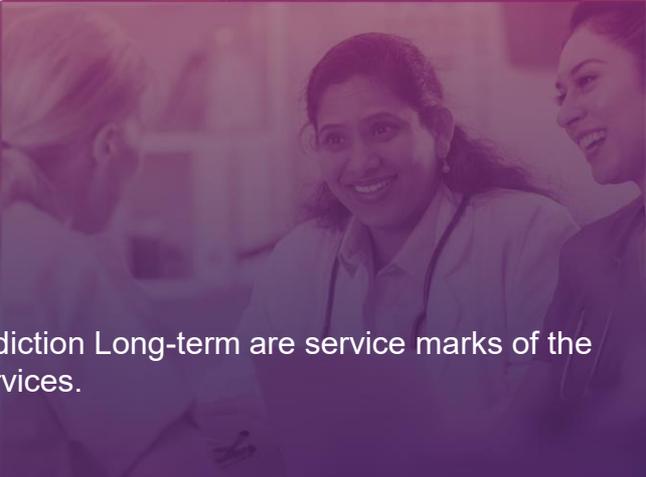# Helping to End Addiction Long-term

Rebecca G. Baker, PhD
Director, HEAL Initiative, NIH OD
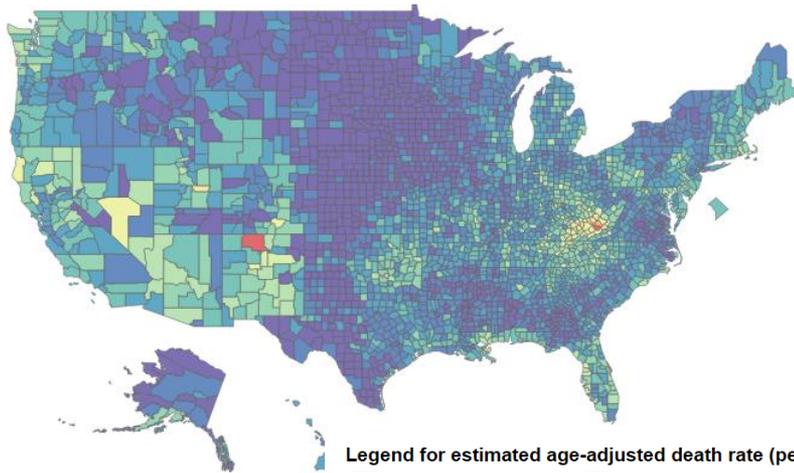
November 19, 2019

NIH HEAL INITIATIVE

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.
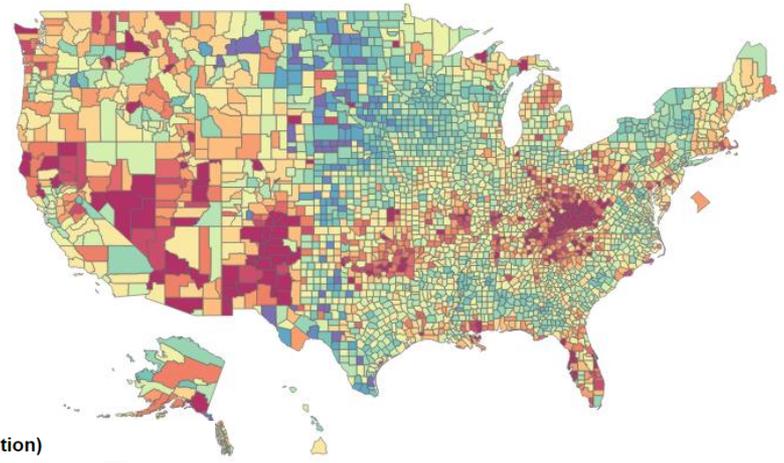
Crisis #1: National Overdose Death Rates

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)

<2	8-9.9	16-17.9	24-25.9
2-3.9	10-11.9	18-19.9	26-27.9
4-5.9	12-13.9	20-21.9	28-29.9
6-7.9	14-15.9	22-23.9	30+

