Accelerating Solutions for the Overdose Crisis: an Effectiveness-Implementation Hybrid Protocol for the HEAL Prevention Cooperative

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Abstract
Given increasing opioid overdose mortality rates in the USA over the past 20 years, accelerating the implementation of prevention interventions found to be effective is critical. The Helping End Addiction Long-Term (HEAL) Prevention Cooperative (HPC) is a consortium of research projects funded to implement and test interventions designed to prevent the onset or escalation of opioid misuse among youth and young adults. The HPC offers a unique opportunity to synthesize and share lessons learned from participating research projects’ varied implementation experiences, which can facilitate quicker integration of effective prevention interventions into practice. This protocol paper describes our hybrid approach to collecting and analyzing information about the implementation experiences of nine of the HPC research projects while they maintain their focus on assessing the effectiveness and cost-effectiveness of prevention interventions. To better understand implementation within this context, we will address five research questions: (1) What were the context and approach for implementing the prevention interventions, and how was the overall implementation experience? (2) How representative of the target population are the participants who were enrolled and retained in the research projects’ effectiveness trials? (3) For what purposes and how were stakeholders engaged by the research projects? (4) What are the adaptable components of the prevention interventions? And finally, (5) how might implementation of the prevention interventions vary for non-trial implementation? This work will result in intervention-specific and general practical dissemination resources that can help potential adopters and deliverers of opioid misuse prevention make adoption decisions and prepare for successful implementation.

Keywords Opioids · Prevention · Youth · Implementation · Scale-up
Background

In 2019, an estimated 10.1 million people 12 years of age or older had misused opioids in the past year (Substance Abuse and Mental Health Services Administration, 2020). More than 800,000 people in the USA have died of a drug overdose since 1999, and of the nearly 71,000 drug overdose deaths in 2019, more than 70% involved an opioid (Centers for Disease Control and Prevention, 2020). With the COVID-19 pandemic, drug overdose deaths in the USA rose 29.4% in 2020 compared with 2019 to an estimated 93,331 total drug overdose deaths, with 75% involving an opioid (Ahmad et al., 2021). Although ensuring access to evidence-based interventions that prevent opioid overdose deaths is critical, it is also paramount to develop and widely implement effective approaches that prevent opioid misuse and escalation to opioid use disorder (OUD), especially among populations with risk.

Among those with a lifetime history of substance use disorder, initiation of substance misuse occurs by 18 years of age for 50% and by 24 years of age for 80% (Compton et al., 2007). In 2019, 1 in 7 high school students reported misusing prescription opioids at least once in their lifetime (Jones et al., 2020), and the number of young adults ages 18 to 25 years who initiated prescription pain reliever misuse in the past year averaged 1100 each day (SAMHSA, 2020). Furthermore, opioid overdose mortality rates increased 24% among people ages 15 to 24 years from 2015 to 2019 (CDCP, 2020). Therefore, adolescents and young adults are two populations for whom effective prevention interventions are critically needed to address underlying factors that lead to opioid misuse and escalation to OUD.

A recent scoping review, however, found few efficacious interventions for the prevention of opioid misuse and OUD with demonstrated behavioral outcomes (Bonar et al., 2020). Those that are supported tend to be delivered to middle school–age youth as universal prevention (Crowley et al., 2014; Spoth et al., 2013). Some brief interventions delivered to youth in health care settings, such as primary care or emergency departments, have also had promising effects on preventing prescription drug misuse more broadly, including opioid misuse (Cunningham et al., 2015; Walton et al., 2014), but more research is needed. More recent school-based work involving youth ambassadors reduced intentions to misuse substances among youth, including heroin and prescription opioids (Evans et al., 2020), but whether it translates to behavior change is unknown. Although policy or prescriber-level interventions are critical in addressing prevention across multiple levels of social ecology (Bohnert et al., 2018; Rhodes et al., 2019), large gaps remain in the availability of evidenced-based behavioral interventions and delivery to adolescents and young adults with risk, especially among racial and ethnic minorities (Bloom, 2016).

