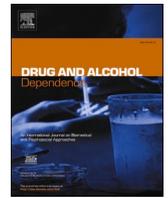


Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Addressing opioid overdose deaths: The vision for the HEALing communities study

Redonna K. Chandler^{a,*}, Jennifer Villani^a, Thomas Clarke^b, Elinore F. McCance-Katz^b, Nora D. Volkow^a

^a National Institute on Drug Abuse, National Institutes of Health, 3WFN, 301 North Stonestreet Ave, Bethesda, MD, 20892, United States

^b Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD, 20852, United States

ARTICLE INFO

Keywords:

Opioid use disorder
Overdose
Medications for opioid use disorder
Evidence-based practices
Implementation
Helping to End Addiction Long-term
HEALing communities study

ABSTRACT

The United States is facing two devastating public health crises— the opioid epidemic and the COVID-19 pandemic. Within this context, one of the most ambitious implementation studies in addiction research is moving forward. Launched in May 2019, the HEALing Communities Study (HCS) was developed by the National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA) as part of the Helping to End Addiction Long-termSM Initiative (National Institutes of Health, 2020). The goal for this research was to reduce opioid overdose deaths by 40 % in three years by enhancing and integrating the delivery of multiple evidence-based practices (EBPs) with proven effectiveness in reducing opioid overdose deaths across health care, justice, and community settings. This paper describes the initial vision, goals, and objectives of this initiative; the impact of COVID-19; and the potential for knowledge to be generated from HCS at the intersection of an unrelenting epidemic of opioid misuse and overdoses and the ravishing COVID-19 pandemic.

1. Background

The devastation of the opioid epidemic in lost lives and economic costs over the last two decades led it to be declared a public health emergency in 2017 (Trump, 2017). The National Survey on Drug Use and Health (NSDUH) estimated that in 2018 approximately 10.3 million Americans aged 12 or older misused opioids in the past year (Substance Abuse and Mental Health Services Administration, 2019a).

Most alarming is the rapid increase in opioid overdose deaths initially from prescription opioids, then exacerbated by heroin, and more recently overtaken by a sharp rise in fentanyl overdoses alongside steep increases in deaths from psychostimulant drugs. From 1999–2018, nearly 450,000 people died from an overdose involving any opioid, including prescription and illicit opioids, with nearly 47,000 in 2018 alone (Centers for Disease Control and Prevention, National Center for Health Statistics, 2020; Wilson et al., 2020). Furthermore, in recent years the burden of opioid overdose deaths has expanded from rural areas to cities and from mostly white to communities of color (Substance Abuse and Mental Health Services Administration, 2020c; Lippold et al., 2019).

1.1. Evidence-based practices and the treatment gap

What makes the opioid crisis even more tragic is that opioid overdose deaths are largely preventable. A range of EBPs have been developed through research, in part supported by the National Institute on Drug Abuse (NIDA) and disseminated by SAMHSA and the Centers for Disease Control and Prevention (CDC) to prevent and treat opioid misuse and opioid use disorder (OUD), reduce opioid overdose deaths, and address related health consequences. Prescription drug monitoring programs and other strategies can decrease inappropriate prescribing and reduce the availability of prescription drugs across communities. Lofexidine, a medication approved by the Food and Drug Administration (FDA), diminishes opioid withdrawal symptoms facilitating the discontinuation of opioid use and the initiation of medications for OUD including the antagonist medication naltrexone. Approved medications to treat OUD (MOUD) include methadone, buprenorphine, and naltrexone. Additionally, naloxone is short acting opioid antagonist, approved by the FDA for the reversal of opioid overdoses. Behavioral interventions effectively promote treatment initiation, engagement, and retention while recovery support services play a critical role in encouraging and

* Corresponding author at: National Institute on Drug Abuse, National Institutes of Health, 3WFN RM 09D02, 301 North Stonestreet Ave, Bethesda, MD, 20892, United States.

