NIH
HEAL
INITIATIVE

HEAL Initiative: Optimizing Multi-Component Service Delivery Interventions for People with Opioid Use Disorder, Co-Occurring Conditions, and/or Suicide Risk (R01 Clinical Trials Optional)

RFA-MH-21-145

Michael C. Freed, Ph.D., EMT, National Institute of Mental Health

Purpose

- Invite research that will optimize multi-component service delivery interventions for people with opioid use disorder (OUD) and co-occurring conditions, to include mental disorders and/or suicide risk
- Support studies that will
  - Test the overall effectiveness of multi-component interventions for OUD and co-occurring conditions and
  - Examine the relative contribution of constituent components to overall effectiveness
- This research will streamline service delivery packages so that they only include components that drive clinical improvements for complex conditions

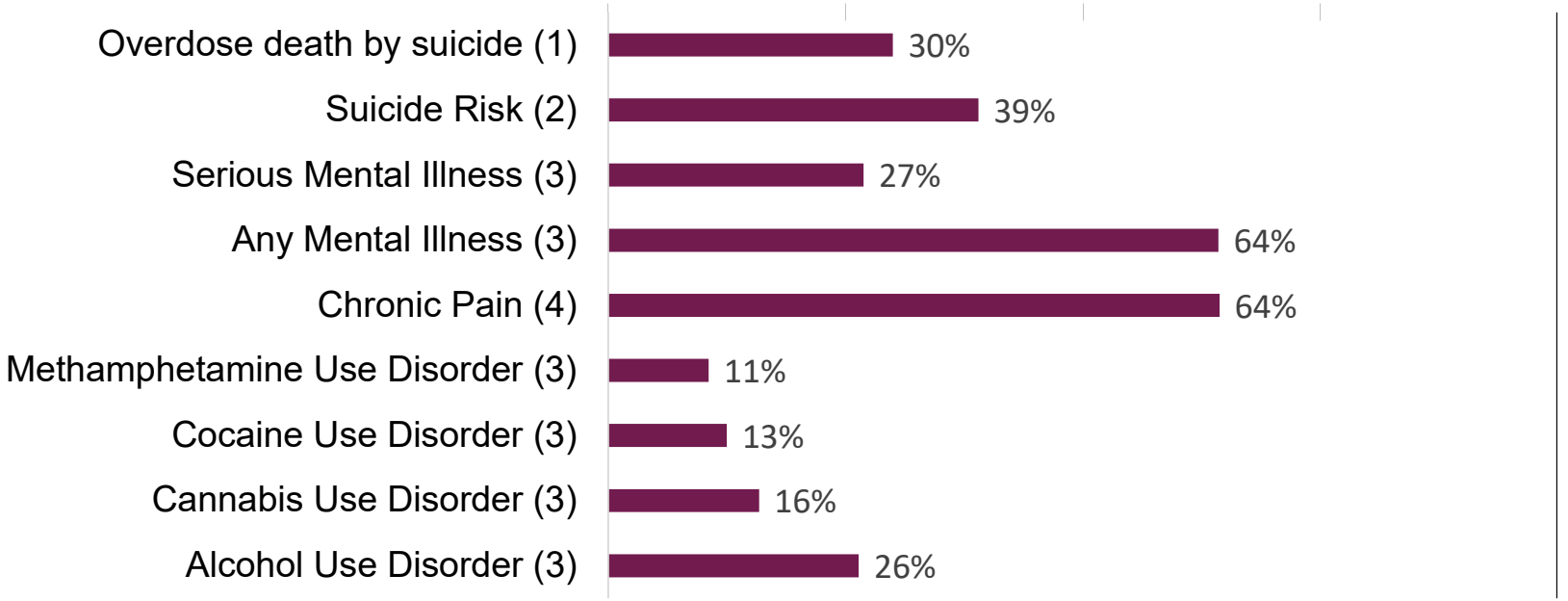
NIH intends to commit $5 million per year to fund up to 3 awards. Projects not to exceed 4 years.

Key Dates*

• Earliest Submission Date	February 18, 2021
• Letter of Intent Due Date	February 18, 2021
• **Application Due Date**	**March 18, 2021**
• Scientific Merit Review	May 2021
• Advisory Council Review	August 2021
• Earliest Start Date	September 2021

*These dates are earlier than those for the IMPOWR RFAs.