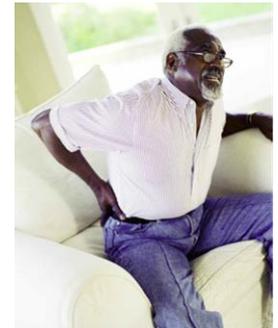Source: https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/index.htm

- 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
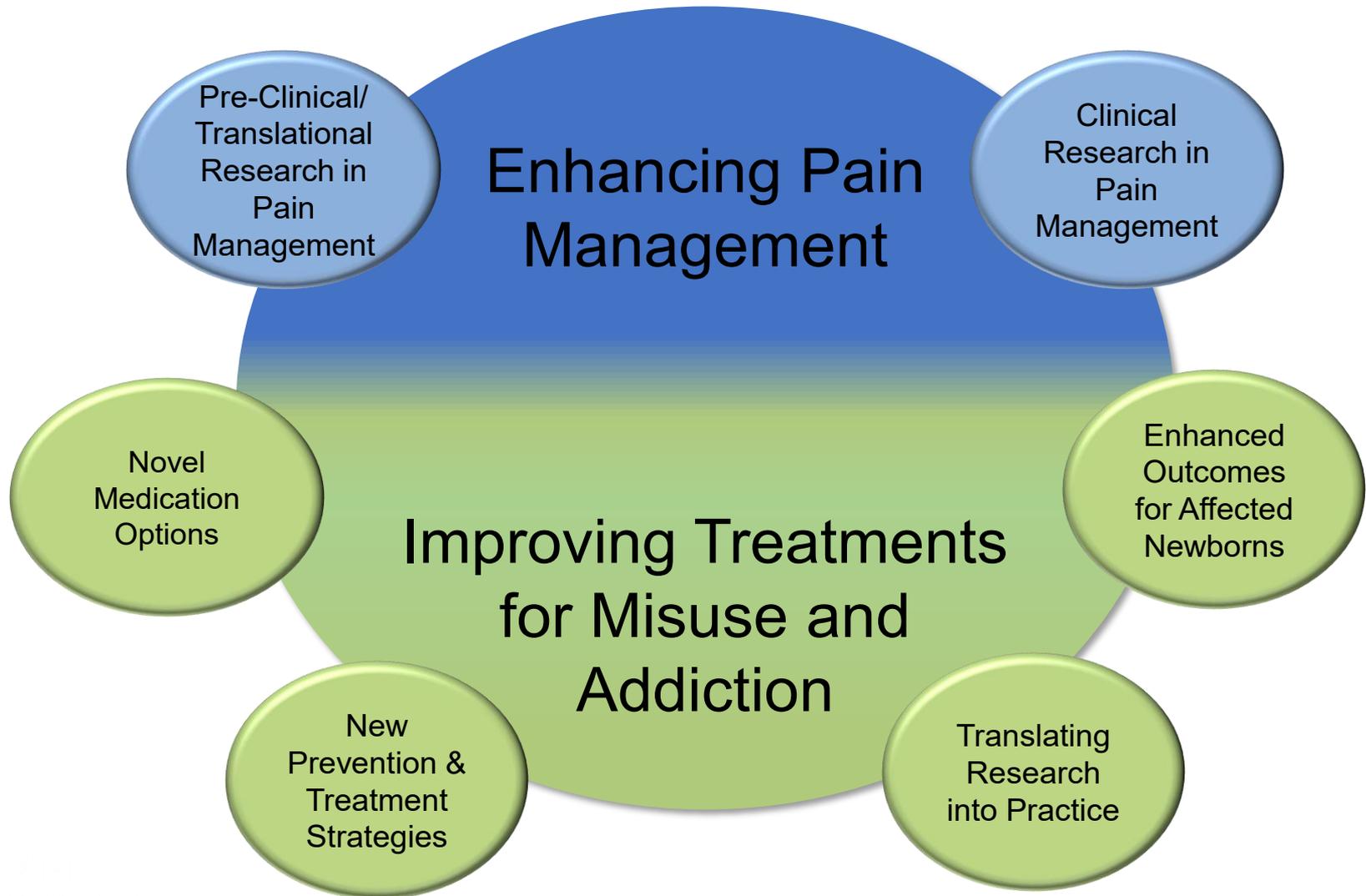- 20 million have high impact chronic pain

