PROVIDENT

The Preventing Overdose Using Information and Data From the Environment (PROVIDENT) Study

STUDY PROTOCOL

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Official Study Title:

Reducing Drug-Related Mortality Using Predictive Analytics: A Randomized, Statewide, Community Intervention Trial

U.S. NIH Grant/Contract Award Number:

R01DA046620

Principal Investigators:

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Magdalena Cerdá (New York University Langone Health)

Scope:

This document covers (a) Phase 1 PROVIDENT model development, (b) the Phase 2 randomized cluster trial (39 Rhode Island municipalities randomized 1:1 to PROVIDENT vs comparator), (c) a parallel Phase 2 implementation study (surveys/focus groups; staff enrollment; no randomization of individuals), and (d) the COVID-19 supplement study. The ClinicalTrials.gov record (NCT05096429) reports only the Phase 2 randomized cluster trial. The implementation study, Phase 1 model development, and COVID supplement are not included.

Brown University
Human Subjects Research Application

Instructions on how to complete this application can be found in our guidance tool.

Study Title: PROVIDENT (Preventing Overdose using Information and Data from the Environment) R01 DA046620

Principal Investigator: Brandon DL Marshall, PhD
If PI is a graduate/medical student, please upload Appendix I: Human Subjects Research Advisor.

1. **Provide the scientific background of the study.**
   Phase 1 – PROVIDENT Model Development (original parent application; approved November 2019): In light of the accelerating and rapidly evolving overdose epidemic, new strategies are needed to identify communities most at risk, and to utilize resources more effectively to curb overdose deaths. To address these public health priorities, we will develop a forecasting tool to predict overdose deaths before they occur, and then conduct a randomized, statewide, community-level intervention to evaluate resource targeting based on these predictions. This tool, called PROVIDENT (Preventing Overdose using Information and Data from the Environment), will be used to identify neighborhoods at high risk of future overdose outbreaks.

   Phase 2 – Cluster Randomized Trial (Amendment 4; approved September 2021): We will conduct a randomized policy experiment to evaluate whether targeting overdose prevention interventions to neighborhoods at the highest risk reduces overdose morbidity and mortality. The state's department of health will receive PROVIDENT model prediction maps for half of the 39 cities/towns in Rhode Island and work with community-based organizations to prioritize and allocate resources according to model predictions. Community-based organizations will access model prediction maps through the secure Web Tool, and maps will be updated every six months.

   Phase 2 – Implementation Study (Amendment 4; approved September 2021): Machine learning methods offer significant potential as an innovative intervention to curb the ongoing and escalating overdose crisis. These methods help to predict, or forecast, persistent and emerging hotspots in neighborhoods at risk for increased overdose activity. Machine learning predictions can enable community organizations and state health departments to better assess, plan, and intervene in a neighborhood in ways that traditional surveillance does not allow. That is because traditional surveillance datasets (i.e., overdose deaths, emergency department visits, and ambulance runs) are limited to past events and subject to greater regional variation over time. Machine learning methods can enhance existing overdose surveillance efforts by leveraging additional structural datasets (such as census data) to identify persistent hotspots.

   However, using machine learning methods to drive service delivery and intervention warrants caution, particularly regarding the support needed for optimal uptake and fidelity of an innovative intervention. Furthermore, the extent to which the intervention is used effectively within organizations and across the state is yet to be determined. To address these concerns, we are conducting an implementation study using an ecological framework, where we will assess factors

across such a framework.

COVID Supplement (Amendment 2; Approved November 2020): The proposed research addresses significant limitations to previous studies of the impacts of 'big events' on drug-related harms. Most research conducted in the aftermath of 'big events', such as natural disasters, are cross-sectional and focusing on the immediate impacts of the 'big event' among convenience samples. This supplemental research uses several population-based datasets to create a representative picture of the variegated impacts of the COVID-19 pandemic and the associated response among PWUD. Further, the use of an interrupted time series design allows for the assessment of both abrupt changes in the short-term and gradual changes in the long-term following the 'big event'. These findings have the strong potential to inform the mitigation of both the immediate and long-last impacts of future public health crises towards the building of more resilient harm reduction and substance use treatment systems.

2. **Identify the research question(s) of the study and how the study will contribute to generalizable knowledge.**
Research Question: How are current responses to the opioid overdose epidemic limited by the available surveillance data?

Most overdose mortality surveillance systems suffer from substantial delays due to the complex nature of overdose death investigations. Thus, many data-driven responses to the epidemic are often based on outdated information, potentially limiting intervention effectiveness. Furthermore, despite myriad federal and statewide initiatives, few interventions are targeted to the most heavily affected communities, thus reducing their potential impact.

To overcome this limitation, we propose a new paradigm in overdose prevention. Rather than target interventions based solely on past overdose burden, we will use predictive analytics methods and timely surveillance data to identify neighborhoods at highest risk of future overdose deaths. Specifically, we will leverage spatial machine learning methods to develop a predictive analytics model. This model, called PROVIDENT (Preventing Overdose using Information and Data from the Environment), will be used to create neighborhood-level overdose risk indices, representing the likelihood of future overdose deaths.

1. PHASE 1: As described in the parent IRB application, we will develop a predictive analytics model to forecast future overdose mortality at the neighborhood level, defined as census block groups. There are 809 populated census block groups in Rhode Island, grouped in 39 cities/towns. We will use a spatiotemporal machine learning approach, in which the outputs of multiple classification and spatial-temporal machine learning prediction models are combined based on minimizing cross-validated risk. An overdose risk index will be generated for each census block group, which represents the forecasted probability of an overdose death in the subsequent 12-month period.

2. PHASE 2: As described in Amendment 4, we will launch the Phase 2 randomized cluster intervention trial and the Phase 2 implementation study. The primary outcome of the PROVIDENT

trial will be annual city/town-level overdose rates, measured from six months after the interventions have been implemented. Data collection methods will include a continuation of secondary data transfers with RIDOH and analyses established in Phase 1. We will evaluate, at the city/town level, whether targeted intervention deployment to neighborhoods at high risk of future overdose reduces population-level overdose morbidity and mortality. Fatal overdoses will be defined as accidental drug-related deaths deemed by a medical examiner to be attributed to a prescription or illicit drug. Non-fatal overdoses will be defined as ED visit for a suspected overdose reported through the state's 48-Hour Overdose Reporting System.

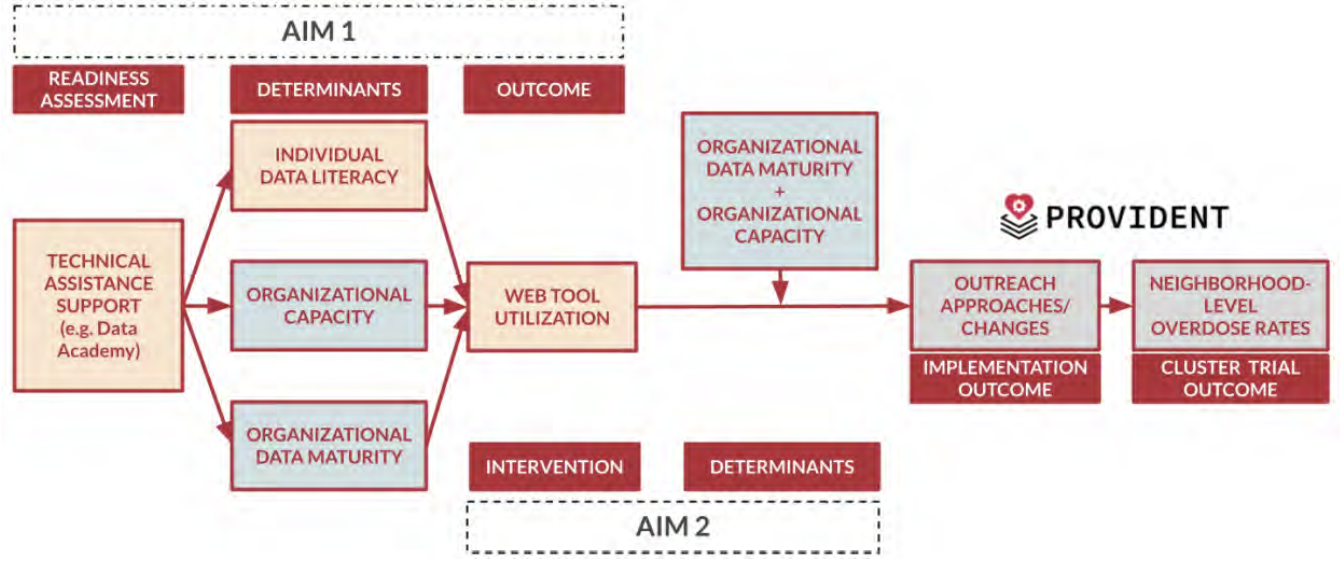
The implementation study is a parallel study designed to better understand how contextual factors and implementation strategies impact the overall uptake, reach, and fidelity of the PROVIDENT prediction tool. Data collection methods include surveys, focus groups, key informant interviews, and a Brown-CIS build Web Tool database. The Ecological Framework (Durlack & Dupre, 2008) highlights five key areas for analyzing both the characteristics of the intervention and the setting in which the intervention is implemented, and seeing how those factors affect the overall success of the larger intervention. Using this framework, we will analyze Community-Level Factors, Provider Characteristics, Characteristics of the Innovation, Organizational Capacity, and the Prevention Support System (Statewide systems) (See Table 1.) Specifically, we want to understand how the roles of individual-level data literacy (defined broadly as knowledge of data quality, data reliability, and understanding data-driven maps) and organizational-level data maturity (defined broadly as an organization's data capabilities across several dimensions) affect the implementation of an innovative intervention at the community and state levels. We also want to understand whether planned technical assistance efforts are enough to increase the fidelity and reach of the PROVIDENT intervention. We hypothesize that by providing timely and responsive technical assistance sessions for these factors both prior to, during, and following the launch of the innovative intervention, we will be able to increase the overall fidelity and reach of the intervention (see Figure 1). Other qualitative themes to assess include organizational structures and activities such as support and oversight for administrative work (administrative supervision); training and support around emotional labor, trauma exposure and outreach skills; themes of stress and burnout among peer workers; and assessing organization's comfort with harm reduction interventions (versus abstinence-focused services or medication for treatment). We believe that the Ecological Framework's themes related to organizational capacity will also play an important role in the implementation and may offer additional insights for adapting or further co-creating elements of the innovation and available harm reduction services to meet the needs of the community.

The primary aim of this study is to understand factors of implementation (individual data literacy, organizational capacity and culture, organizational data maturity) that may influence the utilization of an online mapping tool (The PROVIDENT Web Tool, which is the interface for the PROVIDENT Model results) (See Figure 1). The secondary aim is to assess web tool utilization, including statewide reach of the web tool and harm reduction dosage at the neighborhood level. We will map out how these factors may contribute to the outcomes of the larger intervention trial (reduction in overdose deaths) (See Table 1 in Question 7, Study Procedures)

Theory/Framework/Type of study Prospective Implementation study:

Qualitative mixed methods Ecological Framework, a multilevel framework for understanding effective implementation (Durlak, Dupre 2008).

Figure 1. PROVIDENT Implementation Study Overview



COVID Supplement

Research Question: How do policies enacted as part of the response to the COVID-19 pandemic impact the use of harm reduction and substance use treatment services and rates of non-fatal and fatal overdoses? What is the relationship between acute changes in SARs-CoV-2 diagnoses and COVID-19 hospitalizations and deaths at the community level on rates of non-fatal and fatal drug overdose?

