Improving COVID-19 Vaccine Uptake Among Black and Latino Youth
NCT 05293392
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A. SIGNIFICANCE

A.1 BACKGROUND

Black and Latino communities have experienced higher rates of COVID-19 transmission, morbidity and mortality, as well as greater economic hardships due to the pandemic.[1,2] COVID-19 vaccines can mitigate the health and economic impact of the pandemic; however, Black and Latino adults have experienced reduced rates of COVID-19 vaccination, perpetuating disparities.[3] In Delaware, 15% of Blacks and 13% of Latinos have been fully vaccinated for COVID-19 compared to 21% of Whites.[4] Racial and ethnic disparities also exist in vaccination rates for other infectious diseases (e.g., HPV, influenza) in both adult and pediatric populations.[5,6] **Without intervention, current disparities in vaccination rates are likely to impact Black and Latino youth** for whom COVID-19 vaccines will soon become available and among whom COVID-19 vaccination is critical to reducing community transmission.

There are multiple factors that contribute to disparities in vaccination rates. Vaccine hesitancy, which is impacted by many factors including individual beliefs about the disease, attitudes about vaccination, and influential cues to action, can affect an individual's intention to vaccinate.[7,8] In early large-scale surveys during the pandemic, Black and Latino adults expressed more hesitancy about getting the COVID-19 vaccine compared to White adults.[9-11] **Increasing awareness about the benefits and safety of the COVID-19 vaccine is therefore an important component to any intervention to improve COVID-19 vaccine uptake**. However, interventions to reduce vaccine hesitancy alone are unlikely to be effective at reducing disparities in vaccination rates. Many people in underserved communities also have difficulty accessing vaccines due to systemic factors (e.g., cost, insurance, time, transportation, and technology challenges).[12,13] **Therefore, any intervention to reduce disparities in COVID-19 vaccine uptake must also reduce barriers to vaccine access and ensure equitable allocation of vaccines to communities.**

A.2 RIGOR OF PRIOR RESEARCH

Systematic reviews have shown that multicomponent interventions aimed at educating patients or families and increasing awareness of vaccines can be effective at reducing vaccine hesitancy around other vaccines like influenza and HPV, especially when tailored to populations and their specific concerns about a vaccine.[14] In addition, interventions that reduce barriers to access can improve disparities in vaccination rates.[15] One of the strongest examples of this is the CDC's Vaccine for Children Program, which has been able to provide routine pediatrics immunizations at no charge to children who are uninsured, underinsured or have public insurance through a collaboration between healthcare centers serving underserved populations and public agencies.[16]

A.3 PRELIMINARY WORK

Our research team received a pilot grant through the DE-CTR in September 2020 to examine the impact of the COVID-19 pandemic on pediatric healthcare utilization and family well-being. Based on 450,000+ visits to the Nemours healthcare system we found that Black and Latino families were less likely to attend their scheduled ambulatory care visits than White families before the pandemic *and* that these disparities persisted during the pandemic. We also showed, in 2500+ caregivers of children receiving care in the Nemours healthcare system, that Black and Latino families are exposed to more traumatic aspects of the pandemic and experienced more distress from the pandemic than White families. **Caregivers of Black children also expressed more hesitancy in vaccinating their children against COVID-19 (Table 1)** and were less likely to believe that the vaccine was efficacious. Caregivers of both Black and Latino children were less likely to say that healthcare experts influenced their plan to vaccinate their child than caregivers of White children. Data from Nemours' initial COVID-19 vaccination clinics for our patients over age 16 provides further evidence of disparities in uptake. Only 31% of all caregivers (20% of Black and 27% of Latino caregivers) responded to an e-mail or text to schedule their adolescent for the vaccine. This preliminary work provides insights into the systemic and psychosocial barriers experienced by Black and Latino families in Delaware and ways to improve awareness of and access to the COVID-19 vaccine in these communities.

