CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

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4. https://shotofprevention.com/2017/04/27/materials-for-daycare-facilities-that-help-inspiring-vaccination/
5. https://www.cdc.gov/ncird/careers/immunization-services-division.html; https://www.cdc.gov/ncird/index.html
6. https://health.gov/healthypeople/objectives-and-data/browse-objectives/vaccination

SIP25-006 Overdose Prevention and Treatment Research Network (OPTRN)

Project Description

In 2023, more than 100,000 overdose deaths were reported in the United States; most (>80,000) involved opioids (1). It is unknown which of the recommended prevention strategies to prevent overdoses and overdose deaths should be scaled nationally. As one important example, medications for opioid use disorder (OUD) substantially reduce overdose-related and overall mortality (2) and are strongly recommended by CDC and others (3) but are markedly underused. In 2022, an estimated 9.4 million Americans needed OUD treatment, but only one quarter (25.1%) received medications for OUD (4). From mid-2023 to mid-2024, 224,068 nonfatal overdoses presenting in Emergency Departments (EDs) were recorded in CDC's Drug Overdose Surveillance and Epidemiology (DOSE) system (CDC data). Previous opioid overdose is associated with substantially increased risk for future nonfatal or fatal opioid overdose (5). ED visits and hospitalizations for OUD-related problems, including overdose, represent opportunities for initiation of medications for OUD. Initiation of medications for OUD within 7 days of ED visit or hospitalization has been associated with reduced risk for fatal or nonfatal overdose at 6 months (6). However, at a national level, few patients seen at EDs for OUD or overdose receive medications for OUD (7,8). Clinician-reported barriers to initiating medications for OUD include too little experience treating OUD (9) and uncertainty about where the patient can receive follow-up care to continue receiving medications for OUD. Between 2019 and 2023,

the California (CA) Bridge Program used a combination of support for hospitals for a local clinical champion and a patient navigator along with training and technical assistance to increase initiation of medication (buprenorphine) for OUD in the ED (10). From the first month of implementation to the final month of data reporting, hospitals funded by CA Bridge reported increases in encounters where buprenorphine was administered or prescribed ($P < .001$) from a median of 1 (IQR 0–5; range 0–80) to 5 (IQR 1–15; range 0–167). However, there was wide variation between higher- and lower-performing sites in the CA Bridge initiative (10).

It is unknown whether increases in buprenorphine administration would be sustained without continued external support for patient navigators, whether other innovative approaches (e.g., refinement of existing protocols/resources (11) and implementation of locally-adapted protocols for post-overdose and OUD care, including identification of treatment resources available in the community for continued OUD treatment and establishment of a network of referral options; training and technical assistance for primary care clinicians in the community to continue treatment for patients initiated on buprenorphine in the ED); or other initiatives such as quality performance incentives could improve buprenorphine initiation rates.

CDC's Division of Overdose Prevention seeks to establish the Overdose Prevention and Treatment Research Network (OPTRN) with this special interest project (SIP). The OPTRN will consist of multiple collaborating center recipients and one coordinating center recipient. All recipients of this SIP will identify, implement, and evaluate innovative, feasible, and sustainable strategies to increase effective care for people who use drugs and prevent overdoses, such as ED initiation of buprenorphine for OUD and retention in treatment with medications for OUD after ED encounters. Multiple collaborating centers may work together to facilitate testing of different strategic components as well as sharing of expertise across centers, given existing variation in extent of experience with interventions to increase initiation of and retention in evidence-based care for OUD. The Coordinating Center recipient will facilitate and support collaborative research activities among all OPTRN recipients, their partners, and affiliates; and help support the translation and dissemination of findings. OPTRN Collaborating Centers will complete activities listed in Component A below. This SIP is expected to have the greatest impact for patients presenting to EDs where initiation of buprenorphine for OUD is not yet routine; however, the presence of at least one local clinician initiating buprenorphine for OUD in the ED who can serve as a local champion is likely to increase the success of the SIP. Therefore, applications from potential Collaborating Centers with participating EDs where, at baseline, buprenorphine for OUD is initiated for some (>0%) but not most (<40%) patients presenting with overdose or signs of OUD will be prioritized. The OPTRN Coordinating Center will complete activities included for both Component A and B listed below.