The proposed research aims to identify and assess the magnitude of adverse effects of the COVID-19 pandemic and the associated policy responses on the ongoing drug overdose epidemic. This work will help build an urgently needed evidence base to determine how best to effectively manage these impacts and to support the building of more resilient harm reduction and substance use treatment systems in the face of future unanticipated public health crises (e.g., emerging outbreaks, natural disasters, civil unrest, and war). This work is also well-aligned with the objectives of the NIDA notice of special interest (NOT-DA-20- 47), including research to understand and mitigate the impact of COVID-19 on methadone treatment programs, syringe exchange services, and other interventions. In sum, this work will help build an urgently needed evidence base to determine how best to effectively manage the adverse effects of COVID-19 on the overdose epidemic, and to support addiction-related health and social service systems during unanticipated public health crises in the future.

3. **Describe each participant population for the study and list all eligibility criteria.**

Phase 1, PROVIDENT Model: The study will involve a retrospective review of existing overdose surveillance data in Rhode Island to build the PROVIDENT forecasting model. Secondary overdose surveillance data will help inform the creation of the PROVIDENT forecasting tool. This same overdose surveillance system will be used to capture the primary endpoints. In a review of 2014-2016 data, accidental overdose events among children under 18 years of age were rare. However, we do wish to capture qualifying events for children aged 12 and older, as these may represent emerging

patterns, including an increasing risk of overdose among adolescents. As such, fatal and nonfatal overdoses occurring among individuals under 12 years of age will be included in all analyses. The gender and racial/ethnic breakdown of the participants representing these qualifying events will most likely be similar to that of the available underlying epidemiology of the overdose epidemic in Rhode Island from 2014-2016 data, approximately 72% male, and 80% white, as shown in more detail below:

Overdose Deaths in Rhode Island (2014-2016):
Race: American Indian/Alaska Native 2% (n=10)
Asian 1.5% (n=8)
Native Hawaiian/Other Pacific Islander 1% (n=5)
Black or African American 20% (n=100)
White 60% (n=302)
Mixed race 15% (n=75)
Ethnicity:
Hispanic/Latino Ethnicity 15% (n=75)

Gender:
Female 33% (n=165)

Fatal and nonfatal overdoses in Rhode Island (2014-2016):
Age: 12-17 1% (n=36)
18+ 99% (n=3,745)

In sum, there are no exclusion criteria related to age, sex/gender, or race/ethnicity in this study.

Secondary analyses of overdose surveillance data will help inform the creation of the PROVIDENT forecasting tool. This same overdose surveillance system will be used to capture the primary endpoints described above. Based on 2016 data, we expect to observe approximately 1,800 events of fatal or non-fatal overdoses per year, which will be analyzed to evaluate the effects of the targeted community-level intervention.

Phase 2 Implementation Study
GROUP 1
Inclusion Criteria:

- Participants must be at least 18 years old.
- Participants must be currently employed or volunteer with a harm-reduction or peer recovery organization in Rhode Island; the organization must be a Tier 1 organization.
- Participants must be willing to provide informed consent.
- Participants must attend at least one Technical Assistance workshop to be eligible for a pre and post survey (not a requirement for the focus groups or key informant interviews).
- Participants must not work at law enforcement.

Exclusion Criteria

- Participants must not be currently employed or volunteer with a Tier 2 organization.
- Participants must not work at law enforcement.

There is no upper limit to participant age. Across the community-based non-profit organizations in Rhode Island, the currently employed staff who engage with the RIDOH Task Force and Outreach Worker Meetings are all aged 18 and older. We anticipate that the study sample will reflect this age distribution with a minimum age of 18 years.

There are no exclusion criteria related to age, sex/gender, or race/ethnicity in this study. Every effort

will be made to ensure that women and minority individuals are included in the study sample. The study will enroll individuals aged 18 and older who are current staff or volunteer at a community-based non-profit organization in Rhode Island and the organization where they are employed is recruited through the Rhode Island Department of Health Task Force and Outreach Worker Meetings.

We will recruit a purposive sample of professionals in the community through existing relationships. This means we plan to recruit from organizations with existing harm reduction service contracts with RIDOH. Specifically, RIDOH will refer existing organizational staff from each of their contracted harm reduction and outreach organizations by creating an introductory email. Brown will send follow-up emails to the organizational staff with information on how to participate if interested. Many staff at the organizations are peer-outreach workers and have prior lived experience with substance use. The organizations strive to have their staff reflect the demographics of the populations they serve. Therefore, we feel the sub-study will have overall demographics similar to those in the primary PROVIDENT study, including significant representation from women and minority individuals.

In sum, there are no exclusion criteria related to age, sex/gender, or race/ethnicity in this study.

GROUP 2
Inclusion Criteria:

- Participants must be at least 18 years old.
- Participants must be currently employed or volunteer with a community-based harm-reduction, peer recovery, or health equity organization in Rhode Island; the organization must be a Tier 2 organization.
- Participants must be willing to provide informed consent.
- Participants must attend at least one Technical Assistance workshop to be eligible for a pre and post survey (not a requirement for the focus groups or key informant interviews).

Exclusion Criteria

- Participants must not be currently employed or volunteer with a Tier 1 organization.
- Participants must not work at law enforcement.

There is no upper limit to participant age. Across the community-based non-profit organizations in Rhode Island, the currently employed staff who engage with the RIDOH Task Force and Outreach Worker Meetings are all aged 18 and older. We anticipate that the study sample will reflect this age distribution with a minimum age of 18 years.

There are no exclusion criteria related to age, sex/gender, or race/ethnicity in this study. Every effort will be made to ensure that women and minority individuals are included in the study sample. The study will enroll individuals aged 18 and older who are current staff or volunteer at a community-based non-profit organization in Rhode Island and the organization where they are employed is recruited through the Rhode Island Department of Health Task Force and Outreach Worker Meetings.

We will recruit a purposive sample of professionals in the community through existing relationships. This means we plan to recruit from organizations with existing service contracts with RIDOH within the harm reduction, overdose, and health equity communities (Tier 2 organizations). Many staff at the organizations are peer-outreach workers and have prior lived experience with substance use. The organizations strive to have their staff reflect the demographics of the populations they serve. Therefore, we feel the sub-study will have overall demographics similar to those in the primary

PROVIDENT study, including significant representation from women and minority individuals.

In sum, there are no exclusion criteria related to age, sex/gender, or race/ethnicity in this study.

Anticipated enrollment includes individuals from Groups 1 and 2
Anticipated total enrollment over the course of the two year study *n = 180 (overlap between focus groups, key informant interviews, and surveys is expected)*.
Anticipated enrollment in surveys over the course of the two year study *n = 100 (split between Group 1 and Group 2 organizations)*.
Anticipated enrollment in focus groups and key informant interviews over the course of the two year study *n = 80 (split between Group 1 and Group 2 organizations)*.

The anticipated enrollment will not change by enrolling individuals from Tier 2 organizations to participate in the study through the Tier 2 expansion. Therefore, we are not requesting changes to n.

Phase 2 Cluster Randomized Trial
Inclusion Criteria: Cities and towns in Rhode Island
Exclusion Criteria: There are no exclusion criteria

Target population distribution (e.g., women, minorities, etc.)
The target population will be secondary data events from overdose surveillance records in the State of Rhode Island, randomized at the level of the city/town. Therefore, the target population for this project will be all persons residing in the State of Rhode Island. We anticipate the actual enrollment distribution for qualifying data events will be similar to the underlying epidemiological trends for overdose observed in the state. Currently, fatal and nonfatal overdose events affect all cities and towns across Rhode Island (see Table S2 in the DSMP). We expect the demographic breakdown of the participants representing the overdose-related events will be similar to that of the available underlying epidemiology of the overdose epidemic in Rhode Island from 2014-2016 data, approximately 72% male, and 80% white.

COVID-19 Supplement
The study involves a retrospective review of the same existing overdose surveillance data in Rhode Island that is used for the Phase 1 PROVIDENT Model, therefore we expect the population distribution to be the same. Eligibility criteria include residents of Rhode Island.

3.1 Select all vulnerable populations you intend to target for recruitment.

☐	Brown Faculty, Staff, or Students	☐	Children (30 days – 17 years)	☒	Justice-Involved	☐	Decisionally-Impaired	☒	At Risk for / Experiencing Substance Use Disorder

☐	Students	☐	Known Interpersonal Relationships	☐	At Risk of / Experiencing Homelessness	☐	Unauthorized Immigrants	☐	Refugees
☐	LGBTQ+	☐	Pregnant People	☐	Fetuses / Neonates	☐	American Indian / Alaskan Native	☐	Disabled People / People with Disabilities

Phase 1 PROVIDENT Model Development:

Vulnerable populations selected: Justice-Involved, At Risk for / Experiencing Substance Use Disorder

This research is a retrospective review of surveillance records, and there will be no more than minimal risk to the participants whose records may be included. This study involves no procedures for which written consent is normally required outside of the research context. As stated in attachment Marshall 2566, Subpart C Certification, 07-14-2021.pdf, the Office of Human Research Protections placed the research under category "CFR 46.306(a)(2)(i), "Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects," and authorized the study to include prisoners in human subjects research.

Phase 2 Randomized Cluster Trial:

Vulnerable populations selected: At Risk for / Experiencing Substance Use Disorder

We are not targeting individuals at risk for experiencing substance use disorder for recruitment. We are using secondary data only. We will be enrolling cities and towns in the trial.

Phase 2 Implementation Study:

Vulnerable populations selected: At Risk for / Experiencing Substance Use Disorder

We are enrolling individuals who may be at risk for experiencing substance use disorder for recruitment in Groups 1 and 2. Importantly, the revision request (Amendment 6/Modification 2) submitted to add Group 2 and Tier 2 organizations to the implementation study will not change the vulnerable populations selected for the Phase 2 Implementation Study because this population is approved for the Group 1 participant population, which is currently approved (Amendment 4).

COVID-19 Supplement:

Vulnerable populations selected: Justice-Involved, At Risk for / Experiencing Substance Use Disorder

The study involves a retrospective review of the same existing overdose surveillance data in Rhode Island that is used for the Phase 1 PROVIDENT Model. Similarly, there will be no more than minimal risk to the participants whose records may be included. This study involves no procedures for which written consent is normally required outside of the research context. As stated in attachment Marshall 2566, Subpart C Certification, 07-14-2021.pdf, the Office of Human Research Protections placed the research under category "CFR 46.306(a)(2)(i), "Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects," and authorized the study to include prisoners in human subjects research.

4. **Describe the recruitment methods.** ☐ **N/A**

Phase 1 PROVIDENT Model Development: N/A Secondary Data Analysis

Phase 2 Randomized Cluster Trial: N/A Secondary Data Analysis

Phase 2 Implementation Study:
We will recruit individuals into two groups: Group 1 and Group 2. We will begin recruitment of Group 1 prior to the baseline Technical Assistance series, which will start prior to the launch of the trial, and continue recruitment for the duration of the study. We will begin recruitment of Group 2 one year after the launch of the study and continue recruitment for the remainder of the study.

GROUP 1 (approved in Amendment 4 in September 2021).
Purposive sampling through the Rhode Island Department of Health (RIDOH). Recruitment from three outreach organizations (Tier 1 organizations) with existing service contracts with RIDOH; Tier 1 organizations will receive more intensive training and implementation strategies.

We will recruit a purposive sample of professionals in the community through existing relationships. This means we plan to recruit from organizations with existing harm reduction service contracts with RIDOH. Specifically, RIDOH will refer existing organizational staff from each of their contracted harm reduction and outreach organizations by creating an introductory email. Brown will send follow-up emails to the organizational staff at Tier 1 organizations with information on how to participate if interested and a description of the more intensive study activities for Group 1.