For prevention interventions that are found to be effective, challenges to implementation can range from local implementation barriers to factors hindering scale-up more broadly (National Academies of Sciences et al., 2019). Beyond overcoming initial implementation challenges, efforts to make these interventions a part of routine practice in relevant settings are needed to prevent initiation of opioid misuse and escalation to OUD among young people over the long term. If barriers and facilitators of implementation and routinization are considered during intervention development, prevention interventions could be made available sooner to the communities and populations who urgently need them (Fernandez et al., 2019). Traditionally, the research-to-practice pipeline moves systematically from pilot development, to feasibility, to effectiveness testing. Implementation is typically not considered until effectiveness is established (Brown et al., 2017). This protracted process has been well-cited throughout the implementation science literature, with frequent mention of the 17-year timeframe for integrating evidence-based interventions into regular and widespread practice (Balas & Boren, 2000). Given the widespread impact of the opioid epidemic on vulnerable communities and the individuals within them, though, it is critical to leverage a hybrid approach that simultaneously assesses effectiveness and implementation to shorten this timeline (Curran et al., 2012).

The National Institutes of Health’s (NIH’s) funding opportunity called for Helping End Addiction Long-Term (HEAL) Prevention Cooperative (HPC) grantees to test interventions to prevent the onset or escalation of OUD among youth and young adults 15 to 30 years of age. The awarded research projects are evaluating innovative prevention interventions in settings that range from health care facilities and schools to juvenile justice centers and in the community. As part of their cooperative agreement award, each research project agreed to actively collaborate and coordinate within the HPC. There is thus a unique opportunity in the HPC to overlay a hybrid approach, maintaining the rigor of individual effectiveness trials while also seeking to understand implementation conditions and parameters (Curran et al., 2012; Landes et al., 2019). The HPC research projects can provide critical knowledge about what strategies and resources are necessary for implementing opioid misuse prevention interventions, how to overcome likely challenges, and how to tailor the interventions to meet local needs. The overall objective of the efforts described in this paper is to leverage a hybrid effectiveness-implementation approach to generate implementation-related lessons specific to and
across the HPC research projects. The end goal is to under-
stand these dynamics to prepare for and catalyze real-world
dissemination and implementation after completion of the
effectiveness trials.

Approach

Initial discussions of the overlay began at the HPC kick-
off meeting during a breakout session hosted by the HPCC
Implementation Science Core. The HPCC Implementation
Science Core drafted the overlay protocol and held a series
of individual meetings with each of the nine HPC research
projects to elicit feedback. The final protocol described here
received approval from the HPC Steering Committee.

We will use a multiple case study approach to build an in-
depth understanding of the challenges and requirements of
implementing the promising prevention interventions
the HPC research projects are testing in real-world set-
tings (Crowe et al., 2011). Development of the case stud-
ies will be led by the Implementation Science Core within
the HEAL Prevention Coordinating Center (HPCC) at RTI
International, which not only supports the individual HPC
research projects but also works to generate shared insights
across them.

Sample

We will develop cases for nine of the 10 HPC research pro-
jects. The 10th research project is focused on establishing
intervention efficacy and will require further study before
beginning to prepare it for post-trial dissemination and
implementation. Table 1 summarizes the included research
projects and demonstrates the diverse contexts in which they
are operating. Of the included research projects, two focus
on supporting American Indian/Alaska Native (AI/AN)
youth and young adults, two on justice-involved youth as
they re-enter communities, two on youth and young adults
receiving services in health care facilities, one on students
via school-based health centers, one on youth experienc-
ing homelessness, and one on families with young parents
involved with child welfare services. The prevention inter-
ventions being tested are delivered by a variety of practition-
ers and range in focus, delivery format, and intensity, from
individual screening and brief intervention to group-based
psychosocial interventions and community-wide efforts.