Table 1	**Plan to vaccinate child against COVID-19 when eligible [N (%)]**		
Race/Ethnicity	**Yes**	**No**	**Not sure**
Latino	94 (56.3)	17 (10.2)	56 (33.5)
Black[a]	98 (36.3)	47 (17.4)	125 (46.3)
White	515 (59.3)	96 (11.0)	258 (29.7)
Other	101 (52.3)	20 (10.4)	72 (37.3)

[a] Significantly more "not sure" vs. "yes" and "no" vs. "yes" than all other groups

B. INNOVATION

B1. This is one of the first studies to address barriers to the uptake of the COVID-19 vaccine in pediatric populations. While interventions targeting vaccine uptake related to other diseases in pediatric populations and COVID-19 vaccine uptake in adult populations exist, no published studies describe strategies to increase COVID-19 vaccine uptake in pediatric populations. Although a vaccine is not yet approved for children under age 16, it is important to proactively mitigate barriers to vaccination and pre-register children now for the COVID-19 vaccination. This will expedite vaccine delivery when it becomes available in the near future. Finally, while much can be learned from strategies to increase COVID-19 vaccine uptake among adults, there are likely key differences that will need to be addressed when designing an intervention for children and families. For instance, education must be tailored to both caregivers and children and factors influencing caregivers treatment decisions for their child differ from those influencing decisions for themselves.

B2. This intervention will address multiple factors that contribute to disparities in COVID-19 vaccine uptake using best practice community based participatory research methods and innovative crowdsourcing methods to ensure that the intervention is relevant and acceptable to Black and Latino communities. As seen with vaccine interventions for other diseases like influenza and HPV, the most effective interventions are multicomponent and tailored to specific populations. We will leverage Nemours' existing marketing strategies and digital technologies to develop messaging that is specific to the concerns of the community, delivered by trusted members of the community, and in a format that will have the greatest reach and impact. We will also leverage Nemours' community healthcare workers and large primary care network to increase access to the intervention to communities across the state of Delaware.

B3. We will leverage existing health system technologies and partnerships with public agencies to develop an infrastructure to ensure accountability in the equitable allocation of COVID-19 vaccines to children. By linking pre-registration for the COVID-19 vaccine to information about the child's demographics and health in the Nemours EHR, we will be providing easy registration for families from a trusted source, removing many of the barriers experienced with current registration systems. The EHR-linked registry that will be created will be available to the Nemours primary care network and partners at the Delaware Division of Public Health to ensure that COVID-19 vaccine allocation and distribution to children matches demand when it becomes available and to track any inequities in vaccine delivery in real-time, allowing for continual improvement in our efforts to ensure equitable COVID-19 vaccination among all children in Delaware.[17]

C. APPROACH

C1. OVERVIEW. The proposed study will develop and test a multi-component intervention to improve COVID-19 vaccine uptake among pediatric populations in underrepresented communities in Delaware. An intervention will be developed using best-practice community-based participatory research methods (Aim 1). The intervention will be refined in an iterative process using innovative crowdsourcing methods with Black and Latino youth and caregivers (Aim 2). The intervention will be pilot tested in a cluster randomized controlled trial with four primary care practices in Delaware and the communities they serve (Aim 3). **Overall project goal:** We will develop a culturally-tailored, community-informed approach to increase pediatric COVID-19 vaccine uptake among Black and Latino communities.

Table 2. Research Partners

Community Partners
- Parents/caregivers of Nemours patients
- Youth community group (e.g. The Warehouse)
- Black community group (e.g. Racial Justice Collaborative)
- Latin community group (e.g. Latin Community Center)

Healthcare Partners
- Community healthcare workers
- Primary care providers
- Delaware Division of Public Health
- Sussex County Health Coalition

Advisory Committee
- Harrington Value Institute Community Partnership Fund (Lee)
- UD Partnership for Healthy Communities (Landgraf)
- Nemours National Office of Policy and Prevention (Walker)
- Nemours Division of Infectious Disease (Rellosa)

Nemours Investigators
- Center for Health Delivery Science (Phan, Enlow, Kazak)
- Primary care network (Miller)
- Office of Health Equity and Inclusion (Palaez)