GROUP 2
Purposive sampling through the Rhode Island Department of Health (RIDOH) - Recruitment from organizations that are not one of the three Tier 1 organizations; we will call these organizations Tier 2 organizations. Tier 2 organizations will receive less intensive training and implementation strategies.

We will recruit a purposive sample of professionals in the community through existing relationships. This means we plan to recruit from organizations with existing harm reduction contracts with RIDOH that are not one of the three Tier 1 organizations. Specifically, RIDOH will refer existing organizational staff from each of their contracted harm reduction and outreach or related organizations by creating an introductory email. Brown will send follow-up emails to the organizational staff at Tier 2 organizations with information on how to participate if interested and a description of the less intensive study activities for Group 2.

COVID-19 Supplement: N/A Secondary Data Analysis

5. **Explain the informed consent process.** ☐ **N/A**

Phase 1 PROVIDENT Model: N/A
Waiver of consent: Because Phase 1 is a retrospective review of multiple secondary data sources that are already being collected administratively for other purposes, we requested a waiver of consent. The risk to participants is no greater than minimal risk and is limited to loss of privacy. Our measures to protect against those risks are outlined in the PROVIDENT DSMP. Our research environment in Stronghold is designed to provide the utmost security for these sensitive datasets and all datasets will be transferred under Data Use Agreements with the participating state agencies (BHDDH, RIDOH, RIDOC); all DUAs have been negotiated.

Phase 2 Randomized Cluster Trial: N/A
Waiver of consent: Because the Phase 2 Randomized Cluster Trial involves a retrospective review of existing overdose surveillance secondary data in Rhode Island that is used to build the PROVIDENT forecasting model (approved in Phase 1, November 2019), we requested a waiver of consent. This same overdose surveillance system will be used to capture the primary endpoints of the trial (fatal and nonfatal overdoses). The risk to participants is no greater than minimal risk and is limited to loss of privacy. Our measures to protect against those risks are outlined in the PROVIDENT DSMP. Our research environment in Stronghold is designed to provide the utmost security for these sensitive datasets and all datasets will be transferred under Data Use Agreements with the participating state agencies (BHDDH, RIDOH, RIDOC); all DUAs have been negotiated.

Phase 2 Implementation Study:
We will follow separate consent processes to consent eligible individuals who work or volunteer at Tier 1 organizations (Group 1) and consent eligible individuals who work or volunteer at Tier 2 organizations (Group 2). This includes different informed consent forms: one to participate in surveys and one to participate in focus groups and/or key informant interviews.

<u>GROUP 1: Consent Process for Individuals at Tier 1 Organizations</u>

Baseline informed consent for Group 1 to participate in surveys will be separate from baseline informed consent to participate in focus groups and/or key informant interviews; the consent form for focus groups and key informant interviews will be combined. This includes two, separate informed consent forms.

PRE/POST SURVEYS

Baseline informed consent to participate in the surveys will occur via Brown Qualtrics prior to the start of the Technical Assistance series with electronic signature confirmation. Eligible individuals at Tier 1 community organizations will be emailed a link to the informed consent document in Brown Qualtrics.

FOCUS GROUPS AND KEY INFORMANT INTERVIEWS

Baseline informed consent to participate in focus groups and/or key informant interviews will occur via Brown Qualtrics as each new individual is enrolled, with electronic signature confirmation. Eligible individuals at Tier 1 community organizations will be emailed a link to the informed consent document in Brown Qualtrics.

GROUP 2: Consent Process for Individuals at Tier 2 Organizations

Baseline Informed Consent for individuals from Tier 2 organizations will combine the consent process to participate in surveys, focus groups, and/or key informant interviews. This includes a single, combined, bulleted consent form.

PRE/POST SURVEYS,FOCUS GROUPS, AND KEY INFORMANT INTERVIEWS

Baseline Informed Consent for individuals who work or volunteer at Tier 2 organizations to participate in pre/post surveys, focus groups, and/or key informant interviews will occur via Brown Qualtrics, with electronic signature confirmation. Eligible individuals at Tier 2 organizations will be emailed a link to a bulleted, combined consent document in Brown Qualtrics.

In sum, informed consent will occur via Brown Qualtrics with electronic signature confirmation only.

COVID-19 Supplement: N/A
Waiver of consent: Because the COVID-19 supplement is a retrospective review of multiple data sources that are already being collected administratively for other purposes, we requested a waiver of consent. The risk to participants is no greater than minimal risk and is limited to loss of privacy. Our measures to protect against those risks are outlined in the PROVIDENT DSMP. Our research environment in Stronghold is designed to provide the utmost security for these sensitive datasets and all datasets will be transferred under Data Use Agreements with participating state agencies, which have all been negotiated.

5.1 To request a waiver or alteration of consent, at least one box must be checked ☒ N/A
(Phase 2 Implementation study)

☐ The research involves public benefit and service programs, is conducted by or subject to the approval of state or local officials, and could not practicably be carried out without the waiver or alteration;

☒ The research meets all requirements for a general waiver or alteration of consent (Phase 1 PROVIDENT Model, Phase 2 Random Cluster Trial, COVID-19 Supplement; see Q5 above for explanation)

☐ For the purpose of screening, recruiting, or determining eligibility of prospective participants, the investigator will obtain information or biospecimens either through oral or written communication with participants, or by accessing records or stored identifiable biospecimens.

5.2 To request a waiver of documentation of consent, at least one box must be checked ☒ N/A

☐ The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.

☐ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

☐ Participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

6. Describe if the study design involves deception or incomplete disclosure. ☒ **N/A**

Click or tap here to enter text.

7. Describe the study procedures.

If study procedures involve asking participants about depression, suicide, or the risk of harm to self or others; may result in participants experiencing emotional distress; include populations at high risk for self-injury; administer study medications with a side effect of suicidal ideation, or involve other research components that could increase suicidal risks, please upload Appendix F: Mental Health Safety Plan.

Phase 1 Development of the PROVIDENT model

The methods and procedures outlined here will lead to the development and validation of PROVIDENT, a forecasting model to predict future overdose death.

To develop the PROVIDENT model, we will analyze detailed geospatial data from all overdose fatalities that have occurred in Rhode Island since 2014. Data from publicly available sources (i.e., census records) and the state's multicomponent surveillance system (including hospital visits, opioid prescribing records, emergency medical services calls, and addiction treatment admissions data) will serve as model predictors.

We will forecast future fatal overdose burden using an ensemble machine learning approach, in which multiple classification and spatiotemporal machine learning prediction algorithms are combined based on minimizing cross-validated risk. The PROVIDENT model will generate an overdose risk index that estimates the likelihood of future overdose death in every neighborhood (defined as a census block group) across Rhode Island.

As a conceptual framework for selecting inputs for the PROVIDENT model, we will adopt a theoretical schema for the contextual determinants of drug use-related risks. In this conceptual model, overdose and related risk behaviors are influenced by four domains. First, social capital (the extent and depth of social trust, norms, and networks) and family fragmentation (e.g., divorced, separated, or single-parent families) are positively correlated with overdose mortality rates at the county level. Second, measures of neighborhood disadvantage (including urban deprivation, income inequality, and poverty) have shown strong relationships with neighborhood overdose rates. Third, health and social resources include availability of OAT and opioid treatment programs, which may serve as proxies for underlying opioid use in a population. Finally, the physical environment influences overdose risk, which includes measures of environmental disorder and deterioration of the built environment (e.g., number of houses in dilapidated condition).

Additionally, overdoses tend to cluster in space and time at multiple geographic and temporal

resolutions. Thus, we expect that previous counts of overdoses and other surveillance indicators in the given neighborhood, nearby, and similar neighborhoods may be predictive. These data complement the conceptual model by accounting for unobserved social determinants of risk. We will employ this framework to identify publicly available sources of information that contain relevant geospatial data for predicting overdose. We note that the proposed approach does not seek to estimate causal relationships linking predictors of interest with neighborhood-level overdose rates. Rather, we will include a broad set of potentially relevant variables in the forecasting model so as to achieve optimal predictive ability. The appeal of the machine learning approach is in its ability to find complex relationships between variables and fit flexible functional forms without simply overfitting the observed data, enabling the model to achieve high accuracy when forecasting future data. As the model focuses on forecasting neighborhood-level overdose disease burden, individual-level variables (e.g., cognitive functioning, biological susceptibility to overdose) will not be considered. In this manner, the proposed project complements other research, including the development of clinical prediction algorithms, which seek to estimate individual-level overdose risk.

Phase 2 Cluster randomized trial

Data Collection

The study will involve a retrospective review of existing overdose surveillance data in Rhode Island to build the PROVIDENT forecasting model (approved in Phase 1, November 2019). This same overdose surveillance system will be used to capture the primary endpoints. To ensure adequate power, we will consider as the primary endpoint both fatal and non-fatal overdoses.

Analysis

We will employ standard methods for community intervention and cluster trials. The intervention effect will be quantified as an overdose incidence rate ratio. We will have at least five years of data (from 2014 to 2018) to serve as the pre-intervention period. We will use Poisson regression to estimate incidence rate ratios comparing treatment vs. control overdose rates. Although we will use stratified randomization to reduce pre-intervention differences in the treatment and control groups, potential biases from the imbalance can be corrected by including other covariates in the model. We will allow for a six-month washout period to allow for lagged intervention implementation.

Next, we will construct time-lagged regression models to consider the delayed impact of the interventions by staggering outcomes 0 to 6 months. Finally, we will employ a counterfactual framework for direct, indirect, and spillover effects in group randomized trials to accommodate issues of spillover across treatment and control clusters.

Given our study timeline, we anticipate two years of post-intervention follow-up time. We can therefore elaborate the model to incorporate stochastic variation in the underlying overdose rate (e.g., seasonality and natural temporal variation) and to estimate the effect of the intervention as a function of time. With this approach we can ascertain the rate at which the intervention begins to show

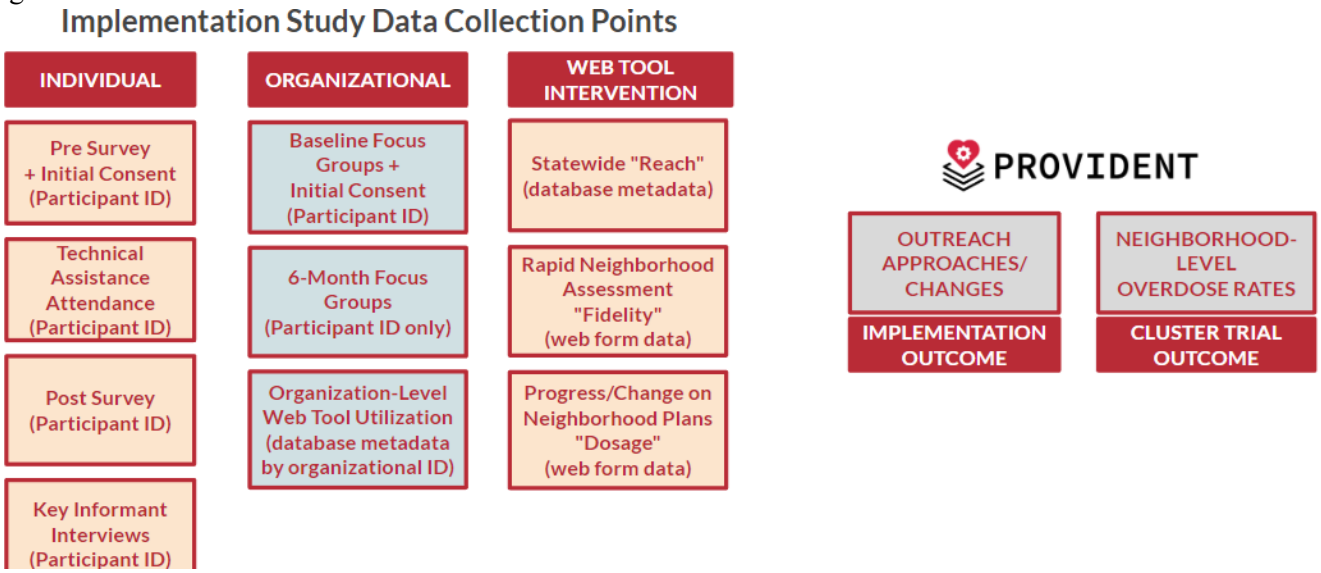
differences. Repeated measures regression can be used for this purpose, with models fit using generalized estimating equations.