Research Questions

The research questions and data collection tools for the
overlay were collaboratively developed by the HPCC
Implementation Science Core and the HPC research pro-
jects and are informed by relevant implementation science
frameworks (Table 2). We will use the Template for Inter-
vention Description and Replication (TIDieR) checklist and
the Framework for Reporting Adaptations and Modifications
to Evidence-based Interventions (FRAME) to describe the
interventions being tested by the research projects and any
adaptations, respectively (Hoffmann et al., 2014; Wiltsie
Stirman et al., 2019). We will use two determinant frame-
works developed in the field of implementation science (i.e.,
the Exploration, Preparation, Implementation, Sustainment
[EPIS] framework and the Consolidated Framework for
Implementation Research [CFIR]) and SAMHSA’s Strate-
getic Prevention Framework (SPF) to probe research pro-
jects to identify barriers and facilitators they encountered
while implementing their interventions (Damschroder et al.,
2009; Moullin et al., 2019; SAMHSA, 2019). Furthermore,
we will use the Expert Recommendations for Implementing
Change (ERIC) taxonomy to help identify and define imple-
mentation strategies the research projects used, and we will
draw on Proctor’s guidelines for specifying implementation
strategies to probe research projects for details on how they
operationalized their selected strategies (Powell et al., 2015;
Proctor et al., 2013).

To develop an in-depth understanding of what is required
to implement different types of prevention interventions for
different populations in different settings, we defined five
key research questions. These questions, listed below and
in Table 2, go beyond the implementation experiences of
the research projects and draw on their teams’ expertise
to provide relevant information for future organizations to
consider when deciding whether to adopt, implement, and
deliver opioid misuse prevention interventions.

1. What were the context and approach for implementing
the prevention interventions, and how was the overall
implementation experience?

To reveal the implementation experiences of each
research project, we will start by describing the settings
and personnel that delivered the prevention interven-
tions. We will explore what resources and activities
were required to engage and prepare these settings and
personnel for intervention delivery, to deliver the inter-
ventions, and, if applicable, to sustain intervention deliv-
er. Additionally, we will work with research projects to
specify the implementation strategies they used in detail
and to understand their perceived utility. We will further
identify which implementation determinants (i.e., barri-
er and facilitators) were anticipated versus experienced
and how they were addressed or leveraged.

2. How representative of the target population are the par-
ticipants who were enrolled and retained in the research
projects’ effectiveness trials?

In their proposals, the research projects reported the
target proportion of trial participants by demographic
| Research project institution                                      | Population of focus                                                                 | Intervention type                                           | Intervention setting                      | Interventionists                                                                 |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------------------------|
| Emory University/Cherokee Nation                                 | Native American and white youth ages 15–20 in rural areas                           | Brief intervention, community-based advocacy                | Schools, community                       | Cherokee Nation Behavioral Health Connect Coaches and community volunteers         |
| Massachusetts General Hospital/ Harvard Medical School           | Youth ages 16–30 receiving mental health treatment (with or without non-opioid SUD) | Screening                                                   | Health care facilities (outpatient clinics) | Administrative staff and clinicians                                                |
| University of Michigan                                          | Youth ages 16–30 who present to emergency departments and report prescription opioid use in past year and an accompanying risk factor or report prescription or illicit opioid misuse in past year | Brief video intervention and/or post-intake follow up messages | Health care facilities (emergency department) | Remote health coaches                                                             |
| The Ohio State University                                       | Homeless youth ages 18–24 without OUD                                              | Financial assistance                                        | Homeless shelters, community             | Trained community advocates                                                       |
| Oregon Social Learning Center                                   | Young parents ages 16–30 involved in child welfare or self-sufficiency services     | Psychosocial intervention                                   | Health care facilities (community clinics) with social service referrals | Licensed para-professionals dually trained as substance use and mental health treatment counselors |
| RAND/University of California, Los Angeles                      | Urban American Indian/Alaska Native emerging adults ages 18–25 who are not opioid dependent | Psychosocial intervention                                   | Community                                | American Indian/Alaska Native facilitators trained as intervention practitioners |
| Seattle’s Children Hospital                                     | Youth ages 15–25 re-entering community after justice involvement (with or without prior opioid use) | Psychosocial intervention                                   | Juvenile justice centers                 | Bachelor’s level staff trained as intervention practitioners                       |
| Texas Christian University                                      | Youth ages 15–25 re-entering community after detainment                              | Psychosocial intervention                                   | Juvenile justice centers                 | Clinicians (e.g., LPC, MSW) trained as intervention practitioners                  |
| Yale University                                                 | Youth ages 16–19 who report having not engaged in prior opioid misuse and who are considered high-risk | Psychosocial intervention                                   | Schools                                  | School-based health center champions                                                |

