Promoting Altruism to Enhance Vaccine Acceptance
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Study Protocol and Statistical Analysis Plan
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Cohort Study to Determine the Effect of an Educational Intervention Focusing on Herd Immunity to Enhance Vaccination Uptake Rates

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Background, Rationale, and Context

Vaccine hesitancy is on the rise in the United States, which is causing a resurgence of vaccine-preventable diseases. Vaccine hesitancy regarding the seasonal influenza vaccine is especially prevalent, with a recent study indicating hesitancy prevalence of 6.1% for routine childhood vaccines but 25.8% for influenza vaccine[1-6]. This trend is particularly concerning today as the world awaits a COVID-19 vaccine, the effectiveness of which will be critically threatened by poor uptake due to vaccine hesitancy. Uniform strategies to address vaccine hesitancy have met challenges due to pervasive online misinformation, and the heterogeneity of the vaccine-hesitant community, which crosses racial, socioeconomic, educational, and political lines[3, 7-26]. However, a common thread that globally may contribute to vaccine hesitancy is rising individualism, the moral stance that the individual takes precedence over a larger social group[27-29]. Altruistic, prosocial motivation seems to be an essential component of vaccine acceptance[30]. Altruism has also been identified as the major motivator in subjects willing to participate in preventative vaccine trials[31]. One potential strategy to increase altruism amongst vaccine hesitant individuals is to provide education on the concept of herd immunity. A recent scenario study found that explicitly communicating the role of herd immunity increased people's intention to accept vaccines, especially in Western, individualist cultures[32]. Strategies like this to promote altruism in order to enhance vaccine uptake could improve public health outcomes. How to best communicate the benefits of herd immunity in an increasingly individualistic, nationalistic climate is unclear but must be addressed.

Pediatric oncology patients represent a potentially excellent population on whom to base a herd immunity educational effort aimed at enhancing altruism in vaccine-hesitant parents: pediatric cancer patients tend to elicit strong sympathetic responses from the public; they come from all communities in the US and are therefore local; and they rely on herd immunity for protection from vaccine-preventable infections because they are largely unable to receive vaccines due to their immunocompromised state[33-46]. Therefore, we hypothesize that a brief educational encounter on herd immunity focusing on local pediatric cancer patients' risk and sponsored by local pediatric oncology providers will increase altruism scores and directly correlate with an increase in seasonal influenza vaccine acceptance. We aim to explore the overall effectiveness of this educational intervention, and also aim to explore whether there may be an identifiable subpopulation most amenable to this type of intervention based on baseline altruism score, race, educational level, or political affiliation.

Objectives

Specific Aim 1: To identify associations with influenza vaccine hesitancy, including parental demographics and altruism score, in families with healthy children attending two pediatric practices.

Specific Aim 2: In the cohort of families with baseline vaccine hesitancy, to assess the effectiveness of a pilot educational intervention focusing on the development of herd immunity for pediatric oncology patients by measuring:

a. The change in vaccine hesitancy scores pre- and post-intervention.
b. The change in the score of question number 6 on the Vaccine Hesitancy Scale, which uniquely and specifically relates to altruism. We will also compare the change in this individual score

with the change in the other individual question scores, which relate to other realms of vaccine confidence, including safety, efficacy, and trust.

c. The rate of influenza vaccine uptake compared to historic controls from previous influenza seasons.

Exploratory Aim: In an effort to further understand the complex interaction between study volunteers (interviewing medical students) and study subjects, including how unique interactions between the study representative(s) and the study subjects may affect questionnaire responses and vaccine acceptance decisions, we aim to conduct motivational interviews with 20 vaccine-hesitant participants, and with four study volunteers. Each motivational interview will be conducted by Dr. Steven Giles, PhD, Associate Professor and Chair of the Department of Communication at Wake Forest University.

We aim to explore the relationship between baseline influenza vaccine hesitancy rates and baseline altruism scores. Effectiveness of our intervention is dependent on parental altruism levels; therefore, we also seek to determine if there is an association between parental altruism and vaccine hesitancy for their children.

Methods and Measures

Setting:

Study subjects will be recruited from two Wake Forest University Baptist Medical Center general pediatric practices: Westgate Pediatrics and Pediatrics - Ford, Simpson, Lively, and Rice. Westgate Pediatrics is located at 3746 Vest Mill Rd, Winston-Salem, NC 27103. Westgate serves a diverse population, with approximately 50% of patients receiving Medicaid services. Pediatrics - Ford, Simpson, Lively, and Rice is located at 2933 Maplewood Ave, Winston-Salem, NC 27103. This latter practice serves a large population that is generally of a higher socioeconomic status than Westgate Pediatrics, with approximately 25% of patients receiving Medicaid services. Study volunteers will be Wake Forest School of Medicine medical students in their 4th year who volunteer to participate in this project as credit for a 4th year elective rotation.

Design:

A single-arm prospective cohort study will be conducted. The study will enroll as study subjects legal guardians of children who are influenza vaccine-eligible to measure their vaccine hesitancy scores, altruism scores, and the impact of an educational intervention focused on herd immunity on the guardians' vaccine hesitancy score.

Inclusion Criteria:

All legal guardians of children aged 6 months and up who are influenza vaccine-eligible and present to the pediatric clinic.

Exclusion Criteria:

Legal guardians of children who are not influenza vaccine-eligible including children less than 6 months of age, children on immunosuppressive medications, and children with underlying medical conditions resulting in an immunocompromised state.

Sample Size:

Specific Aim 1: baseline vaccine hesitancy is 25%[47]. Clinically meaningful difference in hesitancy is defined as 15%. This difference can be detected with 80% power with 250 subjects per group.