E-mail address: redonna.chandler@nih.gov (R.K. Chandler).

<https://doi.org/10.1016/j.drugalcdep.2020.108329>

Received 5 August 2020; Received in revised form 10 September 2020; Accepted 11 September 2020

Available online 1 October 2020

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linking people early in abstinence to needed services (see Winhusen et al., 2020, for a list of behavioral interventions) including housing and employment (Mericle et al., 2016; Laudet and Humphreys, 2013).

While this set of EBPs has the potential to significantly reduce opioid overdose deaths, the gap between those in need of an intervention and those engaged in care is significant. An estimated 2 million people had an OUD in 2018 (Substance Abuse and Mental Health Services Administration, 2019a), yet fewer than 20 % of individuals with an OUD received any form of treatment in the past year (Wu et al., 2016). In a cohort of opioid overdose survivors, fewer than one-third received any MOUD treatment within a year of the overdose event (Larochelle et al., 2018). Missed opportunities to deliver EBPs exist across the entire care continuum including: 1) the failure to recognize opioid misuse or the need for OUD treatment; 2) failure to link people with OUD to MOUD treatment and to provide them with naloxone; and 3) lack of retention of people with OUD in treatment (Williams et al., 2017). Finally, unlike other health conditions, persistent stigma (Corrigan et al., 2017) toward people with OUD and towards MOUD are significant barriers to the uptake of EBPs (Livingston et al., 2018; van Boekel et al., 2013).

System-level factors also contribute to the lack of implementation and availability of EBPs to those at highest risk of an opioid overdose. OUD treatment initiation is not well integrated into general health care settings where people could be provided with EBPs, including hospitals, emergency departments, and primary care practices. The high cost of care, lack of insurance, and complicated reimbursement policies limit access. The delivery of MOUD is governed by a complicated multilateral system of statutes, regulations, and guidelines at the state and federal levels that create barriers to their uptake by health care providers and organizations. For instance, methadone regulations place significant burden on patients, which prior to the COVID-19 pandemic, normally required daily attendance in a special opioid treatment program (methadone clinic), under the direct supervision of a physician, and with ongoing participation in counseling (Substance Abuse and Mental Health Services Administration, 2020e; Providers Clinical Support System, 2020; Haffajee et al., 2018). Buprenorphine is less burdensome to patients than methadone because it can be delivered in general office-based medical settings and does not require daily attendance (Kraus et al., 2011). However, buprenorphine requires prescribing providers to participate in specialized training and limits the number of individuals they can treat at any one time (Substance Abuse and Mental Health Services Administration, 2019b). Healthcare providers are often unwilling to participate in this additional training, and even when they do receive a waiver to prescribe buprenorphine some treat many fewer patients than allowed. While the number of buprenorphine waived physicians has increased, (Knudsen et al., 2017) it remains insufficient to meet the need for treatment.

Venues like the justice system are, for many people with OUD, the primary setting for treatment services. Because people who receive services through the justice system are more likely to receive detoxification treatment rather than MOUD, these individuals are at high risk of overdose death should relapse occur (Binswanger et al., 2007; Ranapurwala et al., 2018). Further, those accessing services through this system may encounter staff who lack the expertise and resources to provide MOUD or naloxone, or to provide linkage to healthcare, behavioral health, or social support systems upon release into the community (Nunn et al., 2009).

1.2. The need for implementation science

Implementation research in addiction science has typically focused on designing strategies to implement a single evidence-based prevention or treatment practice into one or more settings (McGovern et al., 2013). However, it was clear that isolated interventions would not yield a large-scale, EBP implementation approach capable of substantially reducing opioid overdose deaths in highly impacted communities, nor would they create a model for other large-scale substance abuse

implementation studies. The HCS was designed to fill this gap where: 1) multiple EBPs focused on individuals 18 and older would be selected for implementation; 2) EBP implementation would take place in an integrated fashion across many organizations in multiple urban and rural communities in diverse states; 3) community and state engagement would drive the EBP implementation to address needs and maximize resources; and 4) decision making would be guided by data both in the selection of EBPs and ongoing adjustments in implementation.