Phase 2 Implementation Study

We will conduct an Implementation Study in parallel with the PROVIDENT Cluster Randomized Trial, to assess how contextual factors may affect implementation, and ultimately, the outcomes of the trial. The Ecological Framework (Durlack & Dupre, 2008) highlights five key areas for analyzing both the characteristics of the intervention and the setting in which the PROVIDENT Cluster Randomized Trial is implemented, and seeing how those factors affect the overall success of the larger intervention. Using this framework, we will analyze Community-Level Factors, Provider Characteristics, Characteristics of the Innovation, Organizational Capacity, and the Prevention Support System (Statewide systems).

We will assess both individual and organizational level factors related to the uptake of the Web Tool intervention for harm reduction outreach workers and the organizations they work in (See Figure 2).

Figure 2. PROVIDENT Phase 2 Data Collection and Outcomes



(last updated 2024.03.27) https://docs.google.com/presentation/d/1bs2KUUrTE3i71ohVhO-WN7LRmnL7bw8p086QUEKn94A/edit#slide=id.g2c70cb95e37_0_0

Table 1. Data Collection Points for Ecological Framework

Proposed data sources	*Components studied*	*Components assessed*	*Frequency*
Pre Survey (self- report)	data literacy/numeracy, Data Academy learning objectives (understanding the goals of the Trial) (Study ID only)	Fidelity	once (or at each TA session) (descriptive trends)
Post Survey (self-report)	data literacy/numeracy, Data Academy learning objectives (understanding the goals of the Trial). (Study ID only)	Fidelity	once (descriptive trends)
Focus Groups (self report)	organizational culture towards data, data entry, data quality, using data to drive change, organizational definition of harm reduction, organizational capacity. (Study ID only)	Reach	Baseline, every 6 months (qualitative coding)
Key Informant Interviews (self report)	Organizational culture towards data, using data to drive change, , organizational capacity, functionality of the web tool, how it impacted individuals' work, how it can be improved in the future	Reach	once (descriptive trends)
Web Tool Logs (Observation)	Frequency of logins by users, aggregated to organization level; total neighborhoods with rapid assessments, total neighborhoods with brief plans associated w them	Dosage, Reach	Monthly database reporting logs (descriptive trends)
Web Tool Rapid Neighborhood Assessment	Rapid services assessment by census tract (neighborhood data only)	Baseline Dosage, Reach	Baseline, every 6 months
Web Tool 6 month Progress Plans (database forms)	Organization-led 6 month progress plans, approach, changes, goals. (web tool user data aggregated to organization level, neighborhood data)	Dosage, Reach	every 6 months, look at planning progress.
Technical Assistance Support	Per "Series". Each series includes 1-4 sessions on requested topics. Initial 4 sessions (8hrs) for all organizations, with follow-up TA (1-4 sessions) offered every 6 months or as requested by organizations. (not measured as study data)	Training only	technical assistance workshop content to address organizational needs

As part of the Phase 2 implementation study, we will assess both individual and organizational level factors related to the uptake of the Web Tool intervention for harm reduction outreach workers and the organizations they work in. We will work with three community-based harm reduction organizations, which we will call “Tier 1 organizations”, by engaging in on-site outreach, hosting data academies, providing training tools, and sharing video tutorials. The implementation study will enroll individuals from these three Tier 1 community-based harm reduction organizations into Group 1. Recruitment of individuals from Tier 1 organizations into Group 1 will begin prior to the baseline Technical Assistance series, which will start prior to the launch of the two-year implementation study and continue for the duration of the study. Study activities for Group 1 will include more intensive training, engagement, and implementation strategies.

While recruitment and retention of participants from Tier 1 organizations is proceeding without delays or problems, there has been increased interest in the study from organizations outside of these three Tier 1 organizations, including various community-based organizations and groups within the Rhode Island overdose prevention, harm reduction, and health equity communities. Therefore, in addition to engaging the three Tier 1 organizations, we will also engage these other organizations in the study, which we will call “Tier 2 organizations”. And we will enroll individuals from these Tier 2 organizations into Group 2. Recruitment of individuals from Tier 2 organizations into Group 2 will begin one year from the launch of the implementation study and continue for the remainder of the study (one year in total). Study activities for Group 2 will include less intensive training, engagement, and implementation strategies. Less intensive training and implementation strategies will include supplementing the Technical Assistance workshop series offered to Group 1 with virtual technical assistance workshops and other online training resources.

While the entire study procedure used for Group 1 is different than that used for Group 2, Group 1 and Group 2 will both be invited to participate in the pre/post surveys,focus groups, and key informant interviews (i.e., we will administer the same surveys and use the same focus group and interview guides for both Group 1 and Group 2).

STUDY PROCEDURE FOR GROUP 1 PARTICIPANTS AND INDIVIDUALS WHO WORK AT TIER 1 ORGANIZATIONS

PRE/POST-SURVEY

Brief anonymous pre-survey questionnaire (per individual) before each Technical Assistance (TA)

series (anywhere from 1-4 workshops in a series, based on need). Approximately 15 minutes in length for the survey, including a bulleted consent form (Up to 2 pre-tests per year, for 2 years).

- Baseline Informed Consent will occur via Brown Qualtrics prior to the start of the TA series, with electronic signature confirmation. Participants will still be encouraged to come to 121 South Main Street or 66 Pavilion Avenue to take the survey in person, to ensure confidentiality and ease of compensation. Participants who take the survey in person will still complete the Baseline Informed Consent via Brown Qualtrics, with electronic signature confirmation.
- Surveys will be emailed with a secure Qualtrics link to each eligible individual.
- Surveys will be linked by Study ID
- The surveys will be given at 121 South Main Street or 66 Pavilion Avenue in our study offices. Participants will be asked to wear a mask the entire time. Technical assistance workshops will take place in larger conference rooms so that people attending the workshops will be able to distance themselves from others. Though these surveys and workshops will take place in person, participants will also be able to participate in surveys remotely and attend workshops via Zoom. Should cases of COVID-19 rise and Brown University policies change, the surveys and workshops may be held entirely on Zoom.

Brief anonymous post-survey questionnaire (per individual) after each Technical Assistance series. Approximately 15 minutes in length for the survey (Up to 2 post-tests per year, for 2 years).

- Surveys will be emailed with a secure Qualtrics link to each eligible individual.
- Surveys will be linked by Study ID

SAMPLE TECHNICAL ASSISTANCE MENU
The baseline TA series will start prior to the launch of the trial.

- Four 2-hour sessions over a 1 month period (i.e., the Data Academy) that cover data to action concepts and key themes for the Web Tool application and Trial.
- The TA sessions are meant to be responsive to the needs of the community. The TA menu will broadly consist of Data Storytelling, Neighborhood level risks, Maps, Resource Planning, Web Tool coaching, Administrative Supervision, Data Maturity for organizations, Preventing Burnout, DIY Mapping: Google Maps & Google Forms. Other topics may emerge from Focus Group discussions.
- Follow-up TA Sessions will include a similar TA Guidance Menu with pre/post survey at 6 month intervals following the launch of the trial, for 2 years.

FOCUS GROUPS

We will conduct semi-structured, organization-specific (all members from the same employer) focus groups at baseline and every 6 months thereafter for the duration of the clinical trial.

- These focus groups will occur at 121 South Main Street or 66 Pavilion Avenue. Participants will be asked to wear a mask the entire time. Focus groups will take place in a larger conference room so that people attending will be able to distance themselves from others. Though these

focus groups will take place in person, participants will also be able to attend by Zoom. Should cases of COVID-19 rise and Brown University policies change, the focus groups may be held entirely on Zoom.
- Baseline informed consent will occur via Brown Qualtrics as each new individual is enrolled, with electronic signature confirmation prior to participation.
- A brief, voluntary, anonymous survey will be administered to participants who enrolled in focus groups to collect information about demographics. Data collection and security procedures used for the focus group survey are the same as those used for the "pre-test" survey.
- The focus group survey will be linked by Study ID

One focus group per harm reduction organization

- People recruited for the focus groups will include all individuals recruited for the surveys. The focus groups will be open to other staff from the harm reduction organizations, including individuals who have not participated in the surveys.
- These will be used to assess organizational culture toward data, approach to harm reduction, planning and capacity for delivering harm reduction services, and overall use of the web tool application (up to 2024).

Focus groups will be assigned a study ID at both the organizational and individual levels during transcription and analysis. All identifiers will be removed from transcripts prior to analysis. Each focus group will last no more than 90 minutes, and occur every 6 months.

KEY INFORMANT INTERVIEWS
We will conduct semi-structured key informant interviews with individuals after they have been exposed to either the Data Academies or the Web Tool.

- These interviews will occur at 121 South Main Street, 66 Pavilion Avenue, or an individual's workplace. Interviews will take place in private settings. Though these interviews will take place in person, participants will also be able to attend by Zoom. Should cases of COVID-19 rise and Brown University policies change, the interviews may be held entirely on Zoom.
- Informed consent will occur via Brown Qualtrics as each new individual is enrolled, with electronic signature confirmation prior to participation.
- A brief, voluntary, anonymous survey will be administered to participants who enrolled in interviews to collect information about demographics. We will use the same survey used to collect basic demographic information from focus group participants so that individuals will only take the survey once. Data collection and security procedures used for the interview survey are the same as those used for the "pre-test" survey.
- The interview survey will be linked by Study ID.

One key informant interview per person enrolled

- People recruited for key informant interviews will include individuals who have attended any of the Data Academies or have registered in the PROVIDENT Web Tool. The interviews will be

open to other staff from the harm reduction organizations, including individuals who have not participated in the surveys and/or focus groups.
- These will be used to assess how the Web Tool functioned for organizations and how it can be improved to be more useful for harm reduction and direct service organizations. Interviews will also be used to understand how the Web Tool was used or not used toward data-centered approaches to harm reduction, planning and capacity for delivering harm reduction services, and overall use of the Web Tool applications.

Interviews will be assigned a study ID at both the organizational and individual levels during transcription and analysis. All identifiers will be removed from transcripts prior to analysis. Each interview will last no more than 30 minutes.

STUDY PROCEDURE FOR GROUP 2 PARTICIPANTS AND INDIVIDUALS WHO WORK AT TIER 2 ORGANIZATIONS

PRE/POST-SURVEY
Brief anonymous pre-survey questionnaire (per individual) before each Technical Assistance (TA) series (anywhere from 1-4 workshops in a series, based on need). Approximately 15 minutes in length for the survey, including a combined, bulleted consent form (Up to 2 pre-tests per year, for 1 year).