C2. RESEARCH TEAM. Our team (Table 2) is exceptionally well-qualified to conduct this study, with expertise spanning all methodological and conceptual aspects of the proposed work (see Biosketches). **Thao-Ly Phan, MD, MPH (Research Project Lead, RPL)** is an Associate Professor of Pediatrics and Research Scientist with CHDS with expertise in the conduct of behavioral clinical trials and the use of health information technology. **Paul Enlow, PhD (RPL)** is a Pediatric Psychologist and Assistant Research Scientist with CHDS with expertise in behavioral sciences and the evaluation of healthcare disparities. The complimentary expertise of the two MPIs, each with current NIH funding, has resulted in successful collaboration on a DE-CTR grant evaluating the impact of the pandemic on family functioning and engagement with the pediatric healthcare system. **Anne Kazak, PhD, ABPP,** Enterprise Director of the CHDS, is a senior investigator with expertise in family psychosocial interventions and implementation science. She will continue to serve as mentor to the RPLs on this project.

An **Advisory Committee** will provide guidance on the proposed project, leveraging their community engagement expertise, strong connections to community and healthcare stakeholders, and prior experiences with the Delaware Department of Health and Social Services. The Advisory Committee includes four members: **1) Kara Odom Walker, MD, MPH, MSHS**, Senior Vice President and Chief Population Health

Officer for Nemours Children's Health System; **2) Marshala Lee, MD, MPH**, Director of the Christiana Care Harrington Value Institute Community Partnership Fund and Harrington Trust Physician Scholar; **3) Rita Landgraf**, Director of the University of Delaware (UD) Partnership for Healthy Communities and Professor of Practice and Distinguished Health and Social Services Administrator; and **4) Neil Rellosa, MD,** Attending Physician in the Nemours Division of Infectious Disease to provide expertise on the public health response to the pandemic. Finally, this project leverages robust resources offered by the Nemours Primary Care Network (Director **Jonathan Miller, MD**, co-investigator), and the Nemours Office of Health Equity and Inclusion (Research Associate **Lavisha Pelaez, BSPH, MPH**, co-investigator). Nemours Marketing and Center for Health Delivery Innovation (CHDI) will help create intervention prototypes and final intervention components.

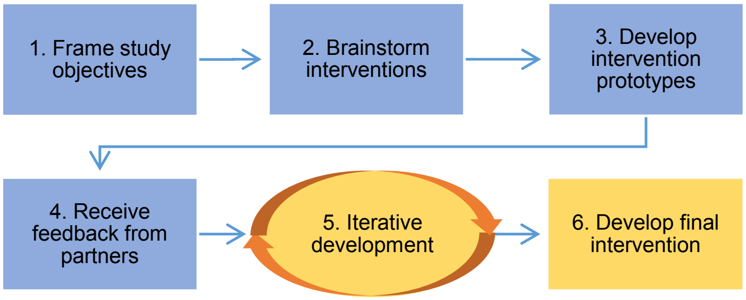
C3. PARTNER ENGAGEMENT PLAN. To create a culturally-tailored and community-informed intervention, community and healthcare stakeholders (Table 2) will be engaged as research partners. Identification and engagement of partners will be facilitated by the UD Partnership for Healthy Communities (Landgraf) and Harrington Value Institute Community Partnership Fund (Lee). This Council of Community and Healthcare Partners will meet regularly throughout the course of the study with our team of investigators. Best practices from the Promising Practices Guide developed by the University of New Mexico's Engage for Equity team will be followed to ensure that community partner engagement is successful.[17-20] In addition, three FYREworks training modules[21] (30 minutes each) will be completed by all community and healthcare partners prior to the first meeting to foster an understanding of their role in the research process.[18,20] The quality of the research partnership will be evaluated using Engage for Equity's Community Engagement Survey[20] following every meeting to ensure partner synergy and alignment of values, modifying our community engagement practices as needed based on responses.

C4. STUDY DESIGN. Please see PHS Human Subjects & Clinical Trials form for detailed eligibility criteria, sample size justification, recruitment/retention plan, timeline, human subjects protection, participant compensation, and data/safety monitoring.

AIM 1. Develop a multi-component intervention to increase COVID-19 vaccine uptake among Black and Latino communities in Delaware in partnership with community and healthcare stakeholders.