Project Objectives and Outcomes

Component A: Research Project (Required)
Objectives:

1. Identify and evaluate effectiveness and sustainability of at least two promising strategies (strategies with a strong rationale or inclusion of characteristics of effective strategies or best practices and limited evidence of and/or sustainability) to increase initiation of

evidence-based care (i.e., medications for OUD) for patients with OUD in the ED and linkage to ongoing evidence-based treatment. Strategies can be implemented and tested in combination in one or more clinical sites, or for Collaborating Centers with more than one participating clinical sites, different strategies can be implemented in different clinical sites. Sustainability might be assessed by evaluating outcomes such as buprenorphine initiation for OUD several months to a year after completing initiation of a new strategy as well as before and immediately after initiation of a new strategy. Estimation of ongoing costs for maintaining a strategy might also contribute to evaluation of sustainability. Promising strategies might include the following:

a. Development and implementation of practice-specific protocols for post-overdose and OUD care that describe elements such as how patients will receive buprenorphine until outpatient treatment is established (e.g., hospital dispensing of a limited supply of buprenorphine), identification of treatment resources available in the community (e.g., local or virtual primary care, addiction medicine, addiction psychiatry, or Opioid Treatment Programs) for continued OUD treatment, and establishment of a network of referral options spanning the levels of care that patients might need to enable rapid collaboration and referral
b. Building capacity of ED clinicians to identify and effectively treat patients with OUD presenting to the ED. Strategies can be tailored to the needs of local clinicians (e.g., mentoring or consultation available in real time while clinicians are managing patients in the ED, and/or webinars available asynchronously on demand) to develop practice-based evidence on effectiveness.
c. Training and technical assistance for primary care clinicians in the community to continue treatment for patients initiated on buprenorphine in the ED.
d. Support for patient navigator(s)
e. Quality performance initiatives (12) (e.g., developing measures and providing feedback to clinicians on numbers or percentages of patients with opioid-related problems who are screened for OUD, initiated on medication for OUD, and linked to outpatient treatment for OUD)
f. For one of their strategies, sites can propose to implement and test another innovative approach with a strong rationale for but unknown effectiveness, or a strategy with evidence of effectiveness but unknown sustainability.

Outcomes:

1. Identify a set of effective and sustainable strategies for increasing buprenorphine treatment for ED patients.
2. Improve knowledge for a set of strategies to build capacity of ED clinicians to identify and effectively treat patients with OUD presenting to the ED.

Component B: Coordinating Center - Optional

Objectives:

1. Facilitate and support collaborative research activities among network members, their partners, and affiliates.

2. Lead and facilitate network discussions related to strategic planning, and the development of research expertise in the application of proven overdose prevention and OUD treatment initiation and linkage strategies in community and clinical settings.
3. Facilitate collaborative research across collaborating centers, network planning and discussions regarding the development and completion of research activities related to implementation of evidence-based overdose prevention and OUD treatment initiation and linkage strategies.
4. Facilitate connections among collaborating centers and non-members such as national, state, and local partners to advance efforts aligned with OPTN's mission.
5. Coordinate the evaluation of network activities and impact.
6. Lead and facilitate network discussions related on identification and evaluation of effectiveness and sustainability of promising strategies to increase initiation of evidence-based care (i.e., medications for OUD) for patients with OUD in the ED and linkage to ongoing evidence-based treatment.
7. Lead and facilitate network discussions related to important measures to consider when implementing initiation of evidence based treatment in ED (e.g., number and percent of individuals entering the ED with a nonfatal opioid-related drug overdose or with other opioid-related problems who are identified as having OUD; who receive buprenorphine in the ED; leave with a prescription for buprenorphine, are referred to ongoing treatment outside of the ED; who receive at least one dose of buprenorphine outside of the E
8. Support translation of findings across the network.
9. Coordinate broad dissemination of findings Nationally (e.g., webinars, technical resources, peer-reviewed publications).

Outcomes:

1. Increase numbers of network-associated ED clinicians who initiate medications (e.g., buprenorphine) for patients with OUD in the ED

2. Increase across the network, for patients presenting to the ED with overdose and other opioid-related problems:

a. ED identification of patients with OUD
b. Initiation of evidence-based treatment (i.e., medications for OUD)
c. Linkage to continued evidence-based treatment (i.e., medications for OUD)

3. Broadly available (beyond the network) resources for EDs, health systems, and clinicians to consult to facilitate initiation of medications for OUD in the ED and linkage to ongoing treatment.

Healthy People 2030 Objectives
Reduce the proportion of people who had opioid use disorder in the past year — SU-18
Increase the rate of persons with an opioid use disorder receiving medications for addiction treatment (developmental objective)

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements for both components listed below:

Component A: Research Project (Required)
The Research Plan for the Collaborating Centers should contain the following sections: (a) Previous experience delivering and testing effectiveness of capacity building approaches to improve clinical practice or previous experience testing effectiveness and sustainability of ED interventions. (b) Research questions, (c) Data sources and data collection, (d) Data Management Plan, (e) Outcomes, and (f) Dissemination of results.

