June 20, 2018
Deputy Director Lawrence A. Tabak
National Institutes of Health
Substance Abuse and Mental Health Services Administration
Department for Health & Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

Submitted via email to: OpioidRFI@nida.nih.gov

RE: Request for Information on the HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis

On the behalf of OCHIN, we appreciate the opportunity to respond to the Request for Information on the HEALing Community Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis. The Department’s efforts to establish a national research effort to intervene in the opioid crisis in an informed manner runs parallel to OCHIN’s efforts to create strong policy out of extensive research on the patient population.

OCHIN is a 501(c)(3) nonprofit community-based health information technology collaborative based in Portland, Oregon. OCHIN receives support from the U.S. Department of Health and Human Services Administration (HRSA), and is a HRSA-designated Health Center-Controlled Network (HCCN). OCHIN’s mission is to pioneer the use of health information technology in caring for the medically underserved. As such, OCHIN serves community health centers (CHCs), including Federally Qualified Health Centers (FQHCs), rural and school-based health centers, safety-net providers and public health and corrections facilities across the nation. OCHIN’s comments are based on our experiences with the opioid crisis’ impact on the members we serve.

Study Design

- OCHIN suggests defining “heavily affected communities” by focusing on populations. Some of the more vulnerable populations include those who are incarcerated or transitioning, veterans, and seniors. We also suggest focusing on those that are migrant or homeless. Through a fully integrated EHR, you can track their movements and determine their proximity and access to services. For context, HHS could consider using the CDC “high-risk county.”

- The study design could be left to the researcher, but OCHIN suggests a staggered design with some randomization/stepped wedge, smart design, experiments (policy comparison) description, and natural. Not just a randomized controlled trial.

- Baseline data should include current rates of opioid use disorder (OUD), overdoses, treatment received, community level data including reports from first responders, EMS, and police, as well as rates of good Samaritan naloxone distribution. Additional information which could provide some baseline data include alternative pain management rates and use of benzodiazepines, morphine, and muscle relaxants. Prevention efforts should also be included in this data, for
example, rates of prescriptions of naltrexone, buprenorphine, and methadone. Sources include national EMS, electronic health records (EHR), and police reports. Challenges could include data integrity of linking unique events and individuals.

- Some confounding variables to be considered are state, clinic, and provider and patient-level variables. Race and ethnicity as well as community characteristics, and access to treatment can also provide additional insight. Diagnosis and comorbidities are essential to consider, along with individual social determinants of health.

- Threats to internal and external study validity include the sheer overwhelming number of new studies and policies concerning opioids. Additionally, co-occurring interventions, such as changes in state policies, should be mitigated by accounting for this in analyses.

- Strategies which could help the Coordinating Center overcome barriers to the facilitation of collaboration and coordination activities with regard to data should include ADVANCE or PCORI model data standardization and datasets, and interventions across multiple industries. There should also be better models for data governance or linkage for unique encounters and modeling like the metric development (CMS).

- Economic questions which should be included as part of the study to inform systems and policy change should include patient income and insurance (churn impact); employment (infrastructure for employers); housing; cost of treatment vs. the cost of lives vs. their societal contribution; the medication costs; the behavioral health costs; inpatient and outpatient treatment and access to treatment; and the social support costs.

- Clinicians want to know how to help patients with chronic pain, and other medically unexplained problems with tools beyond our biomedical pills. They want to present information to stakeholders for community empowerment which can mobilize behavioral health and physical health providers for intervention. Some examples include determining hot spots for overdoses and then targeting those areas with a safe injection site, or registering providers to administer medication-assisted treatment, and then treatment retention.

- Target metrics for feasible outcomes:
  - Rates of non-fatal and fatal overdose
  - Prevalence and incidence of opioid misuse, OUD and Hepatitis C
  - Percent of patients screened for opioid misuse and OUD and who received a brief intervention or were referred to treatment
  - Percent of patients initiated on MAT and retained in medication treatment beyond 6 months
  - Rates of naloxone distribution and overdose reversals
  - Opioid analgesic and benzodiazepine prescription rates
  - Implementation of prevention programs

- Essential interventions for an evidence-based integrated approach to opioid prevention and treatment services require thinking about the right implementation strategies, such as
prescribing buprenorphine, or using the NAITX model to improve access and retention to behavioral health services.

- Measurements should include live interviews and site visits during, and pre (focus groups).
- Effective strategies for meaning penetration of the integrity approach include coaching, educating providers and supplemental staff on opioid management and prescribing reduction, and referral and waivers, as well as stigmas. Access to naloxone, needle exchange, and safe-injection locations could also provide an impact.
- Data for helping metrics are prescribing, diagnosis, and if possible, inpatient data. Also EMS responses, police responses, arrests/criminal justice statistics, social services access, and births or deaths.
- For a community-based pragmatic trial assessing the impact of an evidence based integrated approach to opioid prevention and treatment services a partnership should be formed to provide emergency department and inpatient data to researchers. Additionally, partnerships between prisons, virtual care and behavioral health providers would increase the effectiveness of treating OUD. To increase the impact, prescription licenses should expand, and behavioral health data should be shared more readily between all providers, to create a more complete medical record and increase opportunities for treatment (amend 42 CFR part 2).
- The best approach for fostering collaboration between state, county, and local governments; community stakeholders; medical/clinical service providers; and researchers are building relationships based on transparency, having annual live meetings to foster discussions and connections, have consistent task group check-ins, translating evidence to the audience, and increasing or mandating data transparency for participation.
- An optimal research initiative needs to be EHR-based with aligned incentives. If it’s clinical, ensure the tools and workflows make clinician work more efficient to reduce provider burnout and ensure participation. It has been shown that when clinicians are required to use multiple systems for data sharing, the secondary mechanism is used with less frequency and accuracy, and increases clinician workload, reducing efficiency.

We thank you for your time and consideration of our comments on the Request for Information on the HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis.

Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

Jennifer Stoll
VP, Government Affairs and Public Relations