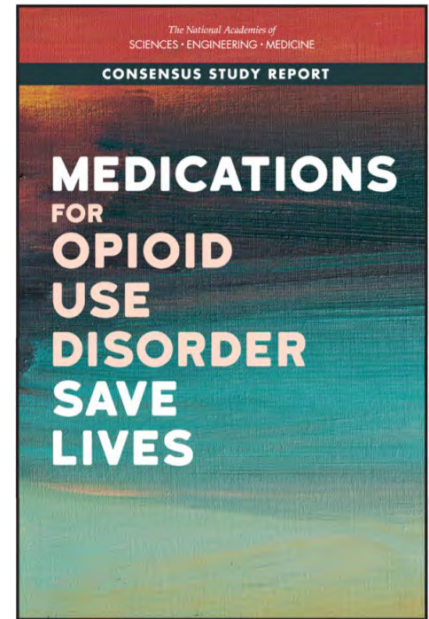


Evolution of the Opioid Crisis



National Academies Report on Medication for OUD (2019): Findings

- OUD: a life-threatening *chronic brain disease*
 - Caused by prolonged use of opioids, heroin
 - *Treatable*
- FDA-approved medications for OUD are effective, save lives
 - Methadone
 - Buprenorphine
 - Extended-release naltrexone
- Most who could benefit from medications *do not receive them*
- Confronting barriers to medication use *will save lives*