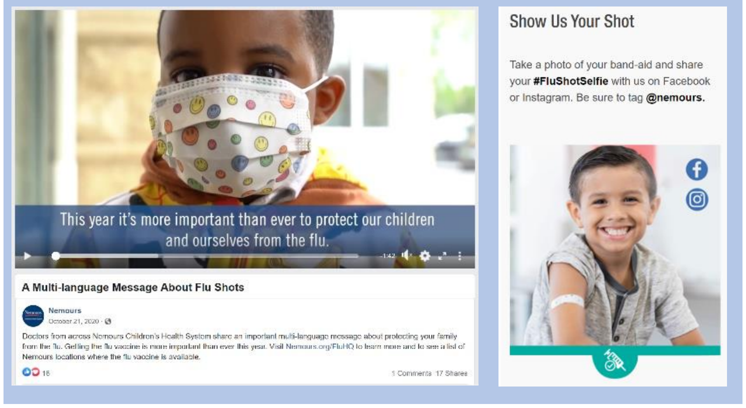
CO-CREATION OF INTERVENTION*:* A 6-step process based on models by Leask[22] and Wallerstein[18,19] will be used to co-create the intervention with community and healthcare partners (Figure 2).

Figure 2. Intervention Development Process



Step 1: In our first 1-hour meeting, we will orient the 8 community partners (2 from each group in Table 2) and 4 healthcare partners (1 from each group in Table 2) to the study aims and review preliminary data from our survey of caregiver intention to vaccinate their child against COVID-19. We will also share Nemours' influenza vaccination campaign that prioritized diversity and inclusion (Figure 3) and the Delaware Division of Public Health's COVID-19 vaccination campaign materials. Community and healthcare partners will be asked to share their experiences with the COVID-19 pandemic and COVID-19 vaccines. We will facilitate a shared vision of the outcomes from this project with the stakeholders and outline strategies to reach these goals.

Figure 3. Nemours Influenza Vaccine Campaign Materials


This year it's more important than ever to protect our children and ourselves from the flu.

A Multi-language Message About Flu Shots

Nemours
October 21, 2020

Doctors from across Nemours Children's Health System share an important multi-language message about protecting your family from the flu. Getting the flu vaccine is more important than ever this year. Visit Nemours.org/FluHQ to learn more and to see a list of Nemours locations where the flu vaccine is available.

16

1 Comments 17 Shares

Show Us Your Shot

Take a photo of your band-aid and share your **#FluShotSelfie** with us on Facebook or Instagram. Be sure to tag **@nemours.**

Step 2: In our second 1-hour meeting with community and healthcare partners, intervention ideas will be brainstormed. Each partner will be asked to write down their ideas to address each of the three A's (awareness, access, and accountability), providing input on content, delivery, and implementation, with a focus on feasibility given available resources and acceptability to target communities. Individual ideas will then be synthesized into broader themes, ensuring equal input and promoting consensus building.[22 23,24]

Table 3. Intervention Prototypes

Example Intervention Component	Example Prototype
Print materials	Drafts of flyers for practice
Social media materials	Drafts of social media posts
Digital materials	Wireframe of webpage
Informational videos	Video story boards
Community healthcare worker contact	Phone or in-person scripts
Community event	Draft of event agenda
Vaccine registration	Wireframe of webpage
Data infrastructure	EHR dashboard

Step 3: Based on the intervention components decided on during the brainstorming session, intervention component prototypes will be developed (Table 3). This will be accomplished leveraging resources from the CDC, state, Nemours Primary Care Network, Nemours Marketing, Nemours CHDI, and Nemours Office of Health Equity and Inclusion to ensure that the prototypes are family-friendly, literacy-sensitive, culturally-relevant, and state-of-the-art.

Step 4: Before our third meeting with community and healthcare partners, intervention component prototypes will be shared and each partner will be asked to rate the acceptability and feasibility of each prototype using the 4-item Acceptability of Intervention Measure (AIM) and 4-item Feasibility of Intervention Measure (FIM).[25] In advance of the meeting, the AIMs and FIMs will be scored (from 1 to 5) and average scores for each prototype will be calculated. During the 1-hour meeting, there will be a robust discussion around how any intervention component prototype that does not achieve an average score above 4 (indicating that participants *"agree"* that it is acceptable) can be modified.

