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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

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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 (SAMHSA, 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 understand 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 settings (Crowe et al., 2011). Development of the case studies 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 projects. 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 experiencing homelessness, and one on families with young parents involved with child welfare services. The prevention interventions being tested are delivered by a variety of practitioners 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 projects and are informed by relevant implementation science

frameworks (Table 2). We will use the Template for Intervention 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; Wiltsey Stirman et al., 2019). We will use two determinant frameworks 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 Strategic Prevention Framework (SPF) to probe research projects 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 implementation 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 interventions. We will explore what resources and activities were required to engage and prepare these settings and personnel for intervention delivery, to deliver the interventions, and, if applicable, to sustain intervention delivery. 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., barriers and facilitators) were anticipated versus experienced and how they were addressed or leveraged.

2. How representative of the target population are the participants 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

Table 1 Overview of included HPC research projects

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

Table 2 Research questions

Research questions	Frameworks
1. What were the context and approach for implementing the prevention interventions, and how was the overall implementation experience?	
a. What are the characteristics of the settings and personnel that implemented these prevention interventions?	TIDieR Checklist
b. What resources and activities were required pre-implementation?	CFIR, EPIS, SPF
c. What resources and activities were required to deliver the prevention intervention?	CFIR, EPIS, SPF
d. What resources and activities were required to monitor and sustain delivery of the prevention intervention?	CFIR, EPIS, SPF
e. What strategies were used to implement and sustain the prevention interventions, and what was their utility?	ERIC, Proctor Guidelines
f. What were the barriers and facilitators to prevention intervention implementation?	CFIR, EPIS, SPF
2. How representative of the target population are the participants who were enrolled and retained in the research projects' effectiveness trials?	
a. How do the populations enrolled and retained in the research projects' trial compare to their target population?	
b. How do enrollment and retention rates compare across population groups?	
c. If enrollment and retention rates are lower than expected, why?	CFIR, EPIS, SPF
3. For what purposes and how were stakeholders engaged by the research projects?	
a. What stakeholder groups were engaged?	CFIR, EPIS, SPF
b. For what purposes, to what extent, and how were stakeholder groups engaged?	ERIC, Proctor Guidelines
c. What were the benefits of engaging the stakeholder groups in this way?	ERIC, Proctor Guidelines
4. What are the adaptable components of the prevention interventions?	
a. What are the components of each prevention intervention?	TIDieR Checklist
b. How, if at all, was the prevention intervention adapted because of the COVID-19 pandemic?	FRAME
c. Which components are considered core to achieving participant outcomes?	TIDieR Checklist
d. How might adaptable components need to be tailored for non-trial implementation?	FRAME
5. How might implementation of the prevention interventions vary for non-trial implementation?	
a. What settings and personnel could implement these prevention interventions?	TIDieR Checklist
b. What level of effort is required to engage and prepare them to implement and deliver the prevention interventions?	ERIC, Proctor Guidelines
c. Which barriers and facilitators are relevant for non-trial implementation?	CFIR, EPIS, SPF
d. What additional barriers and facilitators may come up in non-trial implementation?	CFIR, EPIS, SPF
e. What utility do the implementation strategies used have for non-trial implementation?	ERIC, Proctor Guidelines
f. What other strategies are likely needed for non-trial implementation or sustainment?	ERIC, Proctor Guidelines

CFIR Consolidated Framework for Implementation Research, *EPIS* Exploration-Preparation-Implementation-Sustainment Framework, *ERIC* Expert Recommendations for Implementing Change, *FRAME* Framework for Reporting Adaptations and Modifications to Evidence-based Interventions, *TIDieR Checklist* Template for Intervention Description and Replication Checklist

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,

we will tailor the probes based on information gathered via document review and communication between research projects and HPCC liaisons to date. We will distribute the tailored interview guides to interviewees before their interview to allow time for reflection. A member of the HPCC Implementation Science Core will conduct and record the interview virtually via Zoom. The interviewer will document summary bullets to share back with the interviewee to ensure accurate notes. Once the summary bullets are finalized for each round of interviews, we will update the research projects' case study template to reflect data gathered during the interviews.

Updates and Review for Accuracy

Research project plans, activities, and experiences may change as the trial progress. Annually, the HPCC Implementation Science Core will share a high-level version of each HPC research project's latest case study notes with the Principal Investigators. We will highlight sections for the research project to review and include comments asking them to provide written updates.

Data Analysis

To guide our analytic approach, we will develop a codebook for each research question based on the frameworks that informed data collection. Detailed case study notes drawing on research project documents, communication with HPCC liaisons, and interviews will be initially coded by the data collector as they are recorded. Case study notes will undergo annual review by the HPCC Implementation Science Core to confirm appropriate coding and inform updates to the codebooks. Any disagreements about coding will be resolved through discussion among the team until consensus is reached. Discussion of coding conflicts among the broader team and updated versions of the codebook will facilitate reliable use of codes across data collectors.

