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Introduction to the special issue on the HEALing Communities Study

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ABSTRACT

The severity of the overdose epidemic underscores the urgent need for innovative and high impact interventions that promote the rapid penetration and scale up of evidence-based practices (EBPs) in communities profoundly affected by fatal opioid overdose. This special issue shares scientific advancements in implementation research design and evaluation of a novel data-driven community-based intervention. The HEALing (Helping End Addiction Long-Term) Communities Study (HCS) is a four-year study that is designed to examine the effectiveness of the Communities That HEAL (CTH) intervention. The CTH intervention supports the dissemination of EBPs in 67 communities across four high-burdened states—Kentucky, Massachusetts, New York, and Ohio. The diversity in these communities in terms of rural-urban status, race-ethnicity and other social determinants of health facilitates generalizability of results to other communities across the US.

The nine papers in this special issue describe critical elements that constitute the HCS framework and design. This includes the implementation of EBPs that have a substantial impact on fatal and non-fatal opioid overdose, the Opioid-overdose Reduction Continuum of Care Approach, communication campaigns to increase awareness and demand for EBPs and reduce stigma against people with OUD and MOUD interventions, and the process of community engagement. This includes how to form community coalitions and gain their commitment, and steps taken to mobilize coalitions to pursue EBP implementation and ensure EBPs are adapted for community needs.

The collective papers in this issue demonstrate that the design of any complex study must adapt to unanticipated temporal events, including the rapidly emerging COVID-19 crisis. Readers will learn about the scientific process of the design and implementation of a community-engaged intervention, its methodologies, guiding conceptual models, and research implementation strategies that can be applied to address other health issues.

This special issue includes nine papers produced by a multidisciplinary group of scientists involved in the design and implementation of the HEALing (Helping End Addiction Long-Term) Communities Study (HCS). This four-year study, funded by the National Institute on Drug Abuse (NIDA) in 2019, was designed to address the complex and ubiquitous opioid overdose epidemic in the United States. Between 1999 and 2018, nearly 450,000 Americans experienced a fatal overdose involving prescription and/or illicit opioids ([Centers for Disease Control and Prevention and Statistics, 2020](#)). In 2018, over 47,000 people died from an opioid overdose death in the US, the majority of which were associated with illicit fentanyl and its analogs ([Wilson et al., 2020](#)).

Moreover, since the onset of the COVID-19 pandemic in the US earlier this year, a rise in fatal and non-fatal overdose events have been reported ([American Medical Association, 2020](#)). A precise estimate of these occurrences is not yet known, partially due to a lag in reporting opioid related overdose deaths exacerbated by the pandemic. However, a number of structural and social determinants related to COVID-19 have been mentioned in the literature as contributing to a rise in overdoses, including increased isolation due physical distancing, stay-at-home orders, challenges in accessing medications for opioid use disorder (MOUD) ([Collins et al., 2020](#)) and other socioeconomic factors such as poverty, unemployment, and homelessness ([Jenkins et al., 2020](#)). The

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severity of the overdose crisis underscores the urgent need for innovative and high impact interventions to promote the rapid penetration and scale up of evidence-based practices (EBPs) for opioid use disorders (OUD) in communities profoundly affected by opioid overdose fatalities (Strang et al., 2020).

The HCS is designed to examine the effectiveness of the Communities That HEAL (CTH) intervention to support the penetration of EBPs in 67 communities across four highly-burdened states (Kentucky, Massachusetts, New York, and Ohio) (Chandler et al., 2020). The CTH promotes and supports the implementation of EBPs within three broad categories that have a rapid impact on opioid overdoses and overdose deaths: 1) overdose education and naloxone distribution (OEND); 2) effective delivery and expansion of MOUD; and 3) safer opioid prescribing and dispensing (Martinez et al., 2020). The HCS is being delivered with the assistance of four statewide community advisory boards (CABs) comprised of key government stakeholders, addiction treatment providers, harm reduction staff, criminal justice representatives and people with lived experience. The CTH intervention is working with coalitions in each community to encourage a common vision, establish shared goals, and implement EBPs using a stepwise community change process. This process involves: 1) community engagement; 2) the Opioid-overdose Reduction Continuum of Care Approach (ORCCA) and 3) communication campaigns to increase awareness and demand for EBPs and reduce stigma against people with OUD and MOUD interventions (The HEALing Communities Study Consortium, 2020).