Applications should present a Research Plan that addresses the following content:

1. Demonstrate existing infrastructure and track record to successfully implement this project
2. Baseline frequency of buprenorphine initiation for patients with overdose or signs of OUD
3. Established data collection protocols/systems to enable the applicant to begin collecting data quickly
4. Strategies for sharing insights and promising practices across OPTRN

Component B: Coordinating Center - Optional
The Research Plan for the Coordinating Center should contain the following sections: (a) Previous experience coordinating improvement efforts across clinical practices or EDs (b) Research questions, (c) Approach to supporting the Network members, (d) Data sources and data collection, (e) Data Management Plan, (f) Outcomes, and (g) Dissemination of results.
Applications should present a Research Plan that addresses the following content:

1. Engage and manage a geographically diverse network through facilitated monthly meetings and other communication strategies
2. Facilitate experiential learning by coordinating and/or providing interactive peer-learning education for the network;
3. Provide subject matter expertise and leadership to the network in initiating buprenorphine in the ED and in linkage to ongoing treatment (see Project Objectives and Outcomes section). depth of expertise in building clinician capacity to initiate evidence-based OUD treatment for socioeconomically diverse populations.
4. Provide technical assistance to Component A sites in geographically diverse settings with variable local capacity for linkage to continuing OUD treatment.

Study design and methods
Applications should present a rigorous research study approach/design examining effectiveness and sustainability that is appropriate to capture necessary data components to answer the research questions.

Population of Focus

Component A: Research Project (Required)

Applicants should propose projects that focus on increasing evidence-based care for socioeconomically diverse patients with OUD presenting to EDs. Including disproportionately affected populations (e.g., American Indian/Alaska Native and Black persons, who have high rates of fatal overdose (13); younger and older adults, who are less likely to receive medications when treated for OUD (4), and individuals living in underserved areas, including rural and other counties without Opioid Treatment Programs (14) is desirable and may be factored into scoring). The SIP is expected to have the greatest impact for patients presenting to EDs where initiation of buprenorphine for OUD is not yet routine; however, the presence of at least one local clinician initiating buprenorphine for OUD in the ED who can serve as a local champion is likely to increase the success of the SIP. Therefore, applications for Component A from centers with participating EDs where, at baseline, buprenorphine for OUD is initiated for some (>0%) but not most (<40%) patients presenting with overdose or signs of OUD will be prioritized.

Component B: Coordinating Center - Optional

Applicants should describe how they will provide technical assistance to Component A sites in building clinician capacity to initiate evidence-based OUD treatment for socioeconomically diverse populations in geographically diverse settings with variable local capacity for linkage to continuing OUD treatment.

Collaboration/Partnerships

Component A: Research Project (Required)

Collaborating center recipients will collaborate with EDs as clinical sites for the project and with clinicians in the EDs to increase initiation of and linkage to ongoing treatment for OUD. To develop and evaluate strategies to increase local capacity to accept patients for continuing treatment for OUD, PRCs should engage local programs and outpatient clinicians (e.g., primary care clinicians, psychiatrists) through health systems or other organizations. PRCs may collaborate with partners to deliver technical assistance or training to clinicians or patient navigators. Component A sites will collaborate with the Coordinating Center in building clinician treatment capacity and expertise and in evaluating outcomes across the network.
If collaborating center recipients are located in cities, counties, or states funded by CDC's Division of Overdose Prevention Overdose Data to Action (OD2A) cooperative agreement (which seeks to reduce drug overdoses and the impact of related harms), collaborating center recipients are encouraged to explore partnerships. Among multiple other strategies, funded OD2A jurisdictions work to engage clinicians/health systems, enhance IT/PDMP and increase community-based linkage to care.

Component B: Coordinating Center - Optional (if funding more than 1 PRC)

The Coordinating Center will work with the collaborating center (Component A) recipients to build clinician treatment capacity and expertise and in evaluating outcomes across the OPTRN. Collaborations will include professional clinical organizations such as the American College of Emergency Physicians, the American Society of Addiction Medicine, and the American Hospital Association to facilitate dissemination of results and to promote successful strategies. The Coordinating Center is encouraged to collaborate with CDC's OD2A program and may collaborate with national partners who support at-risk populations. Funded OD2A jurisdictions

work to engage clinicians/health systems, enhance IT/PDMP and increase community-based linkage to care. Collaboration with the PRC's state and/or local jurisdiction(s)' health department is also encouraged.