Community and healthcare partners will attend additional meetings as the study progresses through Aims 2 and 3. In total, partners will attend eight meetings during the study. Community and healthcare partners will be compensated $400 ($50 per meeting x 8 meetings) for their time via Greenphire.

AIM 2. Refine the intervention through a rapid iterative process with families and youth from Black and Latino communities in Delaware.

Aim 2 will comprise steps five and six of intervention development process (Figure 2). Intervention components developed in Aim 1 will be refined in an iterative process with youth and caregivers from Black and Latino communities using a mixed-methods approach to evaluate the acceptability of the intervention components.

PARTICIPANTS*:* We will extract an EHR report containing the following variables for identifying potentially eligible youth and caregivers: child and caregiver name, child race and ethnicity, child gender, child age, caregiver preferred language, caregiver contact information, child's COVID-19 vaccination status, insurance type, and primary care site. Youth (n = 20-30) between 12 and 17 years old who receive their medical care at a Nemours primary care practice, identify as Non-Hispanic Black or Latina/o, and are proficient in English or Spanish will be recruited. Similarly, caregivers (n = 20-30) will be recruited if they are proficient in English or Spanish and are the legal guardian of a child between 5 and 17 years old who receives medical care at a Nemours primary care practice and identifies as Non-Hispanic Black or Latina/o. Potentially eligible participants will be recruited by phone or in-person at clinic visits from an EHR-generated list or by flyers posted at community organizations serving teens from Black and Latino communities. For participants recruited by phone or flyer, all follow-up efforts will be made by phone, text, and/or email, advising participants to contact the research team to learn more about or opt out from the project (see attached materials for each recruitment method). During the initial screening phone call or in-person visit with interested potential participants, a research coordinator will provide a brief description of the study, confirm eligibility, and confirm interest in study participation. For eligible participants who are interested in participating, demographic information will be confirmed and entered into REDCap and a secured REDCap survey link hosting an electronic consent and/or assent form will be sent to the participant or pulled up on a secure tablet used only for research purposes. The research coordinator will complete the consent process over the phone or in-person with the participant. Youth will be able to participate if their caregivers do not and vice-a-versa. To ensure that the intervention components are sufficiently evaluated for both English and Spanish-speaking families, recruitment will be stratified by language and race/ethnicity. Based on the research team's experience in previous studies,[26-28] a sample size of 10-15 youth and 10-15 caregivers from each language group is anticipated to be sufficient to

Table 4. Qualitative Analysis

Step	Example Prototype
1) Review Transcripts	• Upload transcripts to Dedoose • Examine transcripts line by line • Identify key words and phrases
2) Create and Revise Codebook	• Create a-priori codes based on literature • Revise codebook based on key words and phrases from interviews
3) Coding	• Independent coding of transcript subset • Review, discuss, and resolve inconsistencies • Calculate inter-rater reliability calculated via Cohen's K and percentage of agreement • Continue double coding until 80% agreement
4) Final Coding	• Recode all transcripts using final criteria

achieve saturation (i.e., no new themes or insights are added from subsequent data), supporting the comprehensiveness of this type of qualitative data.[29] Furthermore, we will use purposive sampling to ensure we gather diverse perspectives based on caregivers' intention to vaccinate their child (yes, no, or unsure). We will be monitoring recruitment to ensure that we are recruiting youth and caregivers that are representative of the population based on demographics.

DATA COLLECTION*:* Crowdsourcing is a form of online problem-solving in which a problem or question is presented to a group of individuals with relevant experiences and perspectives to solicit pertinent and timely input.[30] Crowdsourcing has been used extensively to conduct research on health behaviors.[31-33] Yammer, a secure collaboration tool that resembles social media sites familiar to most participants, will be used for crowdsourcing. Intervention components (e.g., videos, registration websites) will be posted to Yammer. Participants will be able to view or engage with the intervention components through the platform and will rate the acceptability of each intervention component on the AIM. In addition, participants will be asked to provide feedback via Yammer on why they felt that intervention components were or were not acceptable. Participants will be able to post free-text responses to queries and see others' responses. This simulates participant interactions found in focus groups while reducing logistical barriers to participation (e.g., travel, coordinating schedules), which will facilitate inclusion of healthcare providers and socioeconomically disadvantaged families. Participants will be given the option of completing an electronic survey or qualitative interview with the same questions posed to the online crowds if they feel uncomfortable posting on Yammer. Participants will be compensated, via Greenphire, for each AIM rating and each free-text response. Participants can earn up to $120 once this portion of the study ends, based on number of responses and ratings completed.

