Development and testing of ADEPT: A parent decision support for childhood vaccinations

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Purpose of the Study

The purpose of the study is to develop and evaluate ADEPT: A parent decision support for childhood vaccines, for facilitating positive vaccination decision-making via mitigation of vaccine hesitancy.

Background & Significance

A high priority goal in the United States Health People 2020 initiative is the coverage of all recommended immunizations in children ages 19-35 months. Yet, recent data from the National Immunization Survey suggest that, compared to children from non-Hispanic white families, coverage for most recommended immunizations is lower in children from non-Hispanic black families. [1, 2] In recent years, negative concerns and eroding trust in the safety and efficacy of vaccines have led many parents to decline or delay immunizations for their children – a phenomenon termed vaccine hesitancy. [3-7] Most current interventions to mitigate parental vaccine hesitancy focus on improving provider-patient communication related to vaccines in healthcare settings.[8, 9] However, compared to white parents, more black parents have serious concerns about safety of vaccines as well as lower trust in vaccine information from healthcare providers.[10-12] To-date, few studies have developed and tested interventions outside the healthcare setting, which provide tailored decision support to parents about childhood vaccines and incorporate concerns specific to non-Hispanic black parents. This proposal seeks to bridge the gap by developing and evaluating ADEPT: A parent decision support for childhood vaccines, for facilitating positive vaccination decision-making via mitigation of vaccine hesitancy.

Design & Procedures

Aim 1: To examine contextually-relevant barriers to vaccine uptake among parents of young children to inform the development of ADEPT.
Aim 1a. To compare vaccination knowledge, experiences, concerns, and decision-making among parents of children with delayed vaccine uptake and those with timely vaccine uptake.
Methods: Data from a cohort created for Pro00092782 that includes both NCIR immunization records and Duke patient records will be used to classify children based on timing of routine vaccine uptake (excluding flu vaccine) by age 2 years. In order to specifically recruit vaccine hesitant parents, we may also use relevant ICD codes (e.g., ICD-10-CM: Z28.82 - Immunization not carried out because of caregiver refusal) to filter the cohort described above.
If sample size is not reached using the cohort described above, we will recruit additional participants using the following methods:
Create a new cohort using DEDUCE, screening for children who are between 3-6 years of age on May 20, 2020 and further filter using the ICD codes described above;
POst targeted ads to Facebook and/or Instagram; and
Ask participants or other people contacted for the study to refer their contacts to the study (snowball sampling)

Vaccine uptake will be considered delayed if ≥6 of the 24 recommended shots are late by ≥4 weeks (28 days) beyond the CDC recommended vaccination age-range, for parents who respond “Yes” to either of the questions on the demographic survey related to delay/refusal of vaccines, or if their responses to

the interview questions indicate that they are currently delaying or refusing vaccines. In-depth interviews with parents will assess vaccine-related knowledge, demographic characteristics, vaccination experiences, barriers according to the 5As taxonomy of vaccine hesitancy (Access, Affordability, Awareness, Acceptance, and Activation), healthcare decision-making within households, sources of vaccine information, and intervention preferences. Participants will also be asked to help develop personas (case studies) reflecting parental concerns for use during the intervention development session (aim 2). We will purposively recruit 25 parents of children with delayed vaccine uptake and 25 parents of children with timely vaccine uptake. Vaccine uptake will be considered delayed if ≥6 of the 24 recommended shots are late by ≥4 weeks (28 days) beyond the CDC recommended vaccination age-range, for parents who respond "Yes" to either of the questions on the demographic survey related to delay/refusal of vaccines, or if their responses to the interview questions indicate that they are currently delaying or refusing vaccines. We will purposively recruit non-Hispanic black parents, ideally to comprise 50% of the sample and identify any concerns specific to them compared to other racial groups. However, we may vary the subject population as necessary in order to achieve 50 total participants (e.g., recruiting fewer than 50% non-Hispanic black participants). All participants will be asked to complete a brief survey to collect key descriptive data (including demographics) to characterize the participants. This survey will be administered over the phone, in person or online; either way, information from the survey will be captured using an online tool (e.g., REDCap or Qualtrics). Interviews will be conducted in English either at a mutually agreed upon location or by phone. Reminders will be sent via phone call, email, or text before the scheduled interviews. Interviews will be audio-recorded and transcribed to facilitate data analysis. Recordings will then be electronically transcribed and the transcriptions checked by study staff. We plan to use an automated transcription service to transcribe all interviews. The transcriptions will each be checked for accuracy by study staff. Audio recordings will be deleted once any manuscripts based on this work have been published. They will be stored for no more than six years. The transcriptions will be retained in your research record for six years after the study is completed. Recordings/transcriptions will be stored on the secure Duke server. Both will be also be stored in Box temporarily so that student research assistants can review transcriptions for accuracy.

