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SIP25-005 Understanding the potential of early childcare and education (ECE) centers in promoting childhood vaccines and RSV prevention products

Project Description

ECE centers (i.e., daycare facilities) for infants, toddlers, and preschool aged children can serve as trusted sources of information for parents and guardians of young children. Although ECE centers play a clear role in ensuring young children receive vaccines mandated by law, there is potential for them to play an additional role in promoting other ACIP-recommended vaccines for young children, such as influenza and COVID-19 vaccines, as well as nirsevimab for infants and maternal respiratory syncytial virus (RSV) vaccine for pregnant parents. While many young

children do receive recommended vaccines according to the ACIP immunization schedule, efforts are needed to ensure that children who have missed vaccination are caught up on all routinely recommended vaccines to prevent disease outbreaks (1) and to ensure that as many children as possible are up-to-date for kindergarten entry with all required vaccines (2) Staff at ECE centers can serve as “trusted messengers” to build vaccine confidence among families of preschool aged children. ECE centers communicate directly with parents through multiple means, such as by sending emails and text messages, through school newsletters and social media posts, by sending printed information home with children or at events that include parents. While studies have looked at risk perceptions and health-seeking behaviors among parents of children attending ECE centers (3), and while educational materials on the importance of pediatric vaccinations have been created for ECE centers (4), there is little information about whether and to what extent ECE-originating communications and other simple interventions offering education and encouraging vaccinations beyond those mandated by law, or directing families to vaccination services, can motivate parent behavior. **The purpose of this project is to assess the potential of ECE-originating vaccination-related education, communications, and/or other simple interventions to impact parent attitudes toward uptake of non-mandated childhood vaccines (e.g., COVID- 19, influenza), maternal RSV vaccine, and nirsevimab.** Additionally, the purpose of this project is to identify effective ECE-originating interventions that influence parental/caregiver attitudes toward childhood vaccination, by analyzing how (if at all) parental attitude and intention to vaccinate has changed pre- and post-ECE intervention.

Project Objectives and Outcomes

The primary objective will be to assess the potential of ECE-originating vaccination-related education, communications, and/or other outreach strategies to impact parental knowledge, attitudes, and beliefs towards receiving routinely recommended childhood vaccines, maternal RSV vaccine (if applicable), and nirsevimab (if applicable). The applicant will develop at least one novel ECE-originating vaccination-related education/communication intervention and test that intervention(s) among parents and caregivers of children attending the ECE center. A secondary objective will focus on acceptability of intervention(s) conducted at ECE centers among parents and caregivers. Another secondary objective will focus on assessing the acceptability of various ECE-originating intervention(s) among parents across multiple ECE centers from a variety of socio-demographic backgrounds. Given that there are multiple unique demographic subpopulations with children who are unvaccinated or under-vaccinated, this project should include ECE centers from multiple sociodemographic backgrounds (e.g., high income vs. low income; highly educated parents vs. less educated parents; urban vs. rural) to assess impact of ECE-originating vaccination-related education/messaging among parents from different subpopulations.

The primary outcome will be to develop a report summarizing the novel intervention(s) that was developed and implemented at ECE centers. Additionally, this report should highlight the novel intervention(s) that proved to be particularly effective at improving parental knowledge, attitudes, and beliefs towards childhood immunizations pre- and post- intervention. This report may also highlight how (if at all) the effectiveness of each implemented intervention varied based on ECE sociodemographic factors. A secondary outcome will be to develop a report that summarizes the acceptability of each implemented ECE-originating intervention among parents

and caregivers.

This project meets ISD's and NCIRD's mission to protect individuals and communities from vaccine-preventable diseases (5). Findings from this project will allow for data-informed decision making and development of public health interventions to improve vaccine uptake among young children.

Healthy People 2030 Objectives *(Mandatory)*
This project contributes to multiple Healthy People 2030 goals to increase uptake of routinely recommended vaccines among infants, toddlers, and young children (IID-02, IID-03, IID-04, IID-06, IID-09, IID-D03).

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

Study design and methods
Applicants should describe plans to design, conduct, and analyze a study of parents and caregivers that participate in ECE centers that incorporate various parent/caregiver-focused communications and policy interventions aimed at increasing uptake of routine vaccinations among young children. The applicant should consider employing a rigorous study design (e.g., RCT) that will have adequate power to demonstrate primary outcomes.
Applicants should describe how ECE centers and participants will be recruited. Applicants should select ECE centers that span a range of teaching styles (Montessori vs. traditional), business models (for profit vs. non-profit vs. faith based), size (large vs. small), business locations (residential vs. non-residential), and Head Start programs.
The applicant may consider randomizing ECE centers to an intervention arm(s) or a control arm in which ECE centers continue with standard practices. Specific intervention(s) will be designed by the awardee and will be informed by initial formative research with parents of young children and ECE administration and health officials. Interventions will include at least one arm which includes vaccine-related, parent-focused messaging only. Primary outcome will be to assess the effectiveness of the intervention at improving the knowledge, attitudes, and beliefs among parents and caregivers towards receiving routinely recommended childhood vaccines, maternal RSV vaccine (if applicable), and nirsevimab (if applicable). Secondary outcomes will focus on acceptability of the intervention(s) conducted at ECE centers among parents and caregivers.

