NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.
Welcome and Introduction

Dr. Francis Collins, Director, National Institutes of Health (NIH)
HEAL Portfolio Overview and Recap of Investigators Meeting

Dr. Rebecca Baker, Director, Helping to End Addiction Long-Term (HEAL) Initiative, Office of the Director, NIH
NIH HEAL Initiative: By the Numbers

• Mission: scientific solutions to the opioids crisis
• $500M/year effort
  o Over $945M obligated in FY2019 to over 400 Investigators across 41 states
• Over 25 HEAL research programs
  o 12 NIH Institute and Centers leading,
  o 20 ICs collaborating on HEAL studies

Number of Awards
- 1-5
- 5-10
- 10-15
- >15

HEAL Portfolio Overview and Recap of Investigators Meeting
HEAL Research Expanded through NIH Networks

- Leveraging networks enables HEAL to access research participants in all 50 states
- Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)
  - Neonatal Research Network (NRN)
  - Institutional Development Award (IDeA) States Pediatric Clinical Trials Network in 16 states
- National Drug Abuse Treatment Clinical Trials Network (CTN)
  - 18 Nodes in 15 states
    - Nearly every state engaged in research through community collaboration
- Pain Management Effectiveness Research Network
  - Trial Innovation Network across 28 states
  - NCI Community Oncology Research Program (NCORP) base and community sites
  - Maternal Fetal Medicine Unit Research Network
HEAL Initiative Research Focus Areas

Enhancing Pain Management

- Pre-Clinical Research in Pain
- Clinical Research in Pain Management

Improving Treatments for Opioid Misuse and Addiction

- Expand Therapeutic Options
- Develop New/Improved Prevention & Treatment Strategies
- Enhance Treatments for Affected Newborns
- Optimize Effective Treatments

Clinical Research in Pain Management

NIH HEAL INITIATIVE

HEAL Portfolio Overview and Recap of Investigators Meeting 6
Pre-Clinical and Translational Research in Pain

- Discovery and validation of novel targets for safe and effective pain therapeutics
- 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

- Novel phase 2 clinical trials network: (EPPIC Net)
- Back Pain Research Consortium (BACPAC)
- Integrated approach to pain and opioid use in hemodialysis patients (HOPE)
- Pain Management Effectiveness Research Network (ERN)
- Pragmatic and Implementation Studies for the Management of Pain (PRISM)
New Prevention & Treatment Strategies for Opioid Use Disorder

- Preventing OUD among at risk adolescents
- Managing opioid misuse and low severity OUD
- Understanding the role of sleep dysfunction
- Determining the optimal length of medication treatment
- Optimizing care for people with OUD and common mental disorders
Translation of Research into Practice for Effective Treatments for Opioid Use Disorder

- Enhancing the NIDA Clinical Trials Network to address opioids
- Promoting innovation in the criminal justice system (JCOIN)
- Understanding the role of behavioral health interventions (BRIM)
- Integrating multiple evidence based interventions in communities: HEALing Communities Study
Novel Medication Options for Opioid Addiction and Overdose

• Increase effective medication options:
  o enhanced formulations
  o addressing craving and withdrawal
  o novel targets for addiction and overdose

• Immune-based therapies for heroin and fentanyl
Enhanced Outcomes for Affected Newborns

• Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome: ACT NOW Study
  o Eat-Sleep-Console; weaning from medication; longitudinal study

• Understanding the long-term consequences of early opioid exposure: HEALthy Brain and Child Development Study (BCD)
FY2019 Landscape Analysis
FY19 HEAL Investments by Priority Area

Total Obligation of FY19 Funding

- Opioid Misuse and Addiction: 37%
- Pain Management: 61%
- Research Support: 2%

Total Obligation of FY19 Funding – with multi-year funding costs broken out

- Opioid Misuse and Addiction: 47%
- Pain Management: 19%
- Research Support: 13%
- MYF: 19%

Total = $945,569,913
FY19 Obligation by HEAL Research Focus Area

Preclinical and Translational Research in Pain Management
Clinical Research in Pain Management
New Strategies to Prevent and Treat Opioid Addiction
Translation of Research to Practice for the Treatment of Opioid Addiction
Novel Medication Options for Opioid Use Disorder and Overdose
Enhanced Outcomes for Infants and Children Exposed to Opioids
Research Support