Aim 1b. To identify healthcare providers' perceptions of vaccine-related concerns among parents.
Methods: We will use in-depth interviews based on the 5As taxonomy to identify providers' perceptions of vaccine-related concerns among parents as well as priorities and preferences for a decision-support guide for parents. Participants will be sent a recruitment email that serves as an implied consent. In this email all participants will be asked to complete a brief survey to collect key descriptive data (including demographics) to characterize the participants. Reminder emails will be sent as needed. For providers whose email cannot be located for recruitment, study staff may call provider or provider's office and/or share a printout of the recruitment email.
Survey data will be collected electronically and will be administered in person, by phone, or online. Interviews will be conducted in person in English at the provider's office, other mutually agreed-upon location, or over the phone. Reminders about the interview will be sent via phone call, email or text. Interviews will be audio-recorded and transcribed to facilitate data analysis. Recordings will then be electronically transcribed and the transcriptions checked by study staff. We plan to use an automated transcription service to transcribe all interviews. The transcriptions will each be checked for accuracy by study staff. Audio recordings will be deleted once any manuscripts based on this work have been published. They will be stored for no more than six years. The transcriptions will be retained in your

research record for six years after the study is completed. Recordings/transcriptions will be stored on the secure Duke server. Both will be also be stored in Box temporarily so that student research assistants can review transcriptions for accuracy.

Aim 2. To develop ADEPT in collaboration with parents, and measure its acceptability, and pre-post change in attitudes and knowledge.
Methods: Aim 2 will include three sessions aimed at the development of ADEPT in collaboration with parents. The first two sessions will include the same 12 participants and the third session will include 12 different parent participants. Participants will be recruited from Aim1a participants although we will reach out to parents from outside of the Aim 1a participants for recruitment if sample size targets are not met. The sample will comprise an approximately 1:1 ratio of parents who have children with delayed and timely vaccine uptake. Sessions may be conducted as a group or individually depending on the availability of study participants.
After participants have consented to participation, we will administer a brief technology assessment survey to determine their access to a laptop, tablet or smart phone and to reliable internet connectivity. We will not use this information as an exclusion criteria. Rather, information about technology access will used to determine whether a participant should be schedules fo virtual sessions either over the phone or via Zoom. Sessions will be conducted in English virtually (e.g., using Zoom). Reminders about the sessions will be sent/made before the scheduled sessions. We may mail/email participants of any of the three sessions print materials in advance of the session. Video recordings taken automatically from Zoom will be immediately deleted following the completion of the session. Audio recordings will be saved for transcription and analysis. We may use an outside transcription service company with a Duke approved OSA or BAA on file to transcribe the audio recording of the sessions. Any identifying information will be redacted from transcripts and they will be stored in the SEI folder for a maximum of 6 years, at which point they will be securely deleted.

Pictures may be used to document notes that are created as part of the human -centered design process (e.g., on the whiteboard, post-it notes, screen capture, or other non-audio mechanisms). Participants will not be on video and hence, these pictures will not impact their confidentiality.
Primary outcome is a quantitative and qualitative assessment of intervention acceptability as well as direct feedback on the guide.
Secondary outcomes are immediate change in vaccine attitudes and knowledge measured pre-post intervention using a brief questionnaire electronically.

Sessions 1&2
We will invite twelve parents to participate in two intervention development sessions. If sample size targets are not met, we will reach out outside of Aim 1a participants for recruitment. We will discuss findings from aim 1 during the first session, and brainstorm potential content, layout, and presentation for the decision support guide using principles of human centered design. We will develop prototypes of the guide based on the discussions and present them to the parents during session 2 for feedback.