To generate lessons learned about prevention intervention implementation, we plan to conduct cross-research project analyses to the extent that natural groupings arise. Potential groupings include setting (e.g., community-wide, health care facilities, juvenile justice centers, schools, social service systems), population of focus (e.g., those experiencing homelessness, justice-involved youth, AI/AN youth, health care patients, families, students), intervention approach (e.g., screening, brief intervention, psychotherapy, community engagement), behavior change target (e.g., preventing opioid use or misuse, minimizing escalation to OUD, identifying OUD early), and implementation approach (e.g., training, supervision). Analyzed data will be shared back with permission to involved research projects to facilitate further synthesis and generate shared lessons for dissemination.

Cross-research project analysis will be guided by the three phases of qualitative content analysis: immersion, reduction, and interpretation (Forman & Damschroder, 2007). In the immersion phase, members of the HPCC Implementation Science Core will engage with the detailed case study notes, reading them multiple times to obtain a sense of "the whole." Next, in the reduction phase, 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

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.

Declarations

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 Actively Improving Relationships (FAIR) program, 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.

References

- Ahmad, F., Rossen, L., & Sutton, P. (2021). Provisional drug overdose death counts. Retrieved July 9, 2021, from <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>
- Balas, E. A., & Boren, S. A. (2000). Managing clinical knowledge for health care improvement. *Yearbook of medical informatics*, 9(1), 65–70.
- Bloom, A. W. (2016). Advances in substance abuse prevention and treatment interventions among racial, ethnic, and sexual minority populations. *Alcohol Research*, 38(1), 47–54.
- Bohnert, A. S., Guy Jr, G. P., & Losby, J. L. (2018). Opioid prescribing in the United States before and after the Centers for Disease Control and Prevention's 2016 Opioid Guideline. *Annals of Internal Medicine*, 169(6), 367–375. <https://doi.org/10.7326/m18-1243>
- Bonar, E. E., Coughlin, L., Roche, J. S., Philyaw-Kotov, M. L., Bixler, E. A., Sinelnikov, S., & Walton, M. A. (2020). Prescription opioid misuse among adolescents and emerging adults in the United States: A scoping review. *Preventive Medicine*, 132, 105972. <https://doi.org/10.1016/j.ypmed.2019.105972>
- Brown, C. H., Curran, G., Palinkas, L. A., Aarons, G. A., Wells, K. B., Jones, L., & Cruden, G. (2017). An overview of research and evaluation designs for dissemination and implementation. *Annual Review of Public Health*, 38, 1–22. <https://doi.org/10.1146/annurev-publhealth-031816-044215>
- Centers for Disease Control and Prevention, National Center for Health Statistics. (2020). CDC WONDER (Wide-ranging online data for epidemiologic research). Retrieved Nov 2, 2021, from <http://wonder.cdc.gov>
- Compton, W. M., Thomas, Y. F., Stinson, F. S., & Grant, B. F. (2007). Prevalence, correlates, disability, and comorbidity of DSM-IV drug abuse and dependence in the United States: Results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Archives of General Psychiatry*, 64(5), 566–576. <https://doi.org/10.1001/archpsyc.64.5.566>
- Crowe, S., Cresswell, K., Robertson, A., Huby, G., Avery, A., & Sheikh, A. (2011). The case study approach. *BMC Medical Research Methodology*, 11(1), 100. <https://doi.org/10.1186/1471-2288-11-100>
- Crowley, D. M., Jones, D. E., Coffman, D. L., & Greenberg, M. T. (2014). Can we build an efficient response to the prescription drug abuse epidemic? Assessing the cost effectiveness of universal prevention in the PROSPER trial. *Preventive Medicine*, 62, 71–77. <https://doi.org/10.1016/j.ypmed.2014.01.029>
- Cunningham, R. M., Chermack, S. T., Ehrlich, P. F., Carter, P. M., Booth, B. M., Blow, F. C., & Walton, M. A. (2015). Alcohol interventions among underage drinkers in the ED: A randomized controlled trial. *Pediatrics*, 136(4), e783–793. <https://doi.org/10.1542/peds.2015-1260>
- Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care*, 50(3), 217–226. <https://doi.org/10.1097/MLR.0b013e3182408812>
- Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*, 4(1), 50. <https://doi.org/10.1186/1748-5908-4-50>
- Evans, W., Andrade, E., Pratt, M., Mottern, A., Chavez, S., Calzetta-Raymond, A., & Gu, J. (2020). Peer-to-peer social media as an effective prevention strategy: Quasi-experimental evaluation. *JMIR mHealth and uHealth*, 8(5), e16207. <https://doi.org/10.2196/16207>
- Fernandez, M. E., Ten Hoor, G. A., van Lieshout, S., Rodriguez, S. A., Beidas, R. S., Parcel, G., & Kok, G. (2019). Implementation mapping: Using intervention mapping to develop implementation strategies. *Frontiers in Public Health*, 7, 158. <https://doi.org/10.3389/fpubh.2019.00158>
- Forman, J., & Damschroder, L. (2007). Qualitative content analysis. In *Empirical methods for bioethics: A primer*: Emerald Group Publishing Limited.
- Grimshaw, J. M., Thomas, R. E., MacLennan, G., Fraser, C., Ramsay, C. R., Vale, L., Donaldson, C. (2004). Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*, 8(6), iii–iv, 1–72. <https://doi.org/10.3310/hta8060>
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., & Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *British Medical Journal*, 348, <https://doi.org/10.1136/bmj.g1687>
- Jones, C. M., Clayton, H. B., Deputy, N. P., Roehler, D. R., Ko, J. Y., Esser, M. B., & Hertz, M. F. (2020). Prescription opioid misuse and use of alcohol and other substances among high school students — Youth Risk Behavior Survey, United States, 2019. *Morbidity and Mortality Weekly Report*, 69(1), 38–46. <https://doi.org/10.15585/mmwr.su6901a5>
- Kotter, J. P. (1996). *Leading change*. Boston: Harvard Business School Press.
- Landes, S. J., McBain, S. A., & Curran, G. M. (2019). An introduction to effectiveness-implementation hybrid designs. *Psychiatry Research*, 280, 112513. <https://doi.org/10.1016/j.psychres.2019.112513>
- Manchikanti, L., Vanaparthi, R., Atluri, S., Sachdeva, H., Kaye, A. D., & Hirsch, J. A. (2021). COVID-19 and the opioid epidemic: Two public health emergencies that intersect with chronic pain. *Pain and Therapy*, 10(1), 269–286. <https://doi.org/10.1007/s40122-021-00243-2>
- Marques, L., Youn, S. J., Zepeda, E. D., Chablani-Medley, A., Bartuska, A. D., Baldwin, M., & Shtasel, D. L. (2020). Effectiveness of a modular cognitive-behavioral skills curriculum in high-risk justice-involved youth. *The Journal of Nervous and Mental Disease*, 208(12), 925–932. <https://doi.org/10.1097/nmd.0000000000001232>
- Moullin, J. C., Dickson, K. S., Stadnick, N. A., Rabin, B., & Aarons, G. A. (2019). Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. *Implementation Science*, 14(1), 1. <https://doi.org/10.1186/s13012-018-0842-6>
- National Academies of Sciences, E., Medicine Division of, B., Social, S., Education Board on Children, Y., Youth. (2019). The National Academies Collection: Reports funded by National Institutes of Health. *Fostering Healthy Mental, Emotional, and Behavioral Development in Children and Youth: A National Agenda*. Washington (DC): National Academies Press (US). Copyright 2019 by the National Academy of Sciences. All rights reserved.
- Powell, B. J., Waltz, T. J., Chinman, M. J., Damschroder, L. J., Smith, J. L., Matthieu, M. M., & Kirchner, J. E. (2015). A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project.