- Baseline Informed Consent will occur via Brown Qualtrics prior to the start of the TA series, with electronic signature confirmation. This baseline informed consent document will combine consent to participate in the pre-survey, post-survey, focus groups, and key informant interviews. The informed consent form will include information that they may participate in one or more of these activities. . Participants will still be invited to come to our study offices at 121 South Main Street or 66 Pavilion Avenue to take the survey in person, to ensure confidentiality and ease of compensation. Participants who take the survey in person will still complete the Baseline Informed Consent via Brown Qualtrics, with electronic signature confirmation.
- Consented individuals will be assigned a Study ID code. Contact information, consent, pre/post surveys, and focus group surveys will be linked by Study ID.
- Surveys will be administered via Brown Qualtrics.
- Surveys will be emailed with a secure Qualtrics link to each eligible individual.
- Surveys will be linked by Study ID
- Participants will be able to participate in surveys remotely and attend workshops via Zoom.

Brief anonymous post-survey questionnaire (per individual) after each Technical Assistance series. Approximately 15 minutes in length for the survey (Up to 2 post-tests per year, for 1 year).

- Surveys will be emailed with a secure Qualtrics link to each eligible individual.
- Surveys will be linked by Study ID

SAMPLE TECHNICAL ASSISTANCE MENU
The baseline TA series will start one year after the launch of the trial.

- The TA sessions will cover data to action concepts and key themes for the Web Tool application and Trial.
- The TA sessions are meant to be responsive to the needs of the community. The TA menu will broadly consist of Data Storytelling, Neighborhood level risks, Maps, Resource Planning, Web Tool coaching, Administrative Supervision, Data Maturity for organizations, Preventing Burnout, DIY Mapping: Google Maps & Google Forms. Other topics may emerge from Focus Group discussions.
- Follow-up TA Sessions will include a similar TA Guidance Menu with pre/post survey at 6-month intervals for the remainder of the study.
- Online training and technical assistance videos and resources will be available on the Web Tool and users may access these resources at a time that is convenient for them.

FOCUS GROUPS

We will conduct semi-structured focus groups at baseline and every 6 months thereafter for the remainder of the clinical trial.

- These focus groups will occur at 121 South Main Street or 66 Pavilion Avenue. Though these focus groups will take place in person, participants will also be able to attend by Zoom.
- Baseline Informed Consent will occur via Brown Qualtrics as each new individual is enrolled, with electronic signature confirmation prior to participation. This baseline informed consent document will combine consent to participate in the pre-survey, post-survey, and focus groups. The informed consent form will include information that they may participate in the surveys, focus groups, both, or neither surveys nor focus groups.
- Consented individuals will be assigned a Study ID code. Contact information, consent, pre/post surveys, and focus group surveys will be linked by Study ID.
- A brief, voluntary, anonymous survey will be administered to participants who enrolled in focus groups to collect information about demographics. Data collection and security procedures used for the focus group survey are the same as those used for the “pre-test” survey.
- The focus group survey will be linked by Study ID.

One focus group per harm reduction organization

- People recruited for the focus groups will include all individuals recruited for the surveys. The focus groups will be open to other staff from the harm reduction organizations, including individuals who have not participated in the surveys.
- These will be used to assess organizational culture toward data, approach to harm reduction, planning and capacity for delivering harm reduction services, and overall use of the web tool application (up to 2024).

Focus groups will be assigned a Study ID at both the organizational and individual levels during transcription and analysis. All identifiers will be removed from transcripts prior to analysis. Each focus group will last no more than 90 minutes, and occur every 6 months.

KEY INFORMANT INTERVIEWS

We will conduct semi-structured key informant interviews with individuals after they have been exposed to either the Data Academies or the Web Tool.

- These interviews will occur at 121 South Main Street, 66 Pavilion Avenue, or an individual's workplace. Participants will be asked to wear a mask the entire time. Interviews will take place in private settings. Though these interviews will take place in person, participants will also be able to attend by Zoom. Should cases of COVID-19 rise and Brown University policies change, the interviews may be held entirely on Zoom.
- Baseline informed consent will occur via Brown Qualtrics as each new individual is enrolled, with electronic signature confirmation prior to participation.
- A brief, voluntary, anonymous survey will be administered to participants who enrolled in interviews to collect information about demographics. We will use the same survey used to collect basic demographic information from focus group participants so that individuals will only take the survey once. Data collection and security procedures used for the interview survey are the same as those used for the "pre-test" survey.
- The interview survey will be linked by Study ID

One key informant interview per person enrolled

- People recruited for key informant interviews will include individuals who have attended any of the Data Academies or have registered in the PROVIDENT web tool. The interviews will be open to other staff from the harm reduction organizations, including individuals who have not participated in the surveys.
- These will be used to assess how the Web Tool functioned for organizations and how it can be improved to be more useful toward direct services organizations. Interviews will also be used to understand how the Web Tool was used or not used toward data-centered approaches to harm reduction, planning and capacity for delivering harm reduction services, and overall use of the Web Tool applications.

Interviews will be assigned a study ID at both the organizational and individual levels during transcription and analysis. All identifiers will be removed from transcripts prior to analysis. Each interview will last no more than 30 minutes.

ANALYSIS

Qualitative analyses of focus group and key informant interview themes. Also assess organizational capacity, flexibility, approach to supervision, etc.

Baseline & Follow-Up Analyses:
We will conduct a baseline series of focus groups to better understand overall themes at the start of the trial, including organizational capacity, overall organizational data maturity, and organizational approach to harm reduction. We will conduct 6 month follow up focus groups to examine those themes plus additional themes related to ongoing implementation and uptake of the intervention and the response to maps and technical assistance trainings. We will conduct key informant interviews at the end of the trial to better understand overall themes at the end of the trial, including organizational

capacity, overall organizational data maturity, and organizational approach to harm reduction. We will examine themes related to the uptake of the intervention within each organization.

Aim: To understand contextual factors related to overall uptake of the web tool intervention

Hypothesis: We hypothesize that the stronger the themes around capacity and data maturity of an organization, the greater the uptake of the intervention web tool.

Analytic method: Qualitative coding using Dedoose, Transcription using Daily Transcription

Pre/Post Analysis of Technical Assistance Supports
Use Pre/Post surveys to assess whether learning objectives of TA were achieved, whether individuals feel comfortable with the PROVIDENT model, and using data-driven products such as maps.

Web Tool utilization:
We will use Web Tool forms to assess back-end administrative data to understand at both the organizational and regional levels:
- Fidelity (minimum of 5 logins every 6 months, ideally ~75% for intervention towns)
- Reach (at least 60% of prioritized towns have a neighborhood assessment in any 6 month period)
- Dosage (Of those towns with a neighborhood assessment, at least 75% will show an increase in overall dosage of harm reduction services from baseline)

COVID-19 Supplement
In Specific Aim 1 of this administrative supplement, we will determine how policies enacted as part of the state of Rhode Island's COVID-19 pandemic response have influenced both access to overdose prevention and treatment resources, as well as rates of fatal and non-fatal overdoses in the community. Using an interrupted time series design, we will estimate the impact of Rhode Island's 'stay at home' order on naloxone distribution, initiation, and use of medications for opioid use disorder (OUD), emergency department (ED) visits, and emergency medical services (EMS) runs for non-fatal drug overdose, deaths due to drug overdose, and other harm reduction services.

In Specific Aim 2 of this administrative supplement, we will examine the relationship between acute changes in COVID-19 diagnoses, hospitalizations, and deaths at the community level on rates of non-fatal and fatal drug overdose. We will also determine whether these relationships are particularly strong in economically distressed and racial/ethnic minority communities. Using a combined fixed-effects and time-series design, we will estimate the relationship between COVID-19 disease burden and spikes of ED visits and EMS runs for non-fatal drug overdose and deaths due to drug overdose at the city/town level. Therefore, the study will be randomized at the level of the city/town, rather than at the level of the individual.

8. Describe the compensation. ☐ N/A

Phase 1: N/A
Phase 2 Cluster Randomized Trial: N/A
COVID-19 Supplement: N/A

Phase 2 Implementation Study:
COMPENSATION FOR GROUP 1 PARTICIPANTS

PRE/POST-SURVEY COMPENSATION
Participants will be compensated $25 per survey questionnaire completed (pre and post), for up to $50 each TA workshop series (potential of up to $200 over the course of the 2 year study if someone takes all available survey questionnaires). Participants will be compensated cash or via electronic gift card.

- Further criteria: Participants must attend at least one TA workshop to be eligible for a pre and post survey. Participants who attend the TA workshops can opt out of the surveys if they do not wish to participate.
- Research team staff will pay participants directly in cash or with electronic gift cards, whichever they prefer.
- Research team staff will discuss compensation options with participants at enrollment. The first option is that they may be compensated at 121 South Main Street or 66 Pavilion Avenue offices and participate on-site via zoom, the second option is for research team staff to visit the participants at/near their workplace directly, and the third option is for participants to be compensated via electronic gift card, whatever the participants prefer. If the participant chooses to be compensated with an electronic gift card, research team staff will collect the participant's name and phone number or email for disbursement. This contact information will be collected and stored in Brown Qualtrics and linked to the participant by a study identification number for disbursement and scheduling purposes only. The collection of the participant's name, phone number and/or email is described in the consent form.

FOCUS GROUP COMPENSATION
Compensation for the Focus Groups will be $50 per focus group, up to two times per year, for two years (potential of up to $200 over the course of the 2 year study if someone attends all focus groups). Participants will be compensated in cash or via digital gift card.

- Research team staff will pay participants directly in cash, with an electronic gift card. Participants may be compensated in cash at 121 South Main Street or 66 Pavilion Avenue offices, or research team staff may arrange to visit the participants at their workplace organizations directly, whatever the participants prefer. If the participant chooses to be compensated with an electronic gift card, research team staff will collect the participant's name and phone number or email for disbursement. This contact information will be collected and stored in Brown Qualtrics and linked to the participant by a study identification number for disbursement and scheduling purposes only. Compensation procedures will be covered during the Informed Consent process.

KEY INFORMANT INTERVIEW COMPENSATION
Compensation for the interviews will be $25 per interview

- Research team staff will pay participants directly in cash or with an electronic gift card. Participants may be compensated in cash at 121 South Main Street or 66 Pavilion Avenue offices, or research team staff may arrange to visit the participants at their workplace organizations directly, whatever the participants prefer. If the participant chooses to be compensated with an electronic gift card, research team staff will collect the participant's name and phone number or email for disbursement. This contact information will be collected and stored in Brown Qualtrics and linked to the participant by a study identification number for disbursement and scheduling purposes only. Compensation procedures will be covered during the Informed Consent process.

COMPENSATION FOR GROUP 2 PARTICIPANTS

PRE/POST-SURVEY COMPENSATION
Participants will be compensated $25 per survey questionnaire completed (pre and post), for up to $50 each TA workshop series (potential of up to $100 over the course of the study if someone takes all available survey questionnaires). Participants will be compensated in cash or via digital gift card.

- Further criteria: Participants must attend at least one TA workshop to be eligible for a pre and post survey. Participants who attend the TA workshops can opt out of the surveys if they do not wish to participate.
- Research team staff will pay participants with cash or electronic gift cards, whichever they prefer.
- Compensation procedures will be covered at enrollment. The first option is that they may be compensated at 121 South Main Street or 66 Pavilion Avenue offices and participate on-site via zoom, the second option is for research team staff to visit the participants at/near their workplace directly, and the third option is for participants to be compensated via electronic gift card, whatever the participants prefer. If the participant chooses to be compensated by electronic gift card, research team staff will collect the participant's name and phone number or email for disbursement. This contact information will be collected and stored in Brown Qualtrics and linked to the participant by a study identification number for disbursement and scheduling purposes only. The collection of the participant's name, phone number and/or email is described in the informed consent form.