Session 3
In a third session, we will invite twelve other parents from aim 1a to review the decision guide and provide feedback. Participants in Session 3 will also complete a knowledge survey over the phone before

and after reviewing the study prototype. The initial survey will likely be administered at the time of consent but this may vary based on participant availability. After the participants complete the initial survey, study staff will send them a link to view the intervention prototype. Participants will be asked to briefly review the prototype before the focus group session. The second survey will then be completed over the phone before the Session is held (e.g., when placing a reminder call to the participants).

Session 4
In a fourth session or individual interviews, we will invite approximately 30 parents who did not participate in a previous aim to review the decision support guide prototype and provide feedback. For this aim, we are collaborating with community organizations who will help pass along study information to potential participants. Community organizations will pass out flyers to parents/have flyers available for parents through their existing channels of information dissemination (in person, via email, etc.). Flyers will have study information and a link or QR code to check eligibility and provide contact information, including name and phone number. If parents are eligible, a member of study staff will contact the participant and complete the consent process over the phone.

Participants in Session 4 will also complete a knowledge survey over the phone before and after reviewing the study prototype. The initial survey will likely be administered at the time of consent but this may vary based on participant availability. After the participants complete the initial survey, study staff will send them a link to view the intervention prototype. A pdf or paper version of the survey can be shared instead. Participants will be asked to briefly review the prototype before the focus group session or individual interview. The second survey will then be completed over the phone before the focus group or interview (e.g., when placing a reminder call to the participants). Participants who complete the study would have the opportunity to invite their networks to the study. Study staff would give a flyer and study contact information via email to the participants who want to assist in snowball sampling. Within the flyer there is a link/QR code that would take referred potential participants to an interest and eligibility survey in REDCap.

As part of the fourth session, we will also invite approximately 12 community stakeholders to review the decision support guide and provide feedback either in an individual interview. Potential participants will be reached through a mix of purposive and snowball sampling. Study staff will send an email to stakeholders with a link to a Redcap survey that stakeholders can fill out if they are interested in participating. Study staff will then call potential participants to complete the consent process over the phone. Community stakeholders will not be asked to complete the pre or post knowledge survey but will complete a demographic survey.

Selection of Subjects

Aim 1: To examine contextually-relevant barriers to vaccine uptake among parents of young children to inform the development of ADEPT.
Aim 1a. To compare vaccination knowledge, experiences, concerns, and decision-making among parents of children with delayed vaccine uptake and those with timely vaccine uptake.

Inclusion criteria

At least 18 years of age
Parent or primary caregiver of a child between the ages of 3-6 years who is receiving primary care at Duke. Parents whose child does not receive primary care at Duke will also be included but only if we are unable to recruit a sufficient number of those who receive primary care at Duke.
Fluent in English
Non-Hispanic black race (50% of the sample; the remaining 50% sample will be other races/ethnicities). If we are unable to recruit 50% non-Hispanic black parents, we will continue to recruit all other races until our sample size of 50 has been recruited.
Children vaccinated on time or with delayed vaccinations.

Exclusion criteria
Unable to understand the study objectives, procedures, risks, and benefits
Unable to consent for themselves

Aim 1b. To identify healthcare providers' perceptions of vaccine-related concerns among parents.

Inclusion criteria
At least 18 years of age
Health provider at a Duke or non-Duke affiliated clinic, hospital or organization.
Providing primary care services (including immunizations) to children
Fluent in English
Non-Hispanic black race (50% of the sample; the remaining 50% sample will be other races/ethnicities). If we are unable to reach the proposed sample size for providers at Duke, we will recruit providers outside of Duke, for example, through professional organizations, other hospitals or clinics outside of duke, etc. If we are still short of the sample size of non-Hispanic black providers, we will continue to recruit all other races until our sample size of 12 has been recruited.

Exclusion criteria
Unable to understand the study objectives, procedures, risks, and benefits
Unable to consent for themselves

Aim 2. To develop ADEPT in collaboration with parents and community stakeholders, and measure its acceptability, and pre-post change in attitudes and knowledge.