2. HCS research goals and requirements

The overarching goal of the HCS is to help communities reduce opioid overdose deaths by 40 % in three years. The funding opportunity announcements (National Institute on Drug Abuse, 2018a, b) stated research sites and a data coordinating center would be funded to participate in a multi-site study to: 1) determine the health impact of implementing a data-driven, multi-pronged approach to address opioid misuse and OUD by enhancing the systematic delivery of evidence-based prevention and treatment practices across multiple settings (required settings included health care, behavioral health, and justice); 2) identify facilitators and barriers to implementation and sustainability, including relevant payment policy strategies; 3) determine the incremental cost and cost-effectiveness of this multi-pronged approach; and 4) develop an evidence-based model for deploying this approach in highly affected urban and rural communities across the U.S. This research would apply principles of community-based participatory research design and required partnerships with multiple organizations having the capacity to deliver integrated evidence-based prevention and treatment practices that meet the needs of their population. The implementation research intervention would be delivered to communities through coalitions comprised of key local stakeholders partnered with multiple community-based organizations and key community and state leaders as needed.

Federal sponsors had a special interest in states ranking in the top third of age-adjusted drug overdose death rates in 2016, per CDC data. Thus, research sites were required to partner with multiple highly impacted communities within a single state. Highly affected communities of interest could include counties, towns, or cities (or a justified aggregate of counties, towns, or cities functioning as one community) within states burdened with higher than average rates of opioid overdose morbidity and mortality and other health consequences associated with opioid misuse. To maximize the generalizability of findings, 30 % of participating communities in each research site were required to be rural (Rural Health Information Hub, n.d.). The minimum threshold for "highly affected" communities was defined as at least 150 opioid overdose deaths (15 % of these deaths must be from rural communities) and a rate of at least 25 opioid overdose deaths per 100,000 persons, based on the most recent complete year of data available. A minimum of 15 distinct communities within a single state was required for each research site application.

Prevention and treatment strategies selected for inclusion in HCS applications were required to be evidence-based and have the potential to significantly reduce opioid overdose deaths in a relatively short period of time. The proposed set of EBPs required implementation in multiple settings encountered by people misusing opioids or with OUD including health care, behavioral health, and justice settings.

Required secondary outcomes for the research included: reducing the number of overdose events; decreasing the misuse of opioids; decreasing incidence of OUD and progression in severity to OUD or injection drug use; increasing the number and percentage of individuals with OUD receiving MOUD and/or behavioral treatment; increasing the number and percentage of individuals retained in treatment beyond 6 months; increasing the number and percentage of individuals participating in or completing treatment and receiving recovery support services; and increasing access to naloxone. Other secondary aims and outcomes could target other health conditions including monitoring the

incidence of hepatitis C, HIV, or endocarditis associated with injection drug use. Structural aims intended to change practices related to opioid use and OUD included approaches to change prescribing practices, increase substance abuse treatment programs and health care providers providing MOUD, increasing the availability of naloxone, and improving formal linkages between health care, behavioral health and the justice system.

In 2019, National Institutes of Health announced plans to invest more than \$350 million to support the HCS as a flagship research endeavor of the HEAL Initiative (National Institutes of Health, 2020). A rigorous review process determined the scientific merit and feasibility of the proposed research and ensured strength in both research capacity and community engagement. Research sites were required to demonstrate they had viable state, local, and community partners; administrative data sources and data sharing plans; existing infrastructure and resources to support EBP deployment, including SAMHSA State Opioid Response funding and technical assistance services, such as the SAMHSA Technology Transfer Centers and the Opioid Response Network; the involvement of a key governmental official (KGO) with the ability to influence funding, policy, and service provision for addressing OUD and opioid overdose deaths; and an individual from each community representing the site's Community Advisory Board (CAB). The KGO and CAB members needed to be familiar with the community perspective, represent the diversity of the state's population, and show commitment to guide the study development and deployment. Following the review of research applications, several sites received site visits by members of the review committee.