Recruitment Plan
Applicants for Component A should include a description of the proposed approach for identifying, engaging, and working with one or more EDs with sufficient clinician staff and visit volume to allow for meaningful increases in ED clinician expertise and treatment capacity, and in treatment initiation for individual patients with OUD. Applicants for Component A should describe how clinical sites can contribute diversity (e.g., geographic, socioeconomic) to the overall study population across the network. Applicants for Component A should describe plans to recruit sites that serve the population of focus.

Annual Action Plan
Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted in the Other Plan(s) section of the application.

https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Component A: Research Project (Required)
The applicant should incorporate translation of findings and lessons learned into locally appropriate clinical protocols and disseminate protocols or lessons learned to clinicians and trainees, using methods such as trainings, talks/webinars, and practice tools (e.g., flow charts, EHR prompts). Dissemination of results to the PRC's state and/or local jurisdiction(s)' health department is encouraged. All dissemination and translation efforts are intended to help other EDs adopt and incorporate successful approaches to support ED initiation of buprenorphine for OUD and retention in treatment with medications for OUD after ED encounters.

Component B: Coordinating Center - Optional
The applicant should coordinate broad dissemination of findings beyond the OPTRN (e.g., webinars, technical resources, peer-reviewed publications) and to coordinate production of broadly available (beyond the network) resources (e.g., technical resources, peer-reviewed publications) for EDs, health systems, and clinicians to consult to facilitate initiation of

medications for OUD in the ED and linkage to ongoing treatment. The Coordinating Center is encouraged to collaborate and/or disseminate results to CDC's OD2A program. All dissemination efforts are intended to help other EDs adopt and incorporate successful approaches to support ED initiation of buprenorphine for OUD and retention in treatment with medications for OUD after ED encounters.

Public Health Impact
Medications for OUD substantially reduce overall and overdose-related mortality and are strongly recommended by CDC and others but are markedly underused. ED visits for nonfatal overdose (estimated at 224,068 for the year ending in June 2024 in CDC's DOSE system) represent opportunities for initiation of medications for OUD. Initiation of medications for OUD within 7 days of an ED visit or hospitalization has been associated with reduced risk for fatal or nonfatal overdose at 6 months, yet few patients seen at EDs with OUD or overdose receive medications for OUD. While there have been successful local and regional initiatives to increase ED initiation of and linkage to ongoing evidence-based treatment for OUD, there is a need to understand how to increase initiation and linkage to care more broadly in geographically diverse sites and to understand which components are necessary to be successful and sustainable. This project will inform CDC Division of Overdose Prevention programmatic efforts for jurisdictions funded for CDC's OD2A cooperative agreement, including linkage to care surveillance in OD2A-Local and health system initiatives in OD2A-State.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:

Component A: Research Project (Required)
Special Eligibility Requirement: Access to the proposed study population. Specifically, the PRC must demonstrate previous or current relationships/collaboration with at least one ED where patients present with nonfatal overdose and/or other opioid-related problems.

Responsiveness Criteria: The applicant must provide documentation (e.g., a letter of support or memorandum of agreement), demonstrating evidence of access to the study population and assuring access to the populations in which the study will be conducted in Appendix 1.
Special Eligibility Requirement: The PRC's team must include experts in ED initiation of medications for OUD.

Responsiveness Criteria: The PRC's team includes one or more researcher with expertise in initiation of medications for OUD. Evidence of expertise of team members should be shown in the Research & Related Senior/Key Person Section of the SF424 (R&R).

Component B: Coordinating Center - Optional
Special Eligibility Requirement: The Coordinating Center must include experts in building clinician capacity for initiation of medications for OUD in acute settings. The Coordinating Center must have experience in facilitating and supporting collaboration across a network of organizations.

Responsiveness Criteria: Team includes one or more researcher with expertise in building clinician capacity for initiation of medications for OUD in acute settings. Evidence of expertise of team members should be shown in the Research & Related Senior/Key Person Section of the SF424 (R&R).

Additional Review Criteria

In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

Component A: Research Project (Required)

- Does the applicant have a proposed plan that includes adequate sample size to achieve the study outcomes?
- Does the applicant demonstrate that collaborating EDs at baseline are initiating buprenorphine for OUD in a range including some (>0% but <40%) patients presenting with overdose or signs of OUD?
- Does the applicant's proposed research team demonstrate experience in and commitment to initiating buprenorphine in the ED?
- Does the applicant demonstrate successful experience evaluating the impact of public health interventions?
- Does the applicant demonstrate an understanding of all aspects of the evaluation (i.e., evaluating implementation, costs, effectiveness, scalability)?