Inclusion criteria
At least 18 years of age
For Sessions 1-3: Parent or primary caregiver of a child between the ages of 3-6 years who is receiving primary care at Duke. Parents whose child does not receive primary care at Duke will also be included but only if we are unable to recruit a sufficient number of those who receive primary care at Duke.
Session 4: 1) A parent or primary caregiver of a child between the ages of 0-6 years and pregnant women. The child does not need to be receiving care at Duke to be eligible to participate OR 2) a community stakeholder that has been invited to participate by study staff. The community stakeholder does not need to be a parent to participate.
Fluent in English

(for sessions 1-3) Non-Hispanic black race (50% of the sample; the remaining 50% sample will be other races/ethnicities). If we are unable to recruit 50% of non-Hispanic black parents, we will continue to recruit all other races until our sample size of 12 has been recruited.
Children vaccinated on time or with delayed vaccinations.
Is available to participate on one of the scheduled session dates.
(For sessions 1-3) Participated in aim 1a*
* If the necessary recruitment target is not achieved, we will recruit participants who did not take part in aim 1a activities.

Exclusion criteria
Unable to understand the study objectives, procedures, risks, and benefits
Unable to consent for themselves

Subject Recruitment and Compensation

Recruitment procedures:
Parents from the existing cohort pulled from DEDUCE and participating in aim 1a will be initially reached either by a recruitment letter, by a phone call or by a MyChart message from study staff.
Parents initially contacted via letter will have a recruitment letter mailed to the address on file. Parents will have two weeks from the mailing date to opt-out of the study. If no response is received, or a parent chooses to opt-in to participate, a study staff member will contact them as described below.
In part to ensure the safety of staff during COVID-19, letters will not be sent to parents and the first contact with parents will be the recruitment call. The research opt-out status of both the child and child's mother will be checked in DEDUCE prior to pulling a cohort from PACE. The study team will not contact parents of children with a designation of opt-out of research participation and/or parents of children whose mother has opted out of research participation. If parents are considering study participation but want verification of the legitimacy of the study, study staff will offer to mail the participant a recruitment letter or to set up a phone call between the parent and the study PI. If we are unable to reach target recruitment rates through phone and letter recruitment, study staff may also send a MyChart message to potentially eligible participants and follow-up by phone. Study staff will provide the DOCR team with a list of MRNs based on Duke immunization records and NCIR data, as well as relevant ICD codes that indicate that a parent may have delayed or refused a vaccine for their child. DOCR will first send out a recruitment message to approximately 250 parents. If the recruitment target is not reached from the initial batch of messages sent, DOCR may send more recruitment letters until the target number of study participants is reached. The MyChart recruitment messages will include details about the study and a link to a Redcap eligibility survey. Participants also have the option to click "I'm interested" to have research staff call them regarding participation. If participants do not view the MyChart message after 2 weeks, we will also reach out to them by phone. We will ensure that patients who have opted out of Duke Research Recruitment will not be contacted.

If we are unable to reach target recruitment using the methods described above we will additionally recruit parents using both Facebook and/or Instagram ads and snowball sampling.
Facebook ads will be developed and sent out using the Discover Duke Research account maintained by the Duke Recruitment Innovation Center. Ads will follow the content laid out in the attached Social

Media Marketing Plan. Potential participants will click on a link in the ads and go directly to a short eligibility screen.

For snowball sampling, we will ask participants or other people contacted for the study to refer other potentially interested caregivers to the study. We will send participants an email or text that they can forward on to potentially interested contacts. If interested, recipients can then (1) call the PI's phone number; (2) email the study email address; or (3) click on the link to go directly to the eligibility survey. Potential participants will then either be sent a link to participate in the eligibility survey or go through an eligibility screen with study staff over the phone.

For aim 2 session 4, parents will receive a study flyer with a link and QR code to indicate interest in the study. If parents indicate interest by completing the survey, a member of study staff will contact them to provide more information using the pre-approved script.

For all study aims, potentially eligible participants will be contacted via phone and/or email by a study staff member to assess their interest in participating in the interviews. If participants are not available, a voicemail will be left by a research staff member using an approved script and will not identify the type of study being conducted.

For aims 1a and 2, the staff member using a phone script will describe the study and assess study eligibility. Parents who are reached through MyChart message for aim 1a will also have the option to take a brief eligibility survey prior to being contacted by study staff via phone.