This provided an opportunity to observe commitment to partnerships between applicant organizations and key stakeholders at state and local levels. Four research sites received awards to conduct implementation research within communities in their state: the University of Kentucky, Lexington; Boston Medical Center, Boston; Columbia University, New York City; and the Ohio State University, Columbus. RTI International, based in North Carolina, received an award to serve as the study's data coordinating center (DCC) and be responsible for data analysis, health economics research, and widespread dissemination of research findings over the course of the study.

One month after the DCC and research sites received funding, NIDA and SAMHSA convened a meeting with investigators to determine whether each site would move forward with four separate community-level interventions and collaborate on overarching data harmonization or work together to develop a common intervention and protocol. Ultimately, a decision was made to develop a single intervention to be tested across the combined total of 67 communities. This approach, described in this special issue, offered several advantages including: a strong group-randomized study design, enhanced power to detect a meaningful reduction in opioid overdose deaths, greater generalizability, and a more robust test of community engagement as an implementation strategy (The HEALing Communities Study Consortium, 2020).

3. Impact of recent events

Coronavirus disease 2019 (COVID-19), emerged in the U.S. approximately 8 months after the HCS was launched creating unexpected challenges for the study. Some participating communities have been impacted by high numbers of COVID-19 cases (e.g., Suffolk and Orange County, NY; Essex, MA; etc.) (Johns Hopkins University, 2020). Mitigation strategies implemented in the four states (e.g. stay at home or shelter in place recommendations, prohibition against large gatherings, temporary closing of businesses or reduced hours, closing of syringe service programs and homeless shelters, release of non-violent offenders with OUD into the community, etc.) affected interactions with communities including implementation of the intervention, ability to form partnerships between coalitions and organizational partners (e.g., jails and emergency departments), and data collection. The increased

demand for care to treat severe cases of COVID-19, along with the fear of infection, has also limited the capacity for emergency departments and other clinical services to screen and treat individuals with OUD and to participate in research.

The delivery of EBPs also shifted nationally in key settings like jails, opioid and addiction treatment programs, and primary care practices as a result of COVID-19. Federal agencies worked quickly to respond to challenges in service delivery. The Center for Medicare and Medicaid Services expanded Medicare coverage for telehealth (Centers for Medicare and Medicaid Services, n.d.), which has increased dramatically since the pandemic. SAMHSA provided more flexibilities for opioid treatment programs to administer MOUD in a take-home format (Substance Abuse and Mental Health Services Administration, 2020d) and the Drug Enforcement Administration issued policies allowing registered practitioners to prescribe controlled substances, including buprenorphine, without having to interact in-person with patients (Drug Enforcement Administration, 2020).

In spite of these efforts, some communities are seeing increased opioid overdose deaths since the onset of COVID-19 and reduced numbers of OUD patients entering into MOUD treatment (DeMio, 2020).

During major infectious disease outbreaks, quarantine can be a necessary preventive measure (Brooks et al., 2020). However, those in recovery will be uniquely challenged by social distancing measures (Volkow, 2020). While a slight decrease of 4.6 % in overdose deaths was noted between 2017–2018 (Centers for Disease Control and Prevention, n.d.), preliminary estimates in 2019 indicate a 4.8 % increase and recent evidence suggest further increases since the onset of COVID-19 in early 2020. Specifically, a report based on data entered by first responders into the national Overdose Detection Mapping Application Program indicated an increase of 11 % for fatal overdoses and 18 % for non-fatal overdoses from January to April 2020, compared to that time period in 2019 (Alter and Yeager, 2020). Likewise, the American Medical Association has issued a brief containing national and state reports of increases in opioid overdoses and deaths since the onset of COVID-19 (American Medical Association, 2020). These increases are alarming, and along with the reduction in treatment and community services for substance use disorders, will make the HCS's main goal of reducing opioid overdose deaths by 40 % extremely challenging.

