



National Institute
on Drug Abuse

HEALing Communities Study

Part of the NIH Helping to End Addiction Long-term Initiative and
a partnership between NIH, NIDA, and SAMHSA

National Advisory Council on Drug Abuse

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Background

- ▶ Opioid overdose fatalities continue to rise with a recognized gap between those needing and receiving interventions
- ▶ Multiple effective prevention & treatment interventions exist to address opioid misuse, OUD, and overdose
- ▶ Effective interventions have failed to penetrate community settings
- ▶ Strategies are needed to help communities:
 - ▶ Understand their unique needs
 - ▶ Develop a response strategy that integrates evidence-based prevention & treatment interventions across multiple settings



Goals of the HEALing Communities Study

- ▶ Develop and test strategies to help communities respond rapidly and effectively to their opioid crisis with a focus on significantly reducing opioid-related overdose fatalities and improving other outcomes
- ▶ Measure the impact of integrating evidence-based prevention and treatment for opioid misuse, OUD, overdose, and overdose fatalities across multiple settings (healthcare, behavioral health, justice, etc.)
- ▶ Determine factors (structural, organizational, policy, etc.) that contribute to successful implementation and sustainability of the community strategy and integrated care
- ▶ Determine the incremental costs and cost-effectiveness of a coordinated integrated evidence-based prevention & treatment system compared to standard of care



Primary Outcomes

- ▶ **Primary Outcome:** Reduce opioid related overdose fatalities by 40% in 3 years
- ▶ **Secondary Outcomes:**
 - ▶ Decrease rates of non-fatal opioid related overdose events
 - ▶ Decrease misuse of opioids, OUD, progression in severity to OUD or injection drug use
 - ▶ Increase # individuals receiving medication & behavioral treatment
 - ▶ Increase # individuals retained in treatment beyond 6 months
 - ▶ Increase # individuals receiving recovery support services
 - ▶ Other related secondary outcomes determined by communities & investigators



Target Community Structural Changes

- ▶ Change prescribing patterns to reduce supply of prescription opioids in community
- ▶ Expand prevention, treatment, recovery services in healthcare, behavioral health, and justice settings
- ▶ Increase number of specialized treatment programs providing medication for OUD
- ▶ Increase # providers prescribing/monitoring use of medications for OUD
- ▶ Increase availability of naloxone across a community to reduce fatal overdose
- ▶ Increase use of screening and brief intervention to address opioid misuse within healthcare settings
- ▶ Increase # partnerships between justice settings and healthcare organizations to deliver OUD care to justice population
- ▶ Other structural changes determined by communities & investigators



Research Site Study Requirements (up to 3)

- ▶ Research in *highly affected* communities: Counties, cities, or towns within states burdened with higher than average rates of overdose mortality and opioid-related morbidity, and other complications (all communities in research site from same state, 30% rural,)
- ▶ Leverage federal, state, local, foundation, other resources and infrastructure to: a) collect data; b) deliver prevention & treatment services
- ▶ Research Site key personnel: governmental official with ability to influence contracting, type, quality, and integration of opioid care across all communities
- ▶ Include healthcare, behavioral health, justice settings
- ▶ Apply cluster, rather than individual trial designs
- ▶ Implement common data elements, measures, and approaches



Data Coordinating Center Requirements

- ▶ **Support:**
 - ▶ Study coordination, communication, collaboration
 - ▶ Data management, analyses for cross-site research questions, modeling
 - ▶ Conduct health economics research
- ▶ **Collect and report on metrics to monitor study implementation and progress**
- ▶ **Collect and report on community structural changes necessary to impact primary and secondary outcomes**



Activities to Date:

- ▶ **Planning Meeting (June 18, 2018):**

- ▶ <https://www.drugabuse.gov/drugs-abuse/opioids/nih-heal-initiative>

- ▶ **Request for Information (June 29-July 20, 2018):**

- ▶ <https://grants.nih.gov/grants/guide/notice-files/NOT-DA-18-023.html>

- ▶ **Notice of Intent to Publish FOA's (July 18, 2018):**

- ▶ **Research Sites:**

- <https://grants.gov/grants/guide/notice-files/NOT-DA-18-026.html>

- ▶ **Data Coordinating Center:**

- <https://grants.nih.gov/grants/guide/notice-files/NOT-DA-18-025.html>



Questions