Co-Occurring Conditions are Serious, Common, and a Priority to Address though HEAL



The 16-21% of Americans who have mental health illnesses receive over half of all opioids prescribed in the United States (5,6)

(1) N Engl J Med. 2018 Apr 26;378(17):1567-1569.
(2) Addict Behav. 2018 Nov;86:66-72.
(3) Drug Alcohol Depend. 2019 Apr 1;197:78-82.
(4) J Subst Abuse Treat. 2017 Jun;77:26-30.
(5) J Am Board Fam Med. 2017 Jul-Aug;30(4):407-417.
(6) https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFRPDFWHTML/2019NSDUHFFR1PDFW090120.pdf

Behavioral Health Service Delivery Models in the Wild

- Heterogeneous in terms of composition of constituent components, target condition(s) to be treated, demonstrated evidence of effectiveness, and popularity
- Promoted and implemented ahead of demonstrated effectiveness (1-4)
- Evolving in popularity and evidence for OUD (5)
- Ripe for optimization to meet the complex needs of people with OUD and co-occurring conditions

Examples						
SBIRT	**Collaborative Care**	**Zero Suicide**	**Primary and Behavioral Health Care Integration**	**Co-Location**	**Massachusetts Model**	

(1) JAMA Intern Med, 2016. 176(5): p. 691-2; (2) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5809898/; (3) https://www.samhsa.gov/sbirt; (4) https://www.hrsa.gov/behavioral-health; (5) Journal of Substance Abuse Treatment 60 (2016) 6–13; CTN-0074

Need for Designs that Balance Rigor with Time-to-Practice Urgency

- Clinical trials are the gold standard for intervention testing
  - First-order priority is to detect the main effect of an intervention
  - Not powered or designed to dissect constitute components of bundled intervention packages
- Optimization approaches can generate practice relevant evidence
  - Are powered to *efficiently* and simultaneously test the main effects and interactions of *several* intervention components
  - Can unbundle the intervention package and test the effects of multiple experimental manipulations that would make a parallel arm trial cumbersome

Rigorous Practice Relevant Evidence

Need for Urgent Solutions

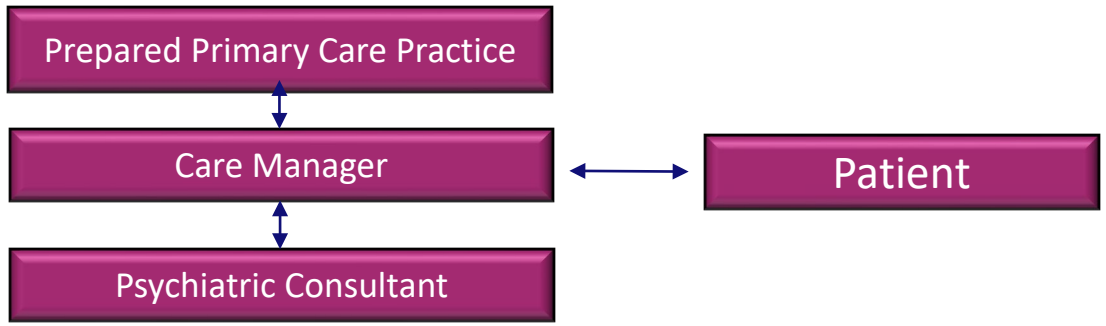
Research Questions (Examples)

- ✓ What are the *high value* components of multi-component service delivery models that drive clinical improvements and should be implemented?
- ✓ In what *sequence* should high value components be implemented, if simultaneously implementing all components of a service delivery model is untenable?
- ✓ When and how should high value components be *intensified* to achieve maximum clinical benefit?
- ✓ What are the *low value* components within multi-component service delivery models that do not contribute to clinical effectiveness and should be de-implemented?
- ✓ What are the *optimal* parameters of multi-component interventions (e.g., parameters like caseload size, makeup of care team, job functions) that yield clinical improvement and maximize intervention reach under real-world resource constraints?