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

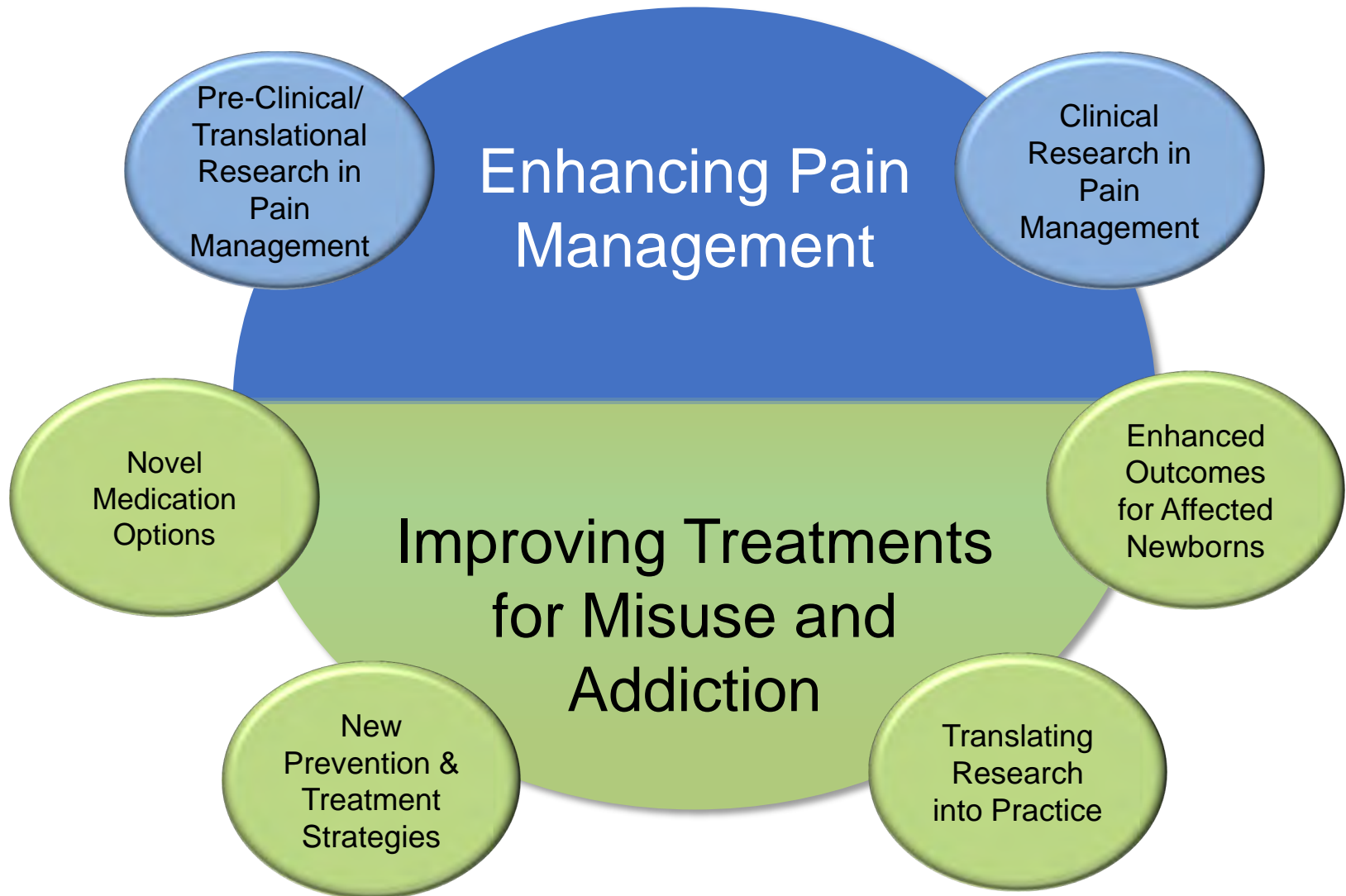


[CDC](#), Morbidity and Mortality Weekly Report, Sept. 2018

The Response: NIH HEAL Initiative

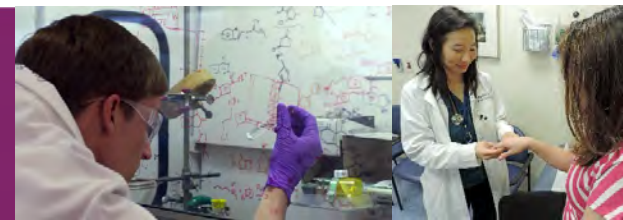
- Mission: scientific solutions to the opioid crisis
- \$500M/year Trans-NIH effort
 - Over \$945M obligated in FY2019
 - 400+ awards, through over 40 funding announcements, in 41 states
- 12 NIH Institute and Centers currently leading 26 HEAL research programs
 - Over 20 collaborating Institutes, Centers and Offices
 - From prevention, basic and translational research, clinical trials, to implementation science

HEAL Initiative Research Overview



Improving Prevention and Treatment Strategies for Opioid Addiction

- Expand therapeutic options for opioid addiction and overdose
 - New, more user-friendly formulations of existing medications
 - Longer duration, more powerful overdose-reversers
 - New approaches to reverse respiratory depression
 - New targets and approaches for treating Opioid Use Disorder (OUD)
 - Immunotherapies for opioids to prevent relapse and overdose



FDA-Approved Medications for Opioid Addiction and Overdose



- Methadone
- Buprenorphine
 - Sublingual
 - Monthly injection
 - Six month implant



- Naltrexone
 - Oral
 - Monthly



- Lofexidine
- Naloxone
 - Parenteral
 - Nasal



- Expand options in close collaboration with FDA

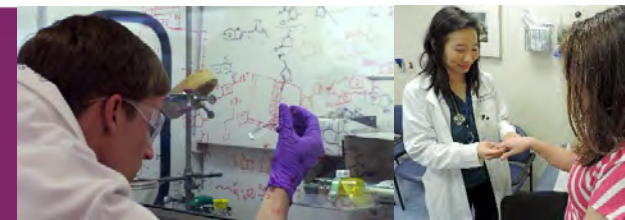
Improving Prevention and Treatment Strategies for Opioid Addiction

- Enhance Outcomes for Affected Newborns with Neonatal Abstinence Syndrome/ Neonatal Opioid Withdrawal Syndrome (NOWS)
 - HEALTHy Brain and Cognitive Development (BCD) Study
 - Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW)
 - Weaning and eat-sleep console studies to establish best screening and interventions
 - Longitudinal cohort study to examine the medical, neurodevelopmental, behavioral, and social outcomes of children exposed to opioids in utero