For aim 1b, the staff member will use an email script and online survey to describe the study and to assess study eligibility.

Only those eligible participants providing consent will be enrolled in the study. Prospective study participants will be identified as follows:
Aim 1: To examine contextually-relevant barriers to vaccine uptake among parents of young children to inform the development of ADEPT.
Aim 1a. To compare vaccination knowledge, experiences, concerns, and decision-making among parents of children with delayed vaccine uptake and those with timely vaccine uptake.
Fifty participants will be recruited from a cohort created for Pro00092782 that includes both NCIR immunization records and Duke patient records. This cohort comprises children who were born at Duke between 2014-2018, and data includes their demographics and contact information for the parents, and vaccination history of the children. From this cohort, we will identify parents who meet eligibility criteria. We will purposively recruit 25 parents of children with delayed vaccine uptake and 25 parents of children with timely vaccine uptake. Vaccine uptake will be considered delayed if ≥6 of the 24 recommended shots are late by ≥4 weeks (28 days) beyond the CDC recommended vaccination age-range, for parents who respond "Yes" to either of the questions on the demographic survey related to delay/refusal of vaccines, or if their responses to the interview questions indicate that they are currently delaying or refusing vaccines. If it becomes difficult to reach our target sample size in either category, we will include an eligibility question in the consent survey, which asks about timely/delayed vaccine uptake, in addition to the demographic survey. Approximately 50% of the sample will comprise non-

Hispanic black parents. If we are unable to recruit 50% of non-Hispanic black parents, we will continue to recruit all other races until our sample size of 50 has been recruited.

A recruitment letter will be mailed to the address on file for potential study participants or parents will be contacted by MyChart message or called by study staff. Parents receiving a letter will have two weeks from the mailing date to opt-out of the study. Those parents receiving a call without a letter will be able to opt out when speaking with study staff. The research opt-out status of both the child and mother will be checked in DEDUCE prior to pulling a cohort from PACE. The study team will not contact parents of children with a designation of opt- out of research participation and/or parents of children whose mother has opted out of research participation.

If we are unable to reach target recruitment using the methods described above we will additionally recruit parents using Facebook and/or Instagram ads and/or snowball sampling (see description above).

A study staff member will call the parent to assess their interest in participating in the interviews. The staff member using a phone script will describe the study and assess study eligibility. If parents are considering study participation but want verification of the legitimacy of the study, study staff will offer to mail the participant a recruitment letter (if not received) or to set up a phone call with the study PI. If participants are not available, a voicemail will be left by a research staff member using an approved script and will not identify the type of study being conducted.

Aim 1b. To identify healthcare providers' perceptions of vaccine-related concerns among parents.
Health care providers will be recruited using a combination of convenience and snowball sampling. Initially, study staff will reach out to providers who are in the professional network of the study PI or mentors.
Providers who are contacted will be asked to recommend others who may be eligible for study participation.

Aim 2. To develop ADEPT in collaboration with parents, and measure its acceptability, and pre- post change in attitudes and knowledge.
Parents recruited for aim 1a will be asked for permission during informed consent to re-contact them for aim 2. For aim 2, study staff will reach out to potential participants using a phone script. If the necessary recruitment target for aim 2 is not achieved from the pool of aim 1a participants, we will recruit other parents using the recruitment strategy specified for aim 1a.

For focus group/interviews for session 4, we are collaborating with community organizations who will be advertising the study to beneficiaries through their existing channels of information dissemination (in person, via email, etc.). Staff of community organizations will distribute the flyers with study information and a link or QR code for parents to check eligibility and provide contact information. In addition, we would ask participants who complete the study in Aim 2 session 4 to refer people within their networks that would want to participate (via word of mouth, email with flyer and study contact information, etc.) If parents are eligible, a member of study staff will contact the participant and complete the consent process over the phone. Study staff will email community stakeholders a link to the study Redcap eligibility and interest survey, and stakeholders will be able to compete the survey if they are interested

in participating. Stakeholders can refer other potential stakeholders that would be interested in the study via snowball sampling (word of mouth, email with study flyer and contact information, etc.). Study staff will then reach out to interested community members by phone to complete the consent process.