Examples for Optimizing Multi-Component Interventions with Prior Evidence of Clinical Effectiveness

- ✓ Identifying the high value components of the collaborative care model to implement and/or informing how to prioritize the implementation of multiple components (e.g., components like routine screening for depression and anxiety, training/hiring a psychiatric consultant, training/hiring care managers, the disease registry) in resource constrained environments.
- ✓ Identifying the relative value of behavioral counseling (to include the specific content of the behavioral counseling) as part of Medications for OUD (MOUD), to improve clinical outcomes for mental health conditions and suicide risk and promote initial and sustained engagement with MOUD.
- ✓ Identifying optimal functions or composition of integrated care teams (e.g., value of a psychiatric consultant who is a psychiatrist versus a nurse practitioner, physician's assistant, or psychologist with prescription privileges).

The Collaborative Care Model[1-3]



(1) J Gen Intern Med 2016, 32(4):404–10
(2) *JAMA Intern Med.* 2017;177(10):1480-1488.
(3) J Gen Intern Med 2019 34(9):1693–4

Examples for Optimizing Multi-Component Interventions with Prior Evidence of Clinical Effectiveness (Continued)

- ✓ Assessing the value of adding, de-implementing, or varying psychosocial treatment modules (e.g., motivational interviewing delivered by a care manger to promote engagement versus problem solving therapy, the brief negotiated interview, or behavioral activation) delivered as part of a multicomponent integrated care model.
- ✓ Evaluating the relative contribution and trade offs of optimizing service provisions, as part of a system of care for high-risk patients in the emergency department (e.g., proactive suicide screening and assessment, referral processes, intervention and aftercare strategies) given the high proportion of patients with comorbid pain, opioid use, and mental health conditions.

Example Topics for Optimizing Multi-Component Interventions <u>without</u> Prior Evidence of Clinical Effectiveness

- ✓ Optimizing the Massachusetts Model to address and treat not only OUD but also other co-occurring problems and suicide risk.
- ✓ Optimizing components of the SBIRT framework, to include specifically adding MOUD, and intensifying referral to treatment where most patients are lost to follow up, in efforts to improve outcomes in people with OUD and co-occurring problems.
- ✓ Prioritizing and sequencing components of the Zero Suicide framework (e.g., Zero Suicide pillars such as staff training, case identification, patient engagement, treatment, care transition, and continuous quality improvement) to also meet the needs of people with co-occurring OUD.

1) Journal of Substance Abuse Treatment 60 (2016); 2) CTN-0074; 3) J Gen Intern Med (2017) 32(4):404–10; 4) JAMA Intern Med. 2018;178(5):613-621; 5) Public Health Rev. 2017; 38: 31; 6) https://www.samhsa.gov/sbirt; 7) https://www.integration.samhsa.gov/clinical-practice/sbirt; 8) Addict Sci Clin Pract. 2017 Aug 7;12(1):18; 9) JAMA. 2018;320(18):1899-1909.

Low Priority Research Projects

- Projects that primarily test implementation strategies rather than test the effectiveness of constituent components
- Projects that will not clearly identify the constituent components hypothesized to drive clinical improvement
- Projects that test constituent components of interventions that extant evidence demonstrates to be ineffective
- Projects that focus on dismantling therapeutic interventions (e.g., components of cognitive behavioral therapy; CBT), rather than examining the contribution of elements of a multi-component service delivery approach

Design Considerations

- Design must unbundle and test components (and/or combinations of components)
- This RFA requires the use of innovative designs that efficiently and simultaneously test the main effects and interactions of several intervention components. Examples designs include the following:
  - Factorial designs and their derivatives (e.g., fractional factorial)
  - Multiphase Optimization STrategy (MOST)
  - Sequential, Multiple Assignment, Randomized Trials (SMART)
  - Randomized encouragement
  - Interrupted time series designs or other quasi-experimental approaches, where randomization may not be possible

Design Considerations (continued)