- Implementation Science*, 10(1), 21. <https://doi.org/10.1186/s13012-015-0209-1>
- Proctor, E. K., Powell, B. J., & McMillen, J. C. (2013). Implementation strategies: Recommendations for specifying and reporting. *Implementation Science*, 8(1), 139. <https://doi.org/10.1186/1748-5908-8-139>
- Rhodes, E., Wilson, M., Robinson, A., Hayden, J. A., & Asbridge, M. (2019). The effectiveness of prescription drug monitoring programs at reducing opioid-related harms and consequences: A systematic review. *BMC Health Services Research*, 19(1), 784. <https://doi.org/10.1186/s12913-019-4642-8>
- SAMHSA. (2019). A guide to SAMHSA's strategic prevention framework. Rockville, MD: Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration.
- Substance Abuse and Mental Health Services Administration (SAMHSA). (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health. Rockville, MD: (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55).
- Spoth, R., Trudeau, L., Shin, C., Ralston, E., Redmond, C., Greenberg, M., & Feinberg, M. (2013). Longitudinal effects of universal preventive intervention on prescription drug misuse: Three randomized controlled trials with late adolescents and young adults. *American Journal of Public Health*, 103(4), 665–672. <https://doi.org/10.2105/ajph.2012.301209>
- Walton, M. A., Resko, S., Barry, K. L., Chermack, S. T., Zucker, R. A., Zimmerman, M. A., & Blow, F. C. (2014). A randomized controlled trial testing the efficacy of a brief cannabis universal prevention program among adolescents in primary care. *Addiction*, 109(5), 786–797. <https://doi.org/10.1111/add.12469>
- Wiltsey Stirman, S., Baumann, A. A., & Miller, C. J. (2019). The FRAME: An expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*, 14(1), 58. <https://doi.org/10.1186/s13012-019-0898-y>

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