Applicants are expected to propose a study that includes the following activities:

1. Applicants should include a plan to solicit participation of ECE centers representing parental sociodemographic diversity, as described above.
2. Applicants should include a plan to conduct formative research to inform an intervention trial. As part of this process, awardee will assess if ECE staff currently serve as "trusted messengers" of health-related information (or how much parents engage ECE staff with questions about pediatric health issues, including vaccination). Awardee will use this formative research to guide and design the appropriate intervention(s).

3. Focus groups of parents of children, ECE administrators, and health officials will be held for message-testing and to explore acceptability and feasibility of the proposed intervention(s).
4. Awardee will develop and propose at least one parent-focused intervention. The intervention(s) may involve a multi-pronged approach and/or require stakeholder buy-in (consider trusted messenger training and vaccine education of ECE staff, etc.).
5. ECE centers will be recruited for the study and then randomized to study arms.
6. A sample of parents from each study arm will be surveyed prior to and following the intervention to assess vaccination-related knowledge, attitudes and other health behaviors (e.g., adherence to well-child visit schedule), trusted sources of health information, personal and child vaccination status, etc. Additionally, parental intent to vaccinate their children will be assessed pre- and post- intervention.
7. Intervention(s) will be implemented.
8. Analysis will be carried out.
9. Awardee will assess the effectiveness, feasibility, acceptability, and cost of the intervention(s).
10. Final report highlighting findings will be developed and disseminated.

Applicants should provide a translation and dissemination plan for their intervention, should it be found to be effective. The material(s), the audience(s), and the setting(s) for the intervention should be described. Additionally, any partner(s) who would be helpful in effectively implementing or disseminating information about the developed intervention(s) should be noted.

Population of Focus

There are multiple unique demographic sub-populations with children who are un-vaccinated or under-vaccinated, so it is important to recruit ECE centers from multiple backgrounds to assess variability in the impact of ECE-originating messaging for parents from different sub-populations. This includes ensuring that there is parental socio-demographic diversity, income diversity, parental educational diversity, urban vs. rural, etc. Additionally, the selected ECE centers should also span a range of teaching styles as much as is practical (Montessori vs. traditional), business models (for profit vs. non-profit vs. faith based), size (large vs. small), business locations (residential vs. non-residential), and Head Start programs.

Collaboration/Partnerships

Community partnerships and engagements are crucial to improving childhood vaccination uptake. The following collaborations and partnerships are expected and the applicant should describe partners, their roles, and how they will be engaged/collaborate throughout the period of performance to accomplish the proposed SIP activities including any partnership groups or advisory boards. The applicant should describe any collaboration with ECEs, healthcare providers, local and state public health, as well as faith-based and non-governmental organizations.

In addition, the applicant should describe partnerships among representatives from the population of focus (e.g., parents and caregivers), such as describing the process of recruiting

parents/caregivers to help inform the development of survey tools and to potentially serve as vaccine champions in their local community.

Recruitment Plan
The applicant should describe their plans to recruit ECE centers to participate in the study. Besides representing diverse socioeconomic backgrounds, the selected ECE centers should also span a range of teaching styles (Montessori vs. traditional), business models (for profit vs. non-profit vs. faith based), size (large vs. small), business locations (residential vs. non-residential), and Head Start programs.

Annual Action Plan

1. Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.
2. Within a 12-month period, establish collaborations and partnerships to recruit ECE centers that serve diverse populations of children from various socioeconomic backgrounds and span a range of size, geographic locations, teaching styles, and business models.
3. Within a 12-month period, develop parameters to assess how ECE-originating vaccination-related education, communications, and other simple interventions impacts parental attitudes toward uptake of non-mandated childhood vaccines (e.g., COVID- 19, influenza), maternal RSV vaccine, and nirsevimab.

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 the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan
A final report highlighting findings from this project will be developed and disseminated, as described above.In addition, job aids and/or fact sheets may be developed and may be used in conjunction with ongoing campaigns or initiatives (e.g., Let's RISE School Toolkit). Such materials will be targeted to education professionals working at ECE centers, and/or public health personnel working at jurisdictional health departments.

Public Health Impact
The goal of this project is to assess the potential of ECE-originating vaccination-related education, communications, and/or other simple interventions to impact parental attitudes toward

uptake of: 1) non-mandated childhood vaccines (e.g., COVID-19, influenza), 2) maternal RSV vaccine, and 3) nirsevimab so that children are up-to-date on vaccinations by kindergarten.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:
None

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:
Prior experience working with ECE centers or conducting ECE intervention research is preferred, but not required. Prior experience with quantitative/qualitative survey research methods (especially among parents/caregivers) is preferred, but not required.

Funding Preferences
The following preferences specific to this SIP will be considered in the funding decision:
None

Research Plan Length and Supporting Material
The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. 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.
N/A

Availability of Funds
It is anticipated that approximately **$1,500,000** is available to fund **1** Prevention Research Center(s) for a **3-year** period of performance. The average award for each recipient is expected to be approximately **$500,000** for year one. The year one ceiling per recipient is **$500,000**. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

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. However, CDC staff will not have contact with human subjects or data collected from human subjects.

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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,