New Prevention & Treatment Strategies for OUD

- Preventing OUD among at risk adolescents
- Understanding the role of sleep dysfunction
- Managing opioid misuse/low severity OUD
- Determining the optimal length of medication treatment
- Optimizing collaborative care for people with OUD and common mental disorders

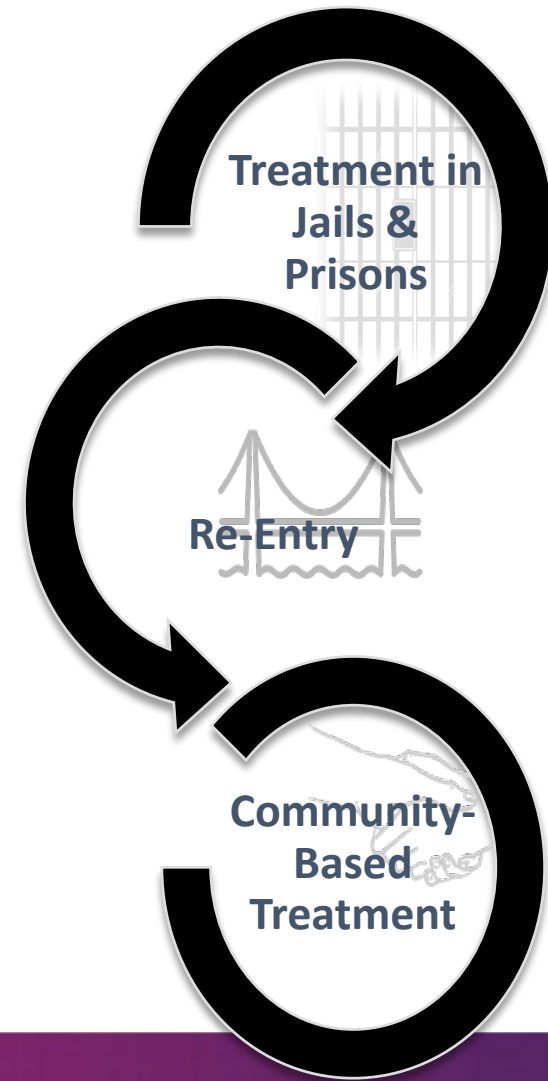


Translate Research into Practice for Effective Treatments for OUD

- Enhancing the NIDA Clinical Trials Network to address opioids
- Promoting innovation in the criminal justice system
- Understanding the role of behavioral health interventions
- Integrating multiple evidence based interventions in communities: HEALing Communities Study

Justice Community Opioid Innovation Network (JCOIN)

- Study quality care in justice populations
- Create partnerships between justice system and community-based treatment providers
- Studies conducted include:
 - A national survey of addiction treatment delivery services within the justice system
 - Effectiveness and adoption of new medications, prevention and treatment interventions, and technologies



The HEALing Communities Study

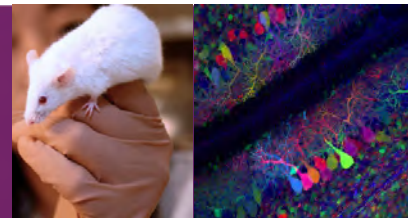
- Reduce opioid overdose deaths by 40% over the course of three years in partnership with SAMHSA
- Test effectiveness of coordinated systems of care to:
 - increase the number of individuals receiving medication for OUD
 - increase the distribution of naloxone
 - reduce high-risk opioid prescribing
- 67 communities in 4 states with high rates of opioid overdose
 - Inclusion of urban and rural communities

The HEALing Communities Study: Settings

Healthcare	Criminal Justice	Community
<ul style="list-style-type: none">• Primary care• Emergency departments• Inpatient hospital care• Behavioral health	<ul style="list-style-type: none">• Jails• Prisons• Parole/probation• Drug courts	<ul style="list-style-type: none">• Families• Schools• Police and fire departments• Faith-based organizations• Housing and employment