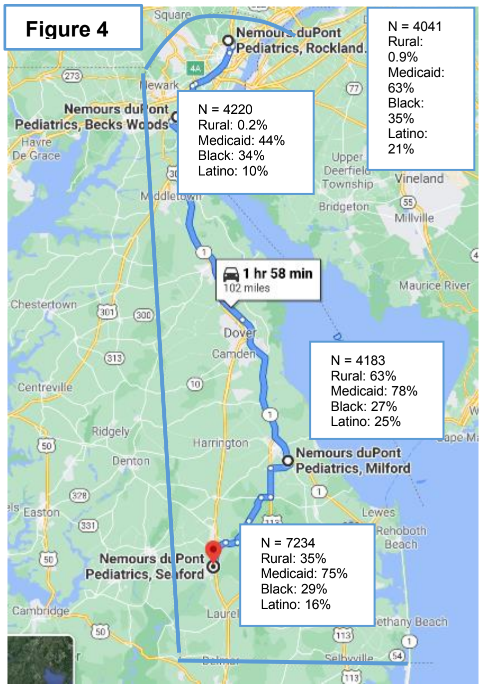
ANALYSIS: <u>Quantitative data</u> (AIM ratings) will be analyzed via descriptive statistics. <u>Qualitative data</u> (free-text responses) will be analyzed using an inductive thematic approach (Table 4). Data will be analyzed until code and meaning saturation has occurred and the findings are reliable and thorough.[34-37] Quantitative and qualitative data will be mixed through the process of *building*[38,39] in which qualitative data are used to provide a more thorough understanding of participants' ratings of acceptability (e.g., codes can be stratified to explore whether different themes emerge for participants based on acceptability ratings).

INTERVENTION REFINEMENT: Ratings on the AIM range from 1 to 5, with higher scores indicating greater acceptability. A score of 4 indicates that participants *"agree"* that interventions are acceptable. Intervention components with a mean score < 4 will be modified based on qualitative responses, with the research team determining what modification can be made based on importance and feasibility. The process of revision and participant feedback will continue until the mean acceptability score is ≥ 4.

AIM 3. Test the preliminary efficacy of the intervention through a pilot cluster randomized controlled trial of the intervention at 4 Nemours primary care sites.

PARTICIPANTS: Four primary care practices will be enrolled in the study (Figure 4), leveraging RPL Phan's prior work with primary care practices in Delaware and co-I's Miller role as Director of the Nemours Primary Care Network. The four primary care practices selected for the study have large and diverse patient populations, with two practices in Northern Delaware (Becks Woods, Foulk Road) and two in Southern Delaware (Milford, Seaford) having comparable patient demographics. All practices are within the Nemours Children's Health System, which provides care to the majority of children in the state, and share an EHR.

Figure 4



STUDY DESIGN: A pilot cluster randomized controlled trial will be conducted, with clustering at the practice level. Enrolled practices will be randomly allocated to receive the intervention (Intervention Practice) or not (Control Practice) using a 1:1 randomization scheme stratified by practice location (Northern or Southern Delaware).

OUTCOME MEASURES

Vaccination Rates: We will extract EHR data about rate of COVID-19 vaccination for all eligible children at each practice.

Accountability for Vaccination: Vaccination rates for each site will be made available and reviewed monthly by the Nemours Primary Care

Network, who will share an overview of de-identified data with the Delaware Division of Public Health and partner with them to ensure that enough COVID-19 vaccines will be allocated and distributed to communities to meet demand and that continual efforts to encourage vaccination.

Disparities: Child race/ethnicity (Black, White, Latino, Other) will be the primary measure of disparity and will be collected from the EHR. Zipcode from the EHR will be used to categorize patients into rural vs. not (RUCA ≥ 4)[40] and to generate a Child Opportunity Index score[41] for each child as secondary measures of disparity. Insurance, sex, medical diagnoses, and caregiver preferred language will also be collected from the EHR.