Component B: Coordinating Center - Optional (if funding more than 1 PRC)

- Does the applicant demonstrate evidence of successful experience working with partners, including a group of academic institutions around a common agenda?
- Does the applicant demonstrate depth of expertise in building clinician capacity to initiate evidence-based OUD treatment for socioeconomically diverse populations?
- Does the applicant demonstrate that they are equipped to provide technical assistance to Component A sites in geographically diverse settings with variable local capacity for linkage to continuing OUD treatment?
- Does the applicant describe experience creating translation and dissemination products targeting public clinicians and/or health care system decision makers?
- Does the applicant describe how the results from the research findings will be translated, disseminated, and ultimately scaled to be used by clinicians and/or ED, hospital or health system leadership?
- Does the applicant demonstrate a successful collaboration and coordination track record (i.e., both capacity and experience) by executing a project of similar scope and complexity.

Funding Preferences

The following preferences specific to this SIP will be considered in the funding decision:

Component A: Research Project (Required)

1. Relevance of the proposed project to program priorities.
2. ED settings where OUD is initiated but for less than 40% of patients.
3. Geographic diversity and/or patient population diversity of study sites
4. Diversity across study sites in intervention components to be studied. In the event that all highest scored applicants study the same strategies, study sites with different objectives might be prioritized for funding to increase diversity of strategies tested.

Research Plan Length and Supporting Material (Components A and B)

All applicants of SIP 25-00X are REQUIRED to apply for Component A (Collaborating Center) and will serve as a member of the OPTRN.

Applicants that wish to serve as the OPTRN Coordinating Center in addition to a collaborating center MAY also apply for Component B.

Only 1 recipient will be funded for BOTH components A and B

- Applicants should indicate at the beginning of the Specific Aims, the respective Component(s) under which the application should be considered (A, or A and B).
- Components A (Collaborating center) and B (Coordinating Center) applicants must follow the Research Strategy page length provided below.

Research Strategy Length	
Components	**Maximum Number of Pages**
A	12
A & B	18

Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the SIP.

Availability of Funds

The estimated total funding (direct and indirect) for the 4-year period of performance is $6,000,000 to support up to 4 awards (as described below). Awards issued under this NOFO are contingent upon availability of funds and enough meritorious applications.

Component A: OPTRN Collaborating Centers

Period of performance: 4 years, 09/30/2025-09/29/2029

Estimated total funding (direct and indirect costs) per year: $1,050,000

Estimated funding (direct and indirect costs) per recipient per year: $350,000

Year 1 Ceiling: $350,000
Estimated number of awards: 3

Component A & B: OPTRN Network Collaborating and Coordinating Center
Period of performance: 4 years, 09/30/2025-09/29/2029
Estimated total funding (direct and indirect costs) per year: $450,000
Year 1 Ceiling: $450,000
Estimated number of awards: 1

Research Status
This project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal- wide assurance number for each performance site.

OMB/PRA
OMB/PRA is not expected to apply.

Award Administration
CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts when appropriate. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

1. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
2. https://www.bmj.com/content/357/bmj.j1550
3. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#recommendations
4. https://www.cdc.gov/mmwr/volumes/73/wr/mm7325a1.htm
5. https://www.acpjournals.org/doi/10.7326/M15-0038
6. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2821275
7. https://www.sciencedirect.com/science/article/pii/S0735675724002468?via%3Dihub
8. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2820177
9. https://www.sciencedirect.com/science/article/pii/S0376871621003069?via%3Dihub
10. https://ajph.aphapublications.org/doi/pdf/10.2105%2FAJPH.2024.307710
11. Illustrative examples of existing protocols/resources, note this is not a comprehensive list, the applicant may propose to refine something else: https://www.naccho.org/uploads/downloadable-resources/ED-based-substance-use-response-toolkit.pdf; https://nida.nih.gov/nidamed-medical-health-professionals/discipline-specific-resources/emergency-physicians-first-responders/initiating-buprenorphine-treatment-in-emergency-department/motivating-patients#case-1-opioid-overdose-ed-initiated-buprenorphine
12. https://www.sciencedirect.com/science/article/pii/S0196064418312083?via%3Dihub
13. https://www.cdc.gov/nchs/data/databriefs/db491-tables.pdf

14. https://www.everycrsreport.com/files/20190624_R45782_ed39091fadf888655ebd69729c3180c3f7e550f6.pdf