Study Interventions

The study intervention is a decision aid to assist parents in the decision to vaccinate their children. The details of the intervention related to the content and format are purposefully left open ended since the intervention will be co-developed with parents in aim 2. Prior to session 3 in aim 2 where the intervention is tested using a pre-post study design, we will submit the intervention details to the IRB through a protocol amendment, as well as the questionnaires for testing intervention content.

Risk/Benefit Assessment

Risks from participation in this study are minimal and commensurate with normal life. Participants will be briefed during the informed consent process regarding the nature of the questions they will be asked, and they can choose not to participate. If any emotional distress is experienced during study participation, participants can choose to skip questions and/or withdraw from the study. The only anticipated risk is that of loss of confidentiality. Measures to minimize the risk of loss of confidentiality are described in the section on privacy, data storage and confidentiality.

Benefits of participation include access to information about immunizations, and contribution to the development of a decision aid for parents. The knowledge gained from the research will help us better understand reasons for vaccine hesitancy locally, and provide insights into information needs of parents related to immunizations. If successful, the intervention may promote timely vaccinations among pediatric primary care patients at Duke.

Data Analysis & Statistical Considerations

Sample size justification:
This study uses qualitative methods with the aim to investigate factors that underly behavior (vaccination), and is concerned with richness rather than representativeness of data. Hence, it requires smaller, focused samples instead of large, random samples. For qualitative interviews and focus groups, evidence suggests that data saturation can occur within 12 interviews, with primary themes arising as early as six interviews (Guest, 2006).

Data analysis:
For aims 1a and 1b, we will import all interview transcripts into a qualitative analysis software package (e.g., NVivo 12) to facilitate organization and analysis. We will use a 5 stage approach to conduct thematic analysis (familiarization; identifying a thematic framework; indexing; charting, and interpretation) (Braun and Clark, 2006; Gale, 2013). Experienced qualitative researchers on the study will conduct the analysis. Familiarization will involve the entire research team reviewing 2-3 transcripts to identify initial coding themes to become familiar with the data. Relevance of a-prori codes based on the interview guide and the 5As taxonomy of vaccine hesitancy (Access, Affordability, Awareness,

Acceptance, and Activation) will be assessed. The identified themes will be used as the initial coding framework to conduct line by line coding of a single transcript. The team will meet to discuss the transcript and modify the initial framework. Next, experienced qualitative researchers will conduct line by line coding of remaining transcripts. Coding will include memos for each transcript to annotated coders questions, decision about the data, and reflections on analysis. Each coder will also create an overview memo to collect observations that cut across individual transcripts during the coding process. After coding is completed, the team will meet to discuss themes, sort codes, and restructure the initial framework as similarities and differences are identified. In the final stage, the team will identify major themes and associated quotes to summarize the results. Methods such as regular debriefing and memo writing throughout the process will be used to enhance rigor and trustworthiness of study findings.

For aim 2, we will develop summaries of workshop proceedings from audio recordings and detailed notes to capture key parental feedback and procedural details in the development of ADEPT. We will also use a Transcription Service company with a Duke approved OSA or BAA on file to transcribe the audio recording of the sessions. Recordings will be shared with the transcription company through a Duke Box folder. Once they have been transcribed they will be removed from Box and kept in the SEI folder, to which only key study staff have access. Any identifying information will be redacted from transcripts and they will be stored in the SEI folder for a maximum of 6 years, at which point they will be securely deleted.

For all aims. descriptive statistics will be used to summarize key characteristics of study participants (e.g., age, gender, race, age of child, timely vaccination status of child)

Data & Safety Monitoring

The risks of participating in this study are minimal and commensurate with ordinary life. For this reason, a data and safety monitoring board will not be convened. The study team will make all study related documents, including consent forms, readily available for inspection by the study's IRBs, and the Office for Human Research Protection (OHRP). On-site study monitoring will be performed by the study PI or her designees, to verify compliance with human subjects and other research regulations and guidelines, assess adherence to the study protocol, and confirm the quality and accuracy of information collected and entered into the study database. The study will be conducted in full compliance with the protocol. With the exception of modifications required to eliminate immediate and unanticipated participant safety concerns, the protocol will not be amended without approval from the study PI.