ANALYSES: Analyses demonstrated the efficiency of the stratified cluster randomized trial in detecting a difference in vaccination rate of 30% among Blacks in the Control Practices compared to an increase in vaccination rate to 60% among Blacks in Intervention Practices, with a sample size of 500, $\alpha < 0.05$ and power of 90%. Proportions of caregivers who vaccinate their child will be compared by level of intervention using chi-square tests. To test the efficacy of the intervention, while accommodating the cluster-randomized design of the study, a multi-level mixed-effects model (MME) logistic regression will be used fit to the data for the primary outcome of child vaccination rate to assess the effect of intervention. MME models will be adjusted for race/ethnicity to evaluate the effect of intervention on reducing this disparity.

C5. POTENTIAL CHALLENGES AND ALTERNATIVE APPROACHES. The state of the COVID-19 pandemic is evolving rapidly. By the time the project begins, more vaccines may become available and to younger age groups; however, we are certain that there will still be families who are unsure of whether to vaccinate their children against COVID-19 or who face barriers to access. As vaccines become more available to children, Nemours Marketing may begin to develop COVID-19 vaccination campaign or registration materials. In this case, we will work closely with them to ensure that the preliminary data we've collected from families and the input of our community partners is considered. Any early development of COVID-19 materials will only expedite our development process since prototypes will already be available. However, it will still be critical to conduct the process of refining and testing any intervention to ensure it is tailored to the needs and values of communities and families. Our ongoing engagement with community partners will also ensure that we are nimble in adapting our approach to be responsive to any other changes in how families are experiencing the pandemic. Finally, it is possible that the reach of the intervention may not extend to as many families in the community as intended with our pilot trial. Therefore, it will be important for us to gather data on the number of families who access different intervention components (e.g. data analytics for digital components, number of families who attend an event). This data can be used to determine intervention reach and provide insight into which components are most impactful.

C6. SCIENTIFIC RIGOR. This study was designed to ensure that it will yield robust results. We are involving community partners throughout the project and using empirically supported practices to engage community partners as members of the research team and co-create the intervention for this study.[42] In addition, we will repeatedly evaluate the quality of community partner engagement using well-validated measures that are associated with both intermediate and distal outcomes of community-academic partnerships[20] and will modify engagement strategies based on these data to ensure high quality partner engagement. The planned sample size for crowdsourcing is based on experience from similar studies[36,37] and we are using well-validated instruments and rigorous qualitative methodology to assess the acceptability and feasibility of the intervention components. We will test the co-created and refined intervention in a cluster randomized controlled trial for maximum impact and have chosen primary care practices because of the large and diverse communities they serve. Finally, rigorous data analytic approaches and transparent reporting guidelines will be followed.

Table 5. Study Timeline

	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
Research Partner Meetings	⬛	⬛	⬛	⬛
Co-Develop Intervention (Aim 1)	🟧			
Conduct Crowdsourcing (Aim 2)		🟩		
Finalize Intervention (Aim 2)			🟩	
Pilot Cluster RCT (Aim 3)			🟨	
Data Analysis & Dissemination				⬛

C7. FUTURE DIRECTIONS AND SUSTAINABILITY. This project will result in a community-informed intervention to increase COVID-19 vaccine uptake among Black and Latino children and provide preliminary evidence of the efficacy of the intervention. Because the intervention is integrated into existing Nemours infrastructure and leverages Nemours resources, it will be readily available for use more broadly across the entire Nemours Children's Healthcare System once the study is complete, contributing to the sustainability of the project and its intended impact. The results from this project will also position the research team to apply for rapid funding from the NIH or other agencies like PCORI to conduct a larger cluster randomized controlled trial of this approach across multiple sites in the state of Delaware, with equitable allocation of the COVID-19 vaccination to children in Delaware as the primary outcome. Finally, findings from this study and our other studies examining the impact of the pandemic on families will inform future research proposals by the research team to design and implement interventions to reduce disparities in the physical and mental health burden of the pandemic on children from underrepresented communities.