CDC, Morbidity and Mortality Weekly Report, Sept. 2018

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The Response: NIH HEAL Initiative

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

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HEAL Initiative Research Overview

Enhancing Pain Management

Improving Treatments for Misuse and Addiction

Pre-Clinical/ Translational Research in Pain Management

Clinical Research in Pain Management

Novel Medication Options

Enhanced Outcomes for Affected Newborns

New Prevention & Treatment Strategies
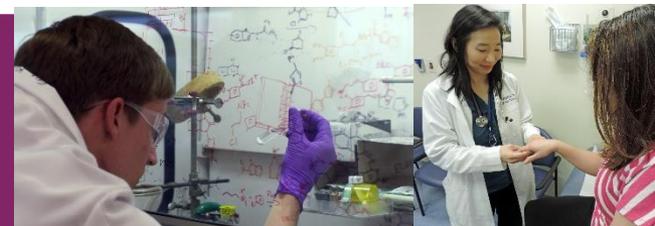
Translating Research into Practice

Improving Prevention and Treatment Strategies for Opioid Addiction

- Novel medication options for opioid addiction and overdose
    - Medications focused on addressing craving, novel targets
    - Immunotherapies for heroin and fentanyl

- Enhanced Outcomes for Affected Newborns
    - Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome: ACT NOW
    - Understanding the long-term consequences of early opioid exposure: HEALthy BCD Study
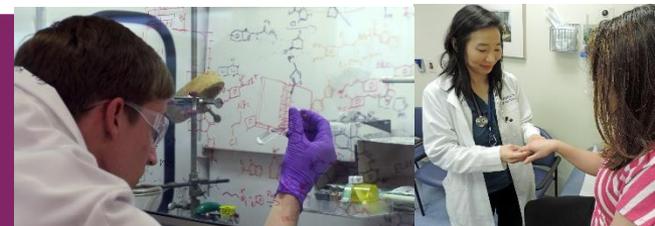
Improving Prevention and Treatment Strategies for Opioid Addiction (cont.)

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

Improving Prevention and Treatment Strategies for Opioid Addiction (cont.)

- Integrate 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

The HEALing Communities Study

- Primary Goal:
  - Develop an evidence-based, integrated and comprehensive strategy that reduces opioid-related overdose fatalities by 40% in 3 years across communities highly affected by the opioid crisis

- Key Outcomes:
  - Reduce overdose fatalities and events
  - Increase naloxone access
  - Decrease incidence of OUD
  - Increase the number of individuals:
    - receiving medication and behavioral treatment
    - retained in treatment beyond 6 months
    - receiving recovery support services

The HEALing Communities Study: Settings

Healthcare

- Primary care
- Emergency departments
- Inpatient hospital care
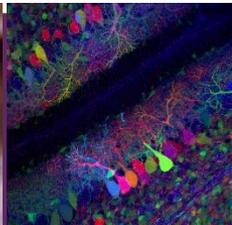- Behavioral health

Criminal Justice

- Jails
- Prisons
- Parole/Probation
- Drug courts

Community

- Families
- Schools
- Police and fire departments
- Faith-based organizations
- Housing & Employment

The HEALing Communities Study: Research Sites

Data Coordination Center: RTI International

Ohio State University
PI: Rebecca Jackson

Columbia University
PI: Nabila El-Bassel

Boston Medical Center
PI: Jeffrey Samet

University of Kentucky
PI: Sharon Walsh

Rural Communities ■   Urban Communities ■

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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

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Back Pain Research Consortium: BACPAC

A patient-centric, translational research program

- <u>BASIC</u>: Integrated model of Low Back Pain through improved understanding of mechanisms

- <u>TRANSLATIONAL</u>: Clinical trails, integrating new therapies into multimodal interventions, combined with deep phenotyping and patient-reported symptoms and outcomes

- <u>CLINICAL</u>: 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

- 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
    - Secure infrastructure that can receive structured data submissions from a wide variety of basic, preclinical, and clinical research programs in HEAL
    - Harmonized measures established by HEAL teams

Discussion

www.heal.nih.gov