The COVID-19 pandemic in the US has also highlighted the large disparities (Substance Abuse and Mental Health Services Administration, 2019a) in access to health care that negatively impact outcomes for certain racial and ethnic groups and the poor, including access to evidence-based prevention and treatment strategies for OUD (Substance Abuse and Mental Health Services Administration, 2020c). The inequities in access to EBPs in OUD treatment further jeopardize the goals of HCS. Though not all of the HCS communities are sufficiently diverse, the HCS will collect data on population demographics (e.g., race/ethnicity, age, sex, socioeconomic) and use this information to tailor intervention delivery, and widely disseminate relevant findings for future research or policy changes. NIH and SAMHSA hope the vision for a community-based, diverse stakeholder, data-driven approach to the implementation of EBPs will provide an avenue to address racial/ethnic and socioeconomic inequalities in access to OUD treatment and support services for recovery, in lieu of incarceration.

4. Conclusion

The HCS was developed to address the devastating consequences of the opioid crisis through testing the impact of a community-based, data-driven approach to implementing a set of EBPs to address opioid misuse, treat OUD, and prevent overdose deaths across multiple settings (health care, behavioral health, justice) in a sample of highly affected communities. Four research sites and a DCC were funded and agreed to collaborate in designing a new intervention and implementation study to be conducted in the combined 67 communities. If effective, this approach could be adapted by communities to address other drug

epidemics and public health crises.

HCS is the largest implementation science study ever funded in addiction research that aims to: 1) study the implementation of multiple EBPs within communities to meet unique needs and challenges of service delivery; 2) determine the effectiveness of community engagement as an implementation strategy; 3) examine the adaptation of EBPs in the context of implementation; 3) test the effectiveness and cost-effectiveness of a multi-pronged approach to address the opioid crisis; 4) develop dissemination and implementation strategies to reduce health disparities and improve quality of care among rural, minority, and other underserved populations; 5) understand the impact of stigma and socioeconomic and educational factors, on the creation, packaging, transmission, and reception of EBPs; and 5) study the impact of policy and other contextual factors on implementation and sustainability of both the community-engaged implementation approach and EBPs to reduce opioid overdose deaths. Finally, since the intervention is being launched amidst the COVID-19 pandemic, with its associated disruption in treatment delivery and social services, the HCS provides a unique opportunity to understand the consequences of the intersection of COVID-19 and opioid epidemics in rural and urban communities. Despite the challenges presented by COVID-19, NIH and SAMHSA remain committed to preventing opioid overdose deaths, expanding and sustaining the implementation of EBPs, and improving overall public health by addressing the opioid crisis while in parallel ensuring equity in access to treatment and recovery services.

Contributors

Redonna K. Chandler developed framework for paper and initial draft. Made substantial edits to address comments. Jennifer Villani drafted introduction, revised text, edited document. Thomas Clarke drafted section on impact of recent events, revised text, edited document. Elinore McCance-Katz contributed to revision and editing of text. Nora Volkow provided substantial edits and comments to initial draft, including recommendation to re-write and include impact of COVID-19 and health disparities on study vision. All authors have read approved the final manuscript.

Declaration of Competing Interest

No conflict declared.

Acknowledgments

We are grateful to many individuals who were instrumental in the development of the HEALing Communities Study (HCS) initiative including those who participated in a planning meeting held at the National Institutes of Health on June 18, 2018, and those who responded to a Request for Information issued on June 29, 2018. In particular, we acknowledge the work of those who served on the review committee for the data coordinating center and research site applications. Your dedication to ensuring a fair and rigorous review of HCS research site applications, including travel for site visits, provided invaluable guidance.

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