LPC licensed professional counselor, MSW Master of Social Work, OUD opioid use disorder, SUD substance use disorder
group (e.g., sex, race, ethnicity) within the broader HPC focus of youth and young adults. We will compare the demographics of participants who were enrolled and retained in each of the research projects’ effectiveness trials to the target demographics in their proposals. This information will enable us to explore whether certain groups had lower-than-expected participation and to compare enrollment and retention rates across groups. If enrollment and retention is low among certain groups, we will work with the research projects to identify potential causes (e.g., client perception of prevention intervention, challenges with engagement, competing priorities) and solutions.

3. For what purposes and how were stakeholders engaged by the research projects?

Engaging key stakeholders across various roles—such as organizational leaders in delivery settings, interventionists, and prevention intervention recipients—is useful for developing, tailoring, and evaluating interventions and their implementation. We will identify which stakeholder groups were engaged by the research projects, for what purpose, and to what extent. We will also explore how research projects engaged stakeholders and the perceived benefits of engaging them.

4. What are the adaptable components of the prevention interventions?

We will draw on research project teams’ in-depth knowledge and experience with their prevention interventions to catalog the intervention components and explore which are believed to be core versus those that
may be adapted to fit local context. We will also explore whether and how prevention interventions had to be adapted in response to the COVID-19 pandemic and what additional adaptations should be considered based on research project experiences.

5. How might implementation of the prevention interventions vary for non-trial implementation?

Although the research projects are testing the prevention interventions in real-world settings, implementation is likely to be different outside of a trial context and with fewer resources. We will probe research projects to explore what other settings and personnel may be well-suited to deliver the prevention interventions; the extent to which those settings and personnel will need to be engaged to adopt, implement, and deliver the prevention interventions; which implementation determinants may be applicable in non-trial settings; what additional determinants may arise; which implementation strategies have the most potential for supporting non-trial implementation; and what additional strategies may be needed to sustain implementation over time.

Data Collection

We plan to collect data for the overlay twice per year by (1) reviewing research project–specific documents, (2) leveraging existing modes of communication between research projects and the HPCC liaisons, and (3) conducting in-depth interviews with key personnel at each research project. Initial data collection will vary for each research project, beginning once enrollment in the project’s effectiveness trial begins. Data collectors will summarize and document data across these sources separately for each of their assigned research projects in detailed case study templates that cover all research questions. The case study notes will include information about data sources, date of data collection, and data collectors. The following sections provide additional detail about each of these data sources.

Document Review

To limit data collection burden on the research projects, members of the HPCC Implementation Science Core will extract relevant information from the research project documents and other material and enter it directly into the case study templates. Research project documents may include supplement proposals, annual reports, journal publications (e.g., protocol papers), and conference posters and presentations. Research projects will be asked to provide any such documents to the HPCC team twice a year. Other material will include information gathered and documented by other HPCC cores (e.g., implementation activities tracked by the HPCC Economics Core, reach and retention measures reported to the HPCC Measures and Data Core, and notes from HPC Steering Committee and HPCC workgroup meetings that engage the research projects). The HPCC team will update the case study notes for each research project based on the latest documentation available before each round of interviews.