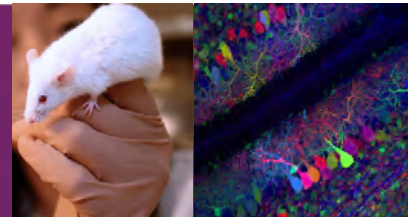
Preclinical and Translational Research in Pain Management

- Discovery and validation of novel targets
- Biomarkers, signatures and endpoints for pain
- Engineering preclinical screening platforms
- Translating discoveries into effective devices for pain treatment
 - e.g. implantable peripheral nerve stimulator for managing phantom limb pain among people with amputations



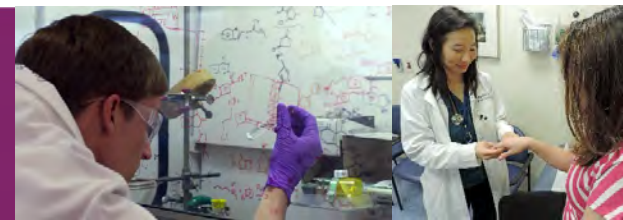
Clinical Research in Pain Management

- 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) Mission and Goals

- Accelerate the early phase testing of promising non-addictive therapeutics and devices to relieve pain
 - Test promising pain treatments (small molecules, biologics, devices) from academia and industry
 - Leverage pain expertise in both academia and industry
 - Train new clinical investigators
 - Characterize multiple different pain conditions
 - Incorporate biomarkers 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, leading to new therapies
- 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

Back Pain Research Consortium: BACPAC

- Multimodal, combination approach of pharmacotherapy plus behavioral therapy to treat negative affect in chronic low back pain
- Characterization of contributors to cLBP, including clinical, biological, behavioral, and biomechanical factors, to establish signatures associated with response to treatment
- Development of:
 - Wearable, nanocomposite biosensing system to capture 3D kinematics of the lumbar spine in full range of motion
 - Digital health platform for use of quantitative spinal motion metrics, PROs and patient preference information to facilitate patient phenotyping and clinical decision-making

Pain Management Effectiveness Research (ERN)

- Inform clinical practice about interventions or management strategies that improve functional outcomes and reduce pain across the continuum of acute to chronic pain
- Phase 3 effectiveness of pharmacologic and nonpharmacologic therapies for a broad array of pain conditions to reduce risk of opioids
 - Leverage NCATS Trials Innovation Network
 - Coordination and harmonization of data across studies
- Eg: Test the efficacy of an innovative behavioral treatment for chronic pain among patients prescribed buprenorphine for the treatment of opioid use disorder



Pragmatic and Implementation Studies for Management of Pain to Reduce Opioid Prescribing: PRISM

- Integrate interventions into health care systems, and implement health care system change toward evidence-based pain management
- Conduct large-scale pragmatic trials to improve pain management
 - Embed the intervention into real world settings
 - Collect data through the electronic records
 - Leverage the NIH Health Care Systems Collaboratory
 - Focus on non-pharmacological approaches
 - Collaboration with CMS for Medicare coverage consideration



Pragmatic and Implementation Studies for Management of Pain to Reduce Opioid Prescribing: PRISM

- Integrate interventions into health care systems, and implement health care system change toward evidence-based pain management
 - Test EHR-imbedded evidence-based bundled nonpharmacological interventions for perioperative pain management
 - Pragmatic trial to compare effectiveness of physical therapy with or without the addition of TENS for patients with fibromyalgia



Cross-cutting HEAL themes

- Engagement of research participants, patients, and stakeholders
- Sharing and open access of data
 - HEAL Public Access and Data Sharing Policy
 - Publications and underlying primary data, immediately and broadly available to the public
 - Harmonized measures established by HEAL teams
 - Secure platform for data submissions from a wide variety of basic, preclinical, and clinical research programs in HEAL



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www.heal.nih.gov