Total = $945,569,913
FY19 Projects by HEAL Research Focus Area

- Preclinical and Translational Research in Pain Management
- Clinical Research in Pain Management
- New Strategies to Prevent and Treat Opioid Addiction
- Translation of Research to Practice for the Treatment of Opioid Addiction
- Novel Medication Options for Opioid Use Disorder and Overdose
- Enhanced Outcomes for Infants and Children Exposed to Opioids
- Research Support

Total = $945,569,913

HEAL Portfolio Overview and Recap of Investigators Meeting
FY19 Projects by HEAL Research Focus Area: Year 1 Project Cost

Preclinical and Translational Research in Pain Management
Clinical Research in Pain Management
New Strategies to Prevent and Treat Opioid Addiction
Translation of Research to Practice for the Treatment of Opioid Addiction
Novel Medication Options for Opioid Use Disorder and Overdose
Enhanced Outcomes for Infants and Children Exposed to Opioids
Research Support

Total = $643,433,665
Total HEAL Investments: Programs launched in 2019

- Target Discovery and Validation
- Preclinical Screening Platform for Pain
- Drugs and Human Cell-Based Screening Platforms
- Optimizing Non-Addictive Therapies to Treat Pain
- Devices for Effective Pain Treatment
- Biomarkers, Endpoints and Signatures for Pain Conditions
- Pain Research SBIR
- EPPIC-Net
- BACPAC
- ERN
- PRISM
- Integrated Approach to Pain and Opioid Use in Hemodialysis Patients
- Prevention of Progression to Moderate or Severe Opioid Use Disorder
- Duration, Retention, and Discontinuation of Medication Treatment
- Sleep Dysfunction
- Collaborative Care for People with OUD & Mental Health Conditions
- Preventing OUD in Older Adolescents
- Opioid Misuse SBIR
- BRIM
- HEALing Communities Study
- JCOIN
- Clinical Trial Network
- Reducing Drug Craving in People with OUD
- Immunotherapies to Prevent Relapse and Overdose
- Medication Development
- HEALthy Brain and Child Development Study
- ACT NOW

Total = $945,569,913
HEAL Investments and Outyears

Total = $2,661,348,661
# Addressing Gaps in Research: Examples of FY20 Investments

<table>
<thead>
<tr>
<th>Understanding the Relationship Between Pain and Addiction</th>
<th>Addressing Opioid Use Disorder and Co-occurring Mental Health Conditions</th>
<th>Reducing Stigma of Addiction and Pain</th>
<th>Understanding Diversity of Care Received Across Health Settings</th>
<th>Increasing Diversity Among HEAL Investigators</th>
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</thead>
<tbody>
<tr>
<td>Targeted Clinical Trials of Palliative Pain Management in the Context of Opioid Use Disorder ($1M)</td>
<td>Social Network Analyses to Reduce American Indian and Alaska Native Opioid Use Disorder and Related Risks for Suicide and Mental Health Disorders ($2.6M)</td>
<td>Strategies to Reduce Stigma in Pain Management and OUD and Addiction Treatment ($3.75M)</td>
<td>Best Management of Specific Pain Conditions in Primary Care, Hospital, DENTAL or Emergency Settings ($28.3M)</td>
<td>Enhance the Workforce Diversity to Grow the Next Generation of HEAL Investigators in HEAL Areas of Research ($5M)</td>
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<td>Pain Management in the Setting of Opioid Use/OUD ($2.75M)</td>
<td>Research to Understand and Manage Common Co-Occurring Conditions and Suicide Risk in People Affected by the Opioid Crisis ($8M)</td>
<td>Workshop: Addressing Social and Economic Determinants of Opioid-Related Health Disparities- Expert Panel Workshop and Planning Meeting</td>
<td>Workshop: Navigating Pediatric to Adult Health Care: Lost in Health Care Transition</td>
<td>Training Supplement for Heal Network Clinical Trials ($2M)</td>
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<td>Workshop: Interventions for Managing Comorbid Chronic Pain &amp; OUD/Physical Dependence ($75K)</td>
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<td>Research Networks for the Study of Recovery Support Services for Persons Treated with Medications for Opioid Use Disorder ($6M)</td>
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<td>FOA</td>
<td>Title</td>
<td>Research Focus Area</td>
<td>Research Program</td>
<td>Expiration Date</td>
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<tr>
<td>NOT-DA-20-033</td>
<td>Notice of Special Interest: HEAL Initiative: Social Network Analyses to Reduce American Indian and Alaska Native Opioid Use Disorder and Related Risks for Suicide and Mental Health Disorders</td>
<td>New Strategies to Prevent and Treat Opioid Addiction</td>
<td>All</td>
<td>5/1/2020</td>
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<td>NOT-MH-20-025</td>
<td>Notice of Special Interest: HEAL Supplements to Improve the Treatment and Management of Common Co-occurring Conditions and Suicide Risk in People Affected by the Opioid Crisis</td>
<td>New Strategies to Prevent and Treat Opioid Addiction</td>
<td>Optimizing Collaborative Care for People with Opioid Use Disorder and Mental Health Conditions</td>
<td>4/8/2020</td>
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<tr>
<td>RFA-HL-20-031</td>
<td>HEAL Initiative: Pharmacotherapies to Reverse Opioid Overdose Induced Respiratory Depression without Central Opioid Withdrawal</td>
<td>Novel Medication Options for Opioid Use Disorder and Overdose</td>
<td>All</td>
<td>3/25/2020</td>
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<td>RFA-NS-19-018</td>
<td>HEAL Initiative: Clinical Devices to Treat Pain</td>
<td>Preclinical and Translational Research in Pain Management</td>
<td>Translating Discoveries into Effective Devices to Treat Pain</td>
<td>2/23/2021</td>
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<td>RFA-EB-18-003</td>
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<td>PAR-20-092</td>
<td>Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional)</td>
<td>Novel Medication Options for Opioid Use Disorder and Overdose</td>
<td>Focusing Medication Development to Prevent and Treat Opioid Use Disorder and Overdose</td>
<td>1/2/2020</td>
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Upcoming HEAL Workshops