FOCUS GROUP COMPENSATION
Compensation for the Focus Groups will be $50 per focus group, up to two times per year, for one year (potential of up to $100 over the course of the study if someone attends all focus groups). Participants will be compensated in cash or via digital gift card.

- Research team staff will pay participants directly in cash or with an electronic gift card. Participants may be compensated in cash at 121 South Main Street or 66 Pavilion Avenue offices, or research team staff may arrange to visit the participants at their workplace

organizations directly, whatever the participants prefer. If the participant chooses to be compensated by electronic gift card, research team staff will collect the participant's name and phone number or email for disbursement. This contact information will be collected and stored in Brown Qualtrics and linked to the participant by a study identification number for disbursement purposes only. Compensation procedures will be covered during the Informed Consent process. The collection of the participant's name, phone number and/or email is described in the informed consent form.

KEY INFORMANT INTERVIEW COMPENSATION
Compensation for the Focus Groups will be $25 per interview

- Research team staff will pay participants directly in cash or with an electronic gift card. Participants may be compensated in cash at 121 South Main Street or 66 Pavilion Avenue offices, or research team staff may arrange to visit the participants at their workplace organizations directly, whatever the participants prefer. If the participant chooses to be compensated by electronic gift card, research team staff will collect the participant's name and phone number or email for disbursement. This contact information will be collected and stored in Brown Qualtrics and linked to the participant by a study identification number for disbursement and scheduling purposes only. Compensation procedures will be covered during the Informed Consent process.

9. Is the study a clinical trial? ☒ Yes ☐ No

10. Describe the possible research risks to participants.

Phase 1 PROVIDENT Model Development
This project uses secondary data exclusively; therefore, confidentiality of human subjects data is of utmost importance. Our research requires the use of existing, identifiable records related to overdose, medical events, and prescribing data. Access to such records for legitimate research purposes has been approved by our data sharing partners through support letters and a forthcoming Data Use Agreement, and our team will work carefully to ensure the protection of these data, as we have in the past.

We recognize that a loss of confidentiality may also result in psychological harm to individuals or in social harm. As such, we will be using Brown's state of the art secure computing environment for the transfer, analysis, and protection of all research data. Data sharing partners (e.g., RIDOH, BHDDH) will share only the required datasets and variables needed for analysis. Additionally, only select members of the analytic team will have access to any identifiable datasets. All data transfer procedures, analytic plans, and datasets will be approved by the Brown IRB, any additional institutional IRBs.

Research Database Infrastructure: This project will benefit from and expand upon data security

resources provided by the Brown University "Stronghold Research Environment for Data Compliance" secure computing system. Stronghold is a secure computing and storage environment that enables Brown researchers to analyze sensitive data, while complying with regulatory or contractual requirements. Stronghold is currently certified to meet the security requirements and controls for HIPAA (Health Insurance Portability and Accountability Act) and is undergoing the certification process for FISMA (Federal Information Security Management Act) and CJIS (Criminal Justice Information Security). We will use the Stronghold secure computing environment to store, maintain, and transfer dataset between Brown University and data stakeholders, including the Rhode Island Department of Health (RIDOH) and other state agencies (e.g., Office of the State Medical Examiners).

This service is customized to the needs of individual users and their data use agreements. Each investigator is given a dedicated environment for their project to support their co-investigators, graduate students, research assistants, interviewers, and other collaborators. Access to the Internet is restricted except for required locations for data imports or necessary software downloads. Import and export controls are in place to limit who can perform data migration, where sensitive data can come from and where desensitized or anonymized data can be moved to. Sensitive data is subject to file system auditing, and real-time alerting is available at the request of the PI.

Additional Security Policies for Project Investigators and Staff: Dr. Marshall has additional requirements regarding credentials, connections methods, or clients based on the nature of the data. Specifically, all systems (workstations, laptops, etc.) used to connect to Stronghold must have the following security precautions in place: A password-protected lock out screen that appears after inactivity of 5 minutes or less. Up-to-date antivirus and malware installed. An up-to-date operating system with all currently available updates installed. Physical security (either card access or keyed locks) in all working environments, such that unauthorized users are prevented from physically accessing the system while it is connected to Stronghold. All study reports, results, and published manuscripts will suppress all identifiable information, and include only aggregated results.

Phase 2 Cluster Randomized Trial and Implementation Study
Potential Risks for Participants: Loss of Confidentiality
Phase 1 of the study, and the analyses for the cluster randomized trial use secondary data that includes identifiers previously approved during Phase 1. Phase 2 uses primary data that includes several identifiers (i.e. name, email address) for enrollment purposes, but will ultimately rely on a Study ID and de-identification of records prior to analysis.

Nevertheless, confidentiality of study data will continue to be of the utmost importance. Access to records will be explicitly used for legitimate research purposes and access to these records will not only be monitored, but access will also be restricted through a user login. Furthermore, we have worked with Brown University Center for Computation and Visualization to design the Web Tool with careful attention to security, protecting an individual's identity, and minimizing risk of loss of confidentiality.

We will continue to receive updated secondary data every six months from our IRB approved data

sharing partners, as described in the original approved Brown University IRB protocol # 1910002566. The updated secondary data will be used to update the model throughout the course of the study through July, 2024 and conduct analyses for the cluster randomized trial. The secondary data used during phase I to develop the model will continue to be transferred to, stored and analyzed in Brown University's Stronghold secure research environment. All project analyses will be done within the Stronghold environment and no data will leave this environment unless it has been aggregated and de-identified. Data used by the PROVIDENT model will solely reside in Stronghold and only de-identified data will leave this environment (by design). The PROVIDENT model data used in the Web Tool will be de-identified data aggregated to the census block group prior to leaving Stronghold. In sum, use of secondary data for the PROVIDENT model for visualization in the Web Tool should not increase the risks or benefits.

For the survey data, all data will be securely captured in Qualtrics and transferred directly to a departmental server (at the School of Public Health) for analyses.

For the Focus Groups, audio records will be recorded on a Brown University device (laptop, desktop, or audio recorder), then uploaded to a password-protected folder on Brown School of Public Health departmental servers, only accessible to designated study staff. Audio files will be transcribed using the secure service Daily Transcription. Once transferred and backed up, audio files will be deleted from the Brown University device, in compliance with university protocol. De-identified transcripts will be analyzed using qualitative software Dedoose.

Potential Risks for Participants: Focus Groups
There is minimal risk to participating in focus groups. We are asking focus group participants about their work culture, how their organization approaches data collection and reporting, and how their workplace delivers overdose prevention services. Participants may experience some discomfort in discussing these topics. Although individuals will be asked about their work, all transcripts will be de-identified prior to analysis. Individuals will have the right to skip any question they do not want to answer or stop participation at any time.

Potential Risks for Participants: Key Informant Interviews
There is minimal risk to participating in key informant interviews. We are asking key informant interview participants about how they used the Web Tool, how we can improve it, and what benefits and/or challenges the webtool presented. Participants may experience some discomfort in discussing these topics. Although individuals will be asked about their work, all transcripts will be de-identified prior to analysis. Individuals will have the right to skip any question they do not want to answer or stop participation at any time.

Potential Risks for Participants: Survey Instruments
There is minimal risk to participating in this study. We are asking individuals working in community organizations about the nature of their work and the surveys are confidential. Although individuals will be asked about their work, we will ensure that questions are not specific as to give away a

person's identity. Data will be captured using Brown Qualtrics. Individuals will have the right to skip any question they do not want to answer or stop participation at any time.

COVID-19 Supplement:
There are no direct individual risks, as only secondary data are being analyzed. The risk is no greater than minimal risk and is limited to loss of privacy. Our measures to protect against those risks are outlined in the PROVIDENT DSMP. Our research environment in Stronghold is designed to provide the utmost security for these sensitive datasets. In brief, although most data required to achieve the aims of this project will be de-identified and aggregated to the municipal level prior to transfer into Stronghold, any sensitive data or datasets containing PHI (specifically, dates and addresses) will be transferred, stored, and analyzed within our team's Stronghold computing environment. PHI accessed in the research under this supplement are limited to dates and addresses only, consistent with Appendix G in the parent study.

Stronghold administrators (Brandon Marshall, Claire Pratty, and Maxwell Krieger) maintain protocols and security groups for regulating access to project data. All data is stored separately from other projects which utilize Stronghold and are assigned a separate security group. Stronghold is actively monitored and logged, including monthly reports detailing active users as well as alerts sent within 15-minute of incoming or outgoing data transfers. Only authorized administrators have access to exporting data outside of Stronghold. All external personnel, which includes those who transfer data into Stronghold, are onboarded by registering a sponsored ID through Brown University which must be reactivated each year.

Data and Safety Monitoring:
A single Data and Safety Monitoring Board (DSMB) is appointed to oversee this project. The DSMB will consist of members outside of the research group conducting this study, but may include individuals who are affiliated with one or more of the data sharing partners, but are not directly related to the project. The DSMB will include, at minimum, one individual with expertise in statistics or biostatistics. Any potential conflicts of interest must be disclosed during the application process. The Brown University IRB will ultimately approve the membership, meeting frequency, and Safety Monitoring Plan for the DSMB.

As outlined in the Data and Safety Monitoring Plan (DSMP), this independent Data and Safety Monitoring Board will assess the progress of a clinical study, the safety data, and critical efficacy endpoints (if appropriate) and provide recommendations to the sponsor. The members of the DSMB serve in an individual capacity and provide their expertise, including recommendations regarding the continuation, modification, or termination of any or all arms of the study. The DSMB will review cumulative study data to evaluate safety, study conduct, scientific validity, and data integrity of the study.

11. **Describe the anticipated benefits to participants.**

Phase 1 PROVIDENT Model
There are no direct individual benefits to the participants of this study, as only secondary data is being analyzed.

Phase 2 Cluster Randomized Trial
There are no direct individual benefits to the participants of this study, as only secondary data is being analyzed.

Phase 2 Implementation Study
There are minimal benefits to participating in the study. There is a chance individuals will learn more about data tools and mapping through their participation. There is a chance that information collected during the focus groups or key informant interviews will improve the PROVIDENT Web Tool, and be used to improve Technical Assistance trainings.

COVID-19 Supplement
There are no direct individual benefits to the participants of this study, as only secondary data is being analyzed.

12. Does the study involve the use of secondary data (identifiable information or identifiable biospecimens)? ☒ Yes (complete Questions 12.1-12.3) ☐ No (skip to Question 16)

12.1 Provide the source of the data.

Phase 1 PROVIDENT Model Development

Table S1 represents the intended data sources for the PROVIDENT forecasting tool. The datasets that contain protected health information or sensitive identifiable information are limited to data from the State Agencies RIDOH, BHDDH, RIDOC, and EOHHS. The other data sources listed provide aggregated or publicly available data by request.