Communication Between Research Projects and HPCC Liaisons

The HPCC has two doctoral-level prevention scientists who serve as liaisons between the HPCC and the HPC research projects. The liaisons coordinate technical assistance and consultation requests and keep the HPCC informed of HPC research project needs through multiple modes of communication (e.g., email, phone calls, attendance at research project team meetings). The liaisons will use a standardized form to document information they receive relevant to the research questions and how and when they received it. This form will enable the liaisons to submit information year-round that is directly pulled into a central database. Twice per year, before each round of interviews, the HPCC Implementation Science Core will review the data collected via the forms and update the case study notes for each research project. Documenting and reviewing information shared with the HPCC liaisons in this way will reduce HPC research project burden by not asking research projects to recount information they have already disclosed to the HPCC.

In-depth Interviews

The HPCC Implementation Science Core will develop a standard interview guide with probes for each research question. We will conduct up to two rounds of interviews with each research project annually from Years 3 to 5 of their projects. Interviewees will include key personnel and staff involved with each research project, identified in collaboration with and based on suggestions from the HPC research projects’ Principal Investigators. Key personnel include members of the research projects’ research team who either lead the study or are directly involved with aspects of implementing the prevention intervention (e.g., supervising interventionists in the effectiveness trial). We will limit staff interviews to project coordinators for their broad, on-the-ground perspective and interventionists for their experience delivering the prevention interventions with the population of interest. Interviewees will be recruited via email one month in advance of each round of interviews.

To prepare for each round of interviews, we will tailor the standard interview guide for each research project. First, we will narrow the questions in the interview guide based on the research projects’ current phase of research (i.e., have started enrolling participants, have had participants enrolled for six months, have had participants enrolled for one year). Next,
to the HPCC team will segment the case study notes by codes to synthesize relevant data across research projects. Lastly, in the interpretation phase, the HPCC team will write descriptive summaries of the data by research question to include main findings by research project grouping, illustrative examples, and an interpretive narrative.

Preparing for Broader Implementation

This work will generate practical information such as research project- and prevention intervention—specific implementation experiences, lessons, and advice for future implementation. The HPCC Implementation Science Core will condense each research project’s case study notes into a summary resource targeting potential adopters and deliverers of the prevention intervention of interest and work collaboratively with each research project to finalize the content. Included at the end will be visualizations summarizing key findings from their effectiveness trials (e.g., impact on primary outcomes, cost-effectiveness) to comprehensively describe the impact the interventions can have and considerations for implementation. This summary resource is intended to aid the research projects in their future work to disseminate and implement their prevention interventions broadly.

Discussion

Opioid-related overdoses have increased over the last 20 years (CDCP, 2020), and during the COVID-19 pandemic, increases in opioid use and related overdoses have further accelerated (Manchikanti et al., 2021). As such, evidence-based interventions to minimize the risk for opioid misuse and escalation to OUD are urgently needed, especially for those who have a higher risk of misusing opioids and developing OUD. The HEAL Prevention Initiative to understand the effectiveness of different approaches to preventing opioid misuse or escalation to OUD among youth and young adults aged 15 through 30 represents one of the federal government’s largest-ever investments to meet this challenge. However, the typical pace of developing evidence-based interventions is slow, and the additional time it takes to reach populations in need can have longstanding consequences, especially in the context of a rapidly evolving epidemic. Developing the

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evidence base for interventions to prevent opioid misuse and OUD while simultaneously preparing them for dissemination and implementation increases the likelihood that effective prevention interventions are quickly scaled to the communities that need them.