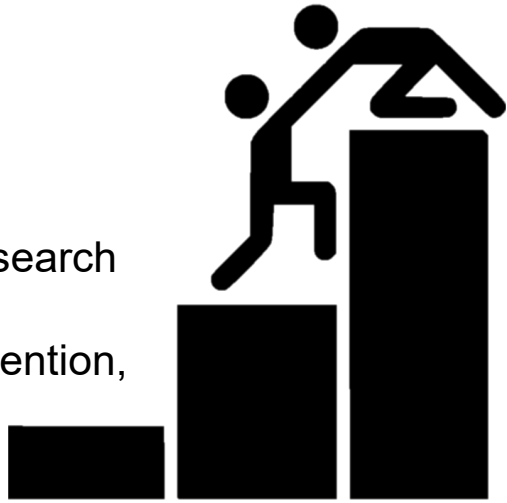
- Consistency with the NIMH experimental therapeutics approach
  - A mechanistic approach to understanding why the components drive improvements in primary outcomes
  - https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml#faq
- Deployment focused
  - Leverage strong and clearly defined research practice partnerships
  - Consider the perspectives of relevant stakeholders and key characteristics of settings intended to deliver optimized service delivery interventions.
  - Interventions should be tested as naturalistically as possible in order to increase the generalizability and potential for translation from research to practice
  - Studies should furnish services through existing providers/vendors of such services and leverage existing financing mechanisms that support clinical care
  - Studies under this announcement should assess the adequacy of existing financing models to support the service delivery models being tested

Collaborations with IMPOWR Project Teams: RFA-DA-21-029 and RFA-DA-21-030

- Collaboration Goals
  - Develop or harmonize common data elements, standard measures, and uniform data collection procedures;
  - Participate in a bidirectional pipeline to facilitate practice-based research and improve early identification, diagnosis, clinical assessment, intervention effectiveness, service delivery, and health outcomes in people affected by the opioid epidemic; and
  - Identify innovative assessment, intervention, and quality improvement practices for broad dissemination

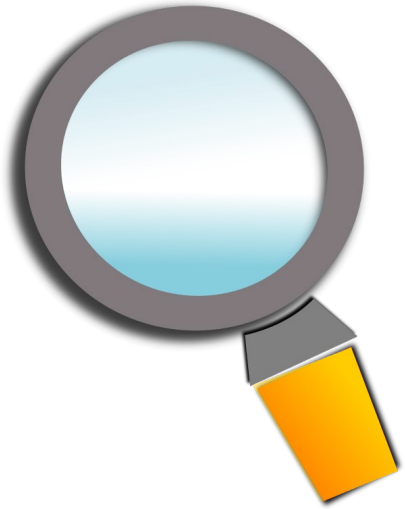
Collaborations with IMPOWR Project Teams: RFA-DA-21-029 and RFA-DA-21-030 (continued)

- Expected participation in shared executive committee meetings, which will meet quarterly and in an annual in-person 2-day meeting throughout the life of the award
- Expected participation in workgroups and breakout sessions that arise to support synergistic activities across HEAL activities (e.g., publication policy, data policy, stakeholder and patient engagement, biostatistics, and subject recruitment).
- Goals of participation:
  - Share research updates;
  - Create opportunities of synergy and collaboration (e.g., data harmonization, protocol modifications);
  - Develop a bidirectional pipeline between the research projects to facilitate practice-based research and improve early identification, intervention effectiveness, service delivery, and optimal components that are driving integrated care delivery for OUD, mental disorders, suicide prevention, and/or chronic pain.



Take Note of These Easy to Miss Sections

- Common Data Elements
  - Include the collection of common data elements per NOT-MH-20-067
  - Provide a rationale that justifies the decision to not include those common data elements
- Required Data Sharing Plan
  - Complies with NIMH data sharing policy (https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-033.html) and
  - Complies with NIH HEAL Initiative Public Access and Data Sharing Policy (https://heal.nih.gov/about/public-access-data).
  - The necessary funds for submitting data to the NIMH Data Archive (NDA) should be included in the requested budget: (https://nda.nih.gov/ndarpublicweb/Documents/NDA_Data_Submission_Costs.xlsx)
- Expertise and Experience
  - Methodological and analytic
  - Familiarity with financing models, clinical delivery of care, etc.



Questions

Peer Review Contact

Nick Gaiano, Ph.D.

National Institute of Mental Health (NIMH)

Telephone: 301-827-3420

Email: nick.gaiano@nih.gov

Financial/Grants Management Contact

Tamara Kees

National Institute of Mental Health (NIMH)

Telephone: 301-443-8811

Email: tamara.kees@nih.gov

Scientific/Research Contact

Michael C. Freed, Ph.D., EMT

National Institute of Mental Health (NIMH)

Telephone: 301-443-3747

Email: michael.freed@nih.gov

Sending a concept paper in advance will help inform a discussion about specific research ideas.