Table 1: Summary of overdose surveillance and neighborhood-level data sources for PROVIDENT model

Domain	Description	Data Source (Agency)
Overdose Deaths	All unintentional drug-related deaths that occur in Rhode Island (model outcome)	SUDORS (RIDOH)
EMS runs for suspected opioid overdose	EMS runs for suspected opioid overdoses (based CDC case definition using ICD-10 codes) [46]	CEMS Database (RIDOH)
Prescribing	Opioid analgesic prescribing rate**	PDMP (RIDOH)
	Rate of patients receiving >90 MME**	PDMP (RIDOH)
	Rate of multiple provider episodes for opioids (≥5 physicians or ≥5 pharmacies over 6 months)	PDMP (RIDOH)
	Number of patients prescribed an opioid and a benzodiazepine within 30-day period	PDMP (RIDOH)
Treatment	Buprenorphine prescribing rate**	PDMP (RIDOH)
	Buprenorphine initiating rate**	PDMP (RIDOH)
	Buprenorphine retention rate**	PDMP (RIDOH)
Rescue	Rate of naloxone distribution by pharmacies**	PDMP (RIDOH)
Social Capital & Family Fragmentation	Social capital (density of civic and charitable organizations, religious organizations, foundations, census response rate)	DBR

	Rate of incarceration and release from settings of incarceration	RIDOC
	Family fragmentation (household composition, proportion of children living in single parent households)	ACS
Neighborhood Advantage/ Disadvantage	Unemployment rate, household income, percent below the poverty line, Gini coefficient, proportion with public assistance	ACS
Health & Social Resources	Rate of licensed addiction treatment programs**	BHDDH
	Health insurance coverage	ACS
Physical Environment	Average age of structures, heating fuel type, monthly owner costs as a percentage of household income, gross rent	ACS
	Occupancy status of residential properties	ACS

* Data collected at the address level but will be aggregated to the census block group (CBG) for analysis; ** All rates expressed as number per 1,000 residents;
American Community Survey (ACS); BHDDH = Department of Behavioral Health, Developmental Disabilities, and Hospitals; BHOLD = Behavioral Health Online Database; Census Block Group = Census Block Group; CEMS = Centers for Emergency Medical Services; CHDAPHI = Center for Health Analysis and Public Health Informatics; DATA = Drug Addiction Treatment Act; MME = morphine milligram equivalents; PONI = Preventing Overdose and Naloxone Intervention; OSME = Office of the State Medical Examiner; RIDOH = Rhode Island Department of Health; RIDOC = Rhode Island Department of Corrections; DBR = Department of Business Regulation

Phase 2 Cluster Randomized Trial

We will evaluate, at the city/town level, whether prioritized intervention deployment to neighborhoods at high risk of future overdose reduces population-level overdose morbidity and mortality. The primary outcome of the trial will be fatal and non-fatal overdose rates, measured at the city/town level. Fatal overdoses will be defined as accidental drug-related deaths deemed by a medical examiner to be attributed to a prescription or illicit drug. Non-fatal overdoses will be defined as ED visits for a suspected overdose reported through the state's 48-Hour Overdose Reporting System. These data are captured in the Rhode Island Office of the State Medical Examiner's drug overdose death records database, and the state's 48-Hour Overdose Reporting System, which requires that all emergency departments report suspected overdoses to the RIDOH within 48 hours.

Phase 2 Implementation Study: N/A

COVID-19 Supplement

We are including a summary of data sources for the supplement in Table 2.

List of data sources and responsible agency (Table S2)

Table 2: Summary of overdose surveillance and neighborhood-level data sources for PROVIDENT COVID-19 administrative supplement

Domain	Outcome	Data Source	Data Source Agency	Smallest Geographic Unit	Access**
Naloxone Distribution	Number of naloxone kits distributed by pharmacies	PDMP	RIDOH	Census Block Group (CBG)*	PROVIDENT
	Number of naloxone kits distributed by community organizations	WuFoo	RIDOH	Zip Code	PROVIDENT

Medications for Treatment of Opioid Use Disorder	Number of individuals actively receiving buprenorphine	PDMP	RIDOH	CBG*	PROVIDENT
	Number of individuals actively receiving methadone	RI-BHOLD	BHDDH	Zip Code	PROVIDENT
Emergency Department Visits	Number of emergency department visits for suspected drug overdose	48-Hour Reporting System	RIDOH	CBG*	Other
Emergency Medical Services	Number of emergency medical services runs for suspected drug overdose Time from dispatch to arrival on scene for suspected drug overdose	NEMSIS/EMS	RIDOH	CBG*	PROVIDENT
Drug Overdose Deaths	All unintentional or undetermined drug overdose deaths	SUDORS	RIDOH	CBG*	PROVIDENT
	All accidental drug-related deaths that occur in Rhode Island	OSME	RIDOH	CBG*	PROVIDENT
STI/HCV/HIV	Number of STI cases	Rapid HCV and/or Syphilis Test Reporting Form	RIDOH	Zip Code	Other
	Number of HCV cases	Rapid HCV and/or Syphilis Test Reporting Form	RIDOH	Zip Code	Other
	Number of HIV cases (with viral load counts included)	eHARS Rapid HIV Test Reporting Form	RIDOH	CBG*	Other
COVID-19	Number of COVID-19 hospitalizations	State COVID-19 Case Databases	RIDOH	CBG*	Other
	Number of COVID-19 cases/ diagnoses	State COVID-19 Case Databases	RIDOH	CBG*	Other
	Number of COVID-19 deaths	State COVID-19 Case Databases	RIDOH	CBG*	Other

BHDDH = Department of Behavioral Health, Developmental Disabilities, and Hospitals; RI-BHOLD = Rhode Island Behavioral Health Online Database; Census Block Group = Census Block Group; EOHHS = Rhode Island Executive Office of Health and Human Services; OSME = Office of the State Medical Examiner; RIDOH = Rhode Island Department of Health; APCD = All Payers Claims Database; WuFoo = Non-pharmacy naloxone distribution data; RIDMAT/MRC = Rhode Island Disaster Medical Assistance Team's Medical Reserve Corps; NEMSIS = National Emergency Medical Services Information System; SUDORS = State Unintentional Death Reporting System; STI = sexually transmitted infection; HCV = Hepatitis C virus; RHCSTRF = Rapid Hepatitis C and/or Syphilis Test Reporting Form; eHARS = Enhanced human immunodeficiency virus, acquired immunodeficiency syndrome (HIV/AIDS) Reporting System; RHTRF = Rapid HIV Test Reporting Form; COVID-19 = coronavirus disease 2019

* Data collected at the address level but will be aggregated to the census block group (CBG) for analysis
**Access: PROVIDENT = access to data source available through parent study; Other = access to data source is a secondary data source that is already being or has already been collected administratively for other purposes.

12.2 Describe the type(s) of data / biospecimens and date range(s) of the data you will use and the characteristics of the study research population (e.g., age range, sex, and any other pertinent demographic information.

Phase 1 PROVIDENT Model

Please see table S1 (above) for a description of the types of datasets. The date range will be for 2016-2019. We will ask for demographic identifiers if they are available for the datasets, as well as geographic identifiers (as listed in S2).

Phase 2 Cluster Randomized Trial

Change in accidental fatal and non-fatal drug overdoses [Time Frame: Baseline up to 2.5 years following intervention, with assessment of primary outcome at 2.5 years]
The primary outcome is the municipal-level rate of fatal and non-fatal drug overdoses. Fatal overdoses will be defined as drug-related deaths deemed accidental by a state medical examiner. The location of these overdose events will be aggregated to the city/town level. Non-fatal overdoses will be defined as an Emergency Department (ED) visit for a suspected overdose reported through the state's 48-Hour Overdose Reporting System. Since patient outcomes are recorded, patients who did not survive or who were dead upon arrival will be excluded to avoid double-counting. There are no exclusion criteria.

COVID-19 Supplement

Please see table S2 (above) for a description of the types of datasets. The date range for the supplemental research is 2016-2021. We will ask for demographic identifiers if they are available for the datasets, as well as geographic identifiers (as listed in S2).

12.3 Describe how will you use, study, or analyze the data / biospecimens.
Analyses are included in Question 7 Study Procedures.

13. **Does the study involve the use of PHI from a HIPAA-covered entity?**
☒ Yes (complete Question 13.1-13.2) ☐ No (proceed to Question 14)

If "yes," please upload Appendix G: Use of Protected Health Information (PHI) in Research. If applicable, upload a HIPAA Authorization form.

13.1 Describe how authorization to access the data will be obtained.
With support from the Office of Research Integrity, Data Use Agreements have been negotiated with each State Agency.

13.2 Is the data considered a limited data set? ☐ Yes ☒ No

14. Does the study involve the use of Family Educational Rights and Privacy Act (FERPA) or Protection of Pupil Rights Amendment (PPRA) data?
☐ Yes (complete 14.1-14.2) ☒ No (proceed to Question 15)

14.1 What type of FERPA or PPRA data will be accessed for this research?
☐ Directory information
☐ Education records
☐ Instructional material
☐ Personally identifiable information (PII)
☐ Data involving a PPRA-protected category
☐ Other, please describe: Click or tap here to enter text.

14.2 Describe how authorization to access the data will be obtained.

Click or tap here to enter text.

15. Is a Data Use Agreement (DUA), Material Transfer Agreement (MTA), or other agreement required by the source to obtain, use, study, or analyze the data / biospecimens?

☒ Yes ☐ No

If "yes," please upload a copy of the Agreement(s) (draft or executed).

16. What type of data will be collected?

☐ Identifiable biospecimens

☒ Personally identifiable Information (PII)

☐ Coded data and the study team has access to the linking file / key

☐ Coded data and the study team does not have access to the linking file / key

☒ Anonymous data

☒ Publicly available data

☐ Other, please describe: Click or tap here to enter text.

17. Briefly describe your plan for managing the integrity of the data and monitoring the safety of participants. ☐ N/A

Phase 1 PROVIDET model development, Phase 2 Cluster Randomized Trial, and the COVID-19 Supplement are each a retrospective review of multiple secondary data sources and are already being collected administratively for other purposes. The risk to participants is no greater than minimal risk, and is limited to loss of privacy. Our measures to protect against those risks are outlined in the PROVIDENT DSMP. Our research environment in Stronghold is designed to provide the utmost security for these sensitive datasets, and all datasets will be transferred under Data Use Agreements with the participating state agencies.

A single Data and Safety Monitoring Board (DSMB) is appointed to oversee this project. The DSMB will consist of members outside of the research group conducting this study, but may include individuals who are affiliated with one or more of the data sharing partners, but are not directly related to the project. The DSMB will include, at minimum, one individual with expertise in statistics or biostatistics. Any potential conflicts of interest must be disclosed during the application process. The Brown University IRB will ultimately approve the membership, meeting frequency, and Safety Monitoring Plan for the DSMB.

As outlined in the Data and Safety Monitoring Plan (DSMP), this independent Data and Safety Monitoring Board will assess the progress of a clinical study, the safety data, and critical efficacy endpoints (if appropriate) and provide recommendations to the sponsor. The members of the DSMB serve in an individual capacity and provide their expertise, including recommendations regarding the continuation, modification, or termination of any or all arms of the study. The DSMB will review cumulative study data to evaluate safety, study conduct, scientific validity, and data integrity of the study. Additional details about data and safety monitoring can be found in the PROVIDENT DSMP, including who will be performing the monitoring, what data will be collected, study stopping rules, and notification procedures.

18. How will you protect the privacy of participants?

Phase 1 PROVIDENT Model Development, Phase 2 Cluster Randomized Trial, COVID Supplement

The model, trial, and supplement use secondary data exclusively; therefore, privacy of study data is of utmost importance. Our research requires the use of existing surveillance records related to overdose, medical events, and prescribing events. Access to such records for legitimate research purposes has been approved by our data sharing partners (including the Rhode Island Department of Health and the Rhode Island Department of Corrections), and our team has worked carefully to ensure the protection of these data.

We recognize that a loss of privacy may also result in psychological harm to individuals or in social harm. As such, the Project Investigator will be using Brown's state of the art Stronghold computing environment for the transfer, analysis, and protection of all research data. Data sharing partners will share only the required datasets and variables. Additionally, only select members of the analytic team will have access to any identifiable datasets. All data transfer procedures, analytic plans, and datasets will be approved by the Brown IRB, any additional institutional IRBs, and the DSMB.