Hybrid effectiveness-implementation studies are an effective tool to accelerate the research process (Curran et al., 2012; Landes et al., 2019). With the HPC, hybrid designs can prioritize the importance of rigorous effectiveness trials for prevention interventions while simultaneously building a thorough understanding of the implementation process and experience. This type of approach can provide crucial information both to understand what is or is not working in current settings and to inform future implementation efforts. Insights about implementation that can be gleaned during effectiveness trials include lessons about the content and approach for prevention intervention implementation, strategies to overcome anticipated implementation challenges, who is being reached and engaged in the studies, what the core components versus the adaptable periphery of the prevention interventions are, and how implementation experiences might vary in non-trial settings. Hybrid designs can build this understanding in the context of effectiveness trials while accounting for the context and resources that come with conducting trials, which would be absent outside of a trial setting. The goal is to speed up implementation of prevention interventions that are found to be effective and position them for accelerated, widespread scale-up.

Although all the HPC research projects included effectiveness and cost-effectiveness components within their proposals, only two (Oregon Social Learning Center and Texas Christian University) were originally designed explicitly as hybrid effectiveness-implementation studies seeking to begin assessing implementation simultaneously. By overlaying the standardized approach to assessing implementation outlined here, which was developed collaboratively to avoid duplication of efforts and supplement results, nine of the HPC research projects form a large and innovative collective hybrid effectiveness-implementation effort. This study may provide important insights as to how best to incorporate implementation science into future funding opportunities and across research projects in the absence of a pre-designed hybrid effectiveness-implementation model. In other words, this study will document challenges and successes of the process of conducting the hybrid effectiveness-implementation effort at a collective level.

Furthermore, this positions the HPC to uniquely consider effectiveness, implementation, and cost-effectiveness of the prevention interventions jointly. Incorporating cost-effectiveness into hybrid designs can provide a more in-depth perspective on emerging interventions. This study will thus provide critically important information for policymakers, payers, communities, and relevant organizations when considering adoption of effective prevention interventions into real-world practice.

Still, experience shows that availability and awareness of interventions are not enough to support their widespread adoption and sustained implementation (Grimshaw et al., 2004; Kotter, 1996). The study leverages the expertise of the research project teams to identify specific factors that might impede adoption and implementation of prevention interventions in real-world practice and potential approaches to overcome them. To fully leverage the lessons learned from the HPC research projects and through this effort, it will be imperative to think innovatively about how to best engage and collaborate with key stakeholders across relevant sectors to overcome barriers, promote integration of effective prevention interventions into their settings, and create communities of healing (Marques et al., 2020).

Interventions designed to prevent opioid misuse and OUD are a critical component of the nation’s strategy to address the longstanding opioid overdose crisis. However, relying on the standard research-to-practice timeline is insufficient given the impact of the crisis on individuals and their communities. The hybrid approach of the HPC is currently the largest initiative dedicated to simultaneously testing the effectiveness of prevention interventions to address the opioid crisis and answering questions about their implementation.

Author Contribution  This study was conceptualized by representatives of the HEAL Prevention Coordinating Center (HPCC) and HEAL Prevention Cooperative (HPC) research projects in the HPCC Implementation Science Workgroup. SVP, JDC, and BL developed the approach and incorporated feedback from the research projects. All authors contributed to drafting the manuscript, provided feedback on the draft, and approved the final manuscript.

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Data Availability  Not applicable.

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 HEAL Initiative.

Ethics Approval  This cross-research project study was designated non-human subjects research and was determined not to need ethics approval by RTI International’s Institutional Research Board (IRB). The individual research projects included within the study received ethical approval from the IRBs at their home institutions.
Consent to Participate Not applicable.

Conflict of Interest Dr. Saldana is the developer of the Families Active Improving Relationships (FAIR) programs, which is available for implementation through Oregon Social Learning Center (OSLC) Developments, Inc. Dr. Fiellin holds equity with Playbl, Inc., a small commercial venture that focuses on the distribution of evidence-based videogames for risk reduction and prevention in youth and young adults. This relationship is extensively managed by Dr. Fiellin and her academic institution.

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