March 2020
Developing meaningful endpoints for pain clinical trials

June 2020
Interventions for Managing Comorbid Chronic Pain & OUD/Physical Dependence

July 2020
Navigating pediatric to adult health care: Lost in health care transition

August 2020
Towards the Use of Buprenorphine in Infants: Scientific and Practical Considerations

September 2020
Target Validation for Non-Addictive Therapeutics Development for Pain - Strategic Approaches and Best Practices
Workshop on the structural and dynamic imaging of myofascial tissues: potential impact on musculoskeletal pain research

TO BE RESCHEDULED
Inaugural HEAL Investigators Meeting
HEAL Investigator Meeting Overview

• HEAL Investigators Meeting on January 16–17 2020, brought together more than 350 researchers who are part of HEAL

• Meeting Goals
  o Establish the HEAL investigator network through streamlined communications and the shared expertise of HEAL researchers
  o Increase awareness of the geographic, thematic and programmatic scope of HEAL
  o Explore commonalities and enhance individual programs to optimize the successes of HEAL
  o Enrich the HEAL initiative through investigator engagement
Plenary Panel Discussions

- Understanding and Addressing Pain
- Understanding and Addressing Opioid Use Disorder
- Reporting from the Front Lines on Pain and Addiction: Perspectives from National Reporters
- Collaborating for Success: Federal Partners in HEAL
- Understanding Stigma and the Impact on Public Health
Collaborating for Success: Federal Partners in HEAL

HEAL Portfolio Overview and Recap of Investigators Meeting
Cross-cutting Topic Breakout Sessions

• Integrating Co-occurring Conditions into HEAL Research  
  *Moderator:* Helene M. Langevin, MD, C.M., Director, NCCIH

• Translating from Basic to Clinical Research  
  *Moderator:* Jack B. Stein, PhD, Chief of Staff, NIDA

• Assessing Pain and Risk for Opioid Use Disorder  
  *Moderator:* Robert H. Carter, MD, Acting Director, NIAMS

• Overcoming Challenges in Therapeutics Development  
  *Moderator:* Donald C. Lo, PhD, Director, Therapeutic Development Branch, NCATS, and Linda Porter, PhD, Director, Office of Pain Policy and Planning, NINDS

• Incorporating Stakeholder Input  
  *Moderator:* Diana W. Bianchi, MD, Director, NICHD
Data Sharing and Harmonization Across HEAL: Group Discussions

- Therapeutics Development
- Basic Science of Pain and Opioid Use Disorder
- Clinical Trials: Phase 2 and Effectiveness Trials
- Clinical Research: Implementation and Sustainability
Investigator Meeting Themes and Next Steps

- Investigators expressed strong desire to continue to connect with one another as studies get underway
  - HEAL PI listserv
  - Website functionalities
  - Central engagement platform
- Need for ongoing engagement between HEAL investigators and NIH across projects, programs, and focus areas
  - Data needs are one important touchpoint
- Voices of research participants, patients, providers are essential
- Importance of ongoing research and funding opportunities
Discussion