Research Database Infrastructure: This project will benefit from and expand upon data security resources provided by the Brown University "Stronghold" computing system. Stronghold is a secure computing and storage environment that enables Brown researchers to analyze sensitive data, while complying with regulatory or contractual requirements. Stronghold is currently self-certified to meet the security requirements and controls for HIPAA (Health Insurance Portability and Accountability Act) and is undergoing the certification process for FISMA (Federal Information Security Management Act) and CJIS (Criminal Justice Information Security). We will use the Stronghold secure computing environment to store, maintain, and transfer data between Brown University and data stakeholders, including RIDOH and other state agencies (e.g., Office of the State Medical Examiners, the Rhode Island Department of Corrections).

Stronghold is a secure virtual computing environment designed for remotely analyzing sensitive data. It uses encrypted SSH (Secure Shell) with two-factor authentication for remote access. Access to each virtual network is limited to a single PI and any additional students or staff who the PI authorizes in writing to Brown University Computing & Information Services (CIS). The PI enters into a written agreement with CIS that authorized users must comply with all necessary training requirements. CIS staff who have access to Stronghold have completed CITI course modules for working with human subject data as required by Brown's Office of Research Protection.

Stronghold is accessible only from within the Brown campus network and by Virtual Private Network connections (using two-factor authentication) from outside the campus network. All network connections to Stronghold pass through at least two firewalls: a dedicated firewall on the Brown campus network and a host-based firewall in the Stronghold environment.

The Stronghold system is physically located in a locked rack in a CCTV monitored data center on the Brown campus. Only certain authorized CIS staff have access to this locked rack. Entry to the data center is limited to authorized Brown IT personnel and their guests, and all entries are logged.

Phase 2 Implementation Study

Participants will be identified by a Participant Study ID in Focus Groups, Key Informant Interviews, and Surveys.

- Focus groups and key informant interviews will be recorded (zoom), recordings will be stored (departmental server), and transcribed (Daily Transcription). Prior to uploading the transcribed focus group text into the qualitative analysis software (Dedoose), the research team will remove any potential identifiers from the transcripts.

- Daily Transcription will have access to audio interview files. No data is stored at Daily Transcription. Audio files will be uploaded onto their secure website. Their transcriptionist will then download the audio files for transcription. Audio files will be kept on Daily Transcription's secure server for 90 days in case revisions are needed. Then all files will be destroyed.

- Surveys will capture only Participant Study ID and will be in Qualtrics. All extracted data and analyses will be stored on the Departmental Server. Some broad demographic information is collected in the pre-survey (year of birth, race, gender, sex) but are only connected to a Participant Study ID.

- Identifiable user or group information collected through the Web Tool will not be presented or made public. Data elements that may enable data linkages to other datasets will not be shared. Web Tool metadata and use statistics will be generalized and aggregated.

19. Does the study have or will you apply for a Certificate of Confidentiality (CoC)?

☒ **Yes** ☐ **No**

20. How will you maintain the confidentiality of participant data?

The model, trial, and supplement use secondary data exclusively; therefore, confidentiality of study data is of utmost importance. Our research requires the use of existing surveillance records related to overdose, medical events, and prescribing events. Access to such records for legitimate research purposes has been approved by our data sharing partners (including the Rhode Island Department of Health and the Rhode Island Department of Corrections), and our team has worked carefully to ensure the protection of these data.

We recognize that a loss of confidentiality may result in psychological harm to individuals or in social harm. As such, the Project Investigator will be using Brown's state of the art Stronghold computing environment for the transfer, analysis, and protection of all research data. Data sharing partners will share only the required datasets and variables. Additionally, only select members of the analytic team will have access to any identifiable datasets. All data transfer procedures, analytic plans, and datasets will be approved by the Brown IRB, any additional institutional IRBs, and the DSMB.

Research Database Infrastructure: This project will benefit from and expand upon data security resources provided by the Brown University "Stronghold" computing system. Stronghold is a secure computing and storage environment that enables Brown researchers to analyze sensitive data, while complying with regulatory or contractual requirements. Stronghold is currently self-certified to meet the security requirements and controls for HIPAA (Health Insurance Portability and Accountability Act) and is undergoing the certification process for FISMA (Federal Information Security Management Act) and CJIS (Criminal Justice Information Security). We will use the Stronghold secure computing environment to store, maintain, and transfer data between Brown University and data stakeholders, including RIDOH and

other state agencies (e.g., Office of the State Medical Examiners, the Rhode Island Department of Corrections).

Stronghold is a secure virtual computing environment designed for remotely analyzing sensitive data. It uses encrypted SSH (Secure Shell) with two-factor authentication for remote access. Access to each virtual network is limited to a single PI and any additional students or staff who the PI authorizes in writing to Brown University Computing & Information Services (CIS). The PI enters into a written agreement with CIS that authorized users must comply with all necessary training requirements. CIS staff who have access to Stronghold have completed CITI course modules for working with human subject data as required by Brown's Office of Research Protection.

Stronghold is accessible only from within the Brown campus network and by Virtual Private Network connections (using two-factor authentication) from outside the campus network. All network connections to Stronghold pass through at least two firewalls: a dedicated firewall on the Brown campus network and a host-based firewall in the Stronghold environment.

The Stronghold system is physically located in a locked rack in a CCTV monitored data center on the Brown campus. Only certain authorized CIS staff have access to this locked rack. Entry to the data center is limited to authorized Brown IT personnel and their guests, and all entries are logged.

The intervention will use a web tool and interactive dashboard to visualize the neighborhood-level risk predictions from the PROVIDENT model. The PROVIDENT Web Tool has undergone a security review with Brown Computing and Information Services (CIS) and the Center for Computation and Visualization (CCV). Use of the Web Tool has been approved and our team has worked carefully to ensure the protection of the model predictions.

We recognize that a loss of confidentiality through unauthorized access to the PROVIDENT Web Tool and model predictions may also result in psychological harm to individuals or in social harm. As such, personnel from the Center for Computation and Visualization will be responsible for administration of the system. Research staff will have logins to manage data and download data. Individuals accessing the web application will have access to only the required information and will share only what is required. Additionally, only select members of the analytic team will have access to any identifiable datasets. All data transfer procedures, analytic plans, and datasets will be approved by the Brown IRB, any additional institutional IRBs, and the DSMB.

PROVIDENT Web Tool Infrastructure: The web application is hosted in Firebase with application data stored in Firestore. The application is intended to be used exclusively by personnel of organizations (e.g non-profits helping opioid overdose prevention). Once an individual has been approved, they may create a username and password. Authentication is managed using Firebase native authentication.

Logged-in individuals interact with a series of surveys, approved by Brown IRB, that collect information about services and programs for opioid overdose prevention available in corresponding neighborhoods. Approved organizations will also have access to the PROVIDENT model predictions through use of the web application. Approved Brown researchers will use the data collected to examine what and how many directed overdose prevention activities are driven in part by the PROVIDENT model to measure fidelity and penetration. Finally, using the surveys, we will regularly query organizations approved to use the Web Tool about unauthorized use in community settings (e.g., inadvertent sharing of PROVIDENT screenshots during a community meeting).

Data will be downloaded from Firebase to Brown University data servers through provided, secure APIs (including web). Firebase and Firestore encrypt data during transfer and at rest. Firebase is certified under major security and privacy standards. Privacy and security information in Firebase can be found here. Data protection is managed through security rules, which in this particular case are set to only allow write access to users that have passed the simple authentication mechanism.

Personnel from the Center for Computation and Visualization will be responsible for administration of the system. Researchers from the People, Place, and Health Collective will have logins to manage data and download data.

21. Who will have access to your study data / biospecimens?

☒ Brown PI and other Brown research team members (including advisor).

Describe how unauthorized access by others will be prevented.

Stronghold is a secure virtual compute environment designed for remotely analyzing sensitive data. It uses encrypted SSH (Secure Shell) with two-factor authentication for remote access. Access to each virtual network is limited to a single PI and any additional students or staff who the PI authorizes in writing to CIS. The PI enters into a written agreement with CIS that authorized users must comply with all necessary training requirements. CIS staff who have access to Stronghold have completed CITI course modules for working with human subject data as required by Brown's Office of Research Protection.

Stronghold is accessible only from within the Brown campus network and by Virtual Private Network connections (using two-factor authentication) from outside the campus network. All network connections to Stronghold pass through at least two firewalls: a dedicated firewall on the Brown campus network and a host-based firewall in the Stronghold environment. The Stronghold system is physically located in a locked rack in a CCTV monitored data center on the Brown campus. Only certain authorized CIS staff have access to this locked rack. Entry to the data center is limited to authorized Brown IT personnel and their guests, and all entries are logged.

The Stronghold system is physically located in a locked rack in a CCTV monitored data center on the Brown campus. Only certain authorized CIS staff have access to this locked rack. Entry to the data center is limited to authorized Brown IT personnel and their guests, and all entries are logged.

All data transfers to and from Stronghold take place through a staging area accessed with the SCP (Secure Copy) protocol using two-factor authentication. Once uploaded, data is only accessible from virtual machines within the Stronghold system. Data must be explicitly moved into the staging area by the PI (or anyone the PI authorizes in writing) before it can be downloaded. All transfers are logged and audited, and real-time alerting can be enabled at the PI's request. All analyses and data will take place and remain on Stronghold. Research collaborators external to Brown must be credentialed through Brown University with explicit written authorization from the PI.

Only authorized research team members will have access to the Google Firestore, Qualtrics,

Zoom, Daily Transcription, and Dedoose accounts. In addition to the AES 256 bit encryption of data within Google Firestore, only designated research staff and CIS staff will have access to the account. The focus group and key informant interview audio files will be uploaded by Brown staff to a password-protected folder on Brown School of Public Health departmental servers, only accessible to designated study staff, before uploading the files to Daily Transcription. All original transcripts will be stored on the Departmental Server, and de-identified transcripts from Daily Transcription will be managed/analyzed in Dedoose.

☐ Data will be shared with research collaborators external to Brown.
Describe how you will securely share / transfer the data outside of Brown.
Click or tap here to enter text.

☐ Data will be shared with a data repository.
Describe how you will securely share / transfer the data outside of Brown.
Click or tap here to enter text.

PRINCIPAL INVESTIGATOR AGREEMENTS & RESPONSIBILITIES

A. Conduct of the Research

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the Belmont Report, Federal Regulations for the Protection of Human Subjects (45 CFR 46) , and Brown University policies.
2. I certify that I will assume responsibility for the proper conduct of this research and compliance with all Brown policies and procedures, and federal and state requirements.
3. I accept responsibility for ensuring that all members of the research team have or will complete human subjects CITI training before any work with participants or identifiable information / biospecimens begins.

B. Ensuring and Maintaining Compliance

1. I will comply with relevant regulatory and institutional reporting requirements, including Brown University's *Reportable Events Policy*.
2. I will notify the Brown HRPP when I have completed all activities involving human subjects or identifiable participant information or identifiable biospecimens.
3. I will maintain approval, as applicable, with collaborative parties, including approvals from other countries or jurisdictions.
4. I will cooperate with any post-approval monitoring or auditing of study activities and/or study records as requested and/or required by the Brown ORI, the Brown IRB, funding entities, sponsors, and/or any federal or state regulatory agencies.

C. Study records, Reports and Documentation

1. I will comply by Brown's *Research Data and Research Materials Management, Sharing and Retention Policy*.
2. I will maintain all research protocol materials and consent materials for the duration of this study.

3. I will maintain research records for at least three years following the end of this research, or for a longer length of time if specified in applicable regulations or sponsor requirements. I will take measures to prevent accidental or premature destruction of these records.

By submitting this document, I certify that I have read and agree to uphold all of the Agreements and Responsibilities in this application.