The HCS is comprised of authentic partnerships between academic centers, key government officials that oversee state responses to behavioral health and substance use disorders, and people in the 67 communities. The diversity of these communities in terms of rural-urban status, race-ethnicity and other social determinants of health will facilitate extension of these results to communities across the US. For example, slightly more than 40 % of the HCS communities are defined as rural ($n = 29$). In addition, 25 % ($n = 17$) are further recognized as Appalachian, a socioeconomically distressed area that disproportionately includes areas with federally designated Health Care Professional Shortages and substantial health inequities. The population size of the average HCS community is just over 129,000, with a total population of 8.67 million persons across all 67 communities who will be exposed to some aspect of the CTH intervention. The HCS communities are racially and ethnically diverse with 15 % of the population from Black/African American communities and 7% Latino-Hispanic populations. Finally, the burden of OUD in these communities is high. The average fatality rate from opioids in the 67 HCS communities from 2016 through 2017 was 33.4 per 100,000 residents, which is more than 2-fold greater than the national opioid overdose death rate during this same time period of 14.1 per 100,000 persons.

The nine papers in this special issue describe many of the critical elements that constitute the HEALing Communities Study framework and design. The guest editors for this special issue are Redonna K. Chandler, Thomas J. Clarke, and Scott T. Walters. The first paper describes the original vision for developing this initiative and reframes the project within the context of the COVID-19 pandemic (Chandler et al., 2020). The next paper (The HEALing Communities Study Consortium, 2020) provides an overarching description of the protocol, including the study design, intervention components, implementation science framework, data elements and statistical approach for the HCS. Papers that follow provide greater detail on the three pillars of the CTH intervention, including the process of developing and facilitating a community engagement strategy (Martinez et al., 2020), the EBP compendium and supportive technical assistance (Winhusen et al., 2020), and public health communication campaigns (Lefebvre et al., 2020). The implementation science framework considers internal and external contextual factors to better understand barriers and facilitators of delivering the CTH intervention (Knudsen et al., 2020). The next paper describes the integration of data operations and community engagement in the development of community-level dashboards to ensure that community

action planning is data-driven (Wu et al., 2020). This is followed by a paper that operationalizes the process of defining critical data outcomes to support the primary and secondary hypotheses across the sites and selecting numerous administrative data systems (Slavova et al., 2020). The final manuscript covers the health economics methodological and analytic approaches used to compare the relative costs and benefits accrued by this large-scale project, in order to inform issues related to needed resources for deployment and sustainability in other settings (Aldridge et al., 2020).

The authors of papers in this special issue come from diverse disciplines and fields, including addiction treatment, health care, implementation science, community-based research, behavioral health, health economics, health communications, systems science, data science, policy analysis, and biostatistics. From the collective papers in this issue, we expect readers to learn about the scientific process of the design and implementation of a community-engaged intervention, its methodologies, guiding conceptual models, and research implementation strategies. These papers can also help researchers understand the steps needed to design a community-engaged intervention to address opioid overdose. This includes how to form community coalitions and gain their commitment, and steps to be taken to mobilize coalitions to pursue EBP implementation and ensure EBPs are adapted to the communities' specific needs. Moreover, readers will learn about the primary, secondary, and structural outcomes used to measure the impact of the CTH intervention and the success of the project. The collective papers in this special issue demonstrate that the design of any complex study—particularly one addressing substance use problems—needs to adapt to unanticipated temporal events. The nature and scope of these events confronted during the implementation of the HCS are unprecedented. The unexpected advent of the COVID-19 pandemic in the midst of the intervention's launch in Wave 1 communities has affected the HCS but remains within the sphere of sphere of surprising changes to be managed in the course of conducting pragmatic research studies.

This special issue shares innovative scientific advancements in implementation research design and evaluation of a novel data-driven community-based intervention to address the national opioid overdose crisis. These scientific advances have important implications for future community-based research in addiction and related fields. As principal investigators of the study, we believe that the nine papers in this special issue provide important multidisciplinary perspectives on the scientific components of the HCS. Together, this collection provides an overview of the challenges that communities have faced in dealing with the opioid crisis, as well as a robust discussion of the barriers and opportunities presented by a community-level trial of such unparalleled scale. Lessons learned from this research may guide future studies on other health conditions including HIV, Hepatitis C, and even COVID-19.

We express our gratitude to the authors who are among the investigative team of the HCS for their excellent and timely contributions. We hope that the following articles address the public health crisis that the HCS has been tasked to address—to illuminate effective and timely paths to reducing opioid overdose deaths that can be implemented locally, across the country.

Trial registration

Clinical Trials.gov: <http://www.clinicaltrials.gov>; Identifier: NCT04111939.

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Contributors

NE, RDJ, JS and SLW conceptualized the paper. NE drafted the paper, with contributions from RDJ, JS and SLW. All authors have approved the final article.

Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or its NIH HEAL Initiative.

Declaration of Competing Interest

The authors report no declarations of interest.

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