Specific Aim 2: We anticipate our intervention could reduce vaccine hesitancy from the national baseline of 25% to 15% on the post-intervention survey. Identifying this reduction from 15% to 15% in paired proportions with 80% power requires enrollment of 312 subjects who complete both tests (i.e. enrolling 312 subjects identified as vaccine-hesitant).

Exploratory Aim: Motivational interviews with study subjects (20) and study volunteers (4) will not be powered or statistically analyzed.

Interventions and Interactions

We will conduct a prospective cohort study of families with children aged 6 months and up who are eligible to receive the seasonal influenza vaccine. Subjects who consent to this study will answer questions which will include demographic questions, a baseline 20-item Altruism Scale, and an 8-item Vaccine Hesitancy Scale. The 20-item Altruism Scale will be scored based on a 5-point Likert scale, with each question scoring from 1-5, then added together to give a cumulative score. Higher scores indicate higher altruism. The Vaccine Hesitancy Scale will be scored as previously described: scoring responses for each item will be scored as follows: strongly agree = 1, agree = 2, disagree = 4, and strongly disagree = 5, such that higher values always indicated greater hesitancy. We will then calculate the average score of the 8 items included in the scale, and use the pre-defined average score of ≥ 3 as "hesitant." Subjects identified as vaccine-hesitant based on a Vaccine Hesitancy Score ≥ 3 will be given an educational handout and provided a standardized, brief educational session overviewing the educational handout. At the end of the doctor's visit, subjects will complete a second identical 8-item Vaccine Hesitancy Scale.

We will also conduct a retrospective chart review of all patients who participated in the initial survey to determine whether the child received the influenza vaccine. Retrospective chart review will also be conducted to estimate the influenza vaccine acceptance rates for each pediatrics practice over the same time period from one year prior.

Two study volunteers will be at each pediatric clinic. A volunteer will approach an eligible parent/guardian in the waiting room prior to their scheduled appointment and obtain informed consent to participate in the study. A consenting subject will complete the Vaccine Hesitancy Scale[47] orally with the study volunteer. The Vaccine Hesitancy Scale is positive if the average of all questions is greater than or equal to 3. When the study volunteer is inputting and grading the Vaccine Hesitancy Scale in a REDCap survey tool on an iPad, the subject will complete the Self-Report Altruism Scale[48] and several demographic questions on paper. If the guardian screens positive for vaccine hesitancy (i.e., vaccine hesitancy score average ≥ 3), they will be given the informational handout along with a brief script. The parent will have the opportunity to review the intervention in the waiting room and during the visit while the provider is out of the room. If the guardian was deemed vaccine hesitant and was given the intervention, the study volunteer will remain at the nurse's station and wait for the visit to be completed. Once the family is finished, the study volunteer will approach the participant once again and complete the Vaccine Hesitancy Scale orally prior to check out. The subject's child's electronic health record will then be accessed to document whether that patient received the seasonal influenza vaccine that day.

Following study volunteer participation and subject participation in the study, up to four study volunteers and up to 20 vaccine-hesitant study subjects will be contacted by Dr. Steven Giles, PhD, to request an interview. The interviews will take place virtually, by phone or video, by Dr. Giles. Study subjects will have already provided written consent to this interview, but Dr. Giles will review the purpose of this phone call and provide an opportunity for study subjects to opt out. All study volunteers will be provided a Study Information Sheet when they orient as study volunteers on this project, which details the purpose of the research project and that up to four of the volunteers will be interviewed following their participation. This is not mandatory; it is voluntary. For study volunteers, Dr. Giles will review/re-provide a Study Information Sheet, detailing the purpose of the interview, but there will be no written consent for the study volunteers.

Analytical Plan

For Specific Aim 1, our primary outcome is vaccine hesitancy, which is dichotomized as hesitant (mean score ≥ 3) or not hesitant (mean score <3) based on results of the Vaccine Hesitancy Scale. Exposures will

include general demographic and clinical characteristics along with the Self-Report Altruism Scale (expresses as a continuous score from 20 to 100). The children's clinical status will be categorized using the Pediatric Medical Complexity Algorithm v3.1[49]. Results will be analyzed initially using descriptive statistics to determine the prevalence of hesitancy. Associations between hesitancy and potential exposures will be assessed using chi square or ANOVA. Associations found to be statically significant in the bivariate analysis will be incorporated into a mixed-effects multivariable logistic regression model, which will treat practice location as a random effect. A p value of 0.1 will be used for inclusion of variables in the model; otherwise, a p value <0.05 will be the cutoff for statistical significance.

For Specific Aim 2, our primary outcome will be the change in vaccine hesitancy scores pre- and post-intervention, which will be assessed with a paired t-test or Wilcoxon signed-rank test, following review of the score distribution. We will also measure the change in Question #6 (the only Altruism-specific question on the questionnaire) independently, and also compared with each other individual question on the questionnaire, and pre- and post-intervention change will be assessed with a paired t-test or Wilcoxin sign-ranked test, following review of the score distribution. As a secondary outcome, the rate of influenza vaccine uptake will be compared qualitatively to historic controls.

For the Exploratory Aim, we will capture qualitative data and seek trends. No statistical computation will be done on these data.

All data will be entered directly into a Research Electronic Data Capture database and analyzed using SAS v9.4 (Cary, NC).

Human Subjects Protection

Risks for participation are not more than minimal. There is risk of accidental unauthorized release of identifiable personal information. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. Participation in a post-study interview by the study volunteers will not require written consent, but it is voluntary. The grading for the elective course is Pass/Fail, and will be exclusively based on their participation in the actual study, and not the post-study interview, which is voluntary.

Subject Recruitment Methods

All parents who present to either pediatric clinic with children 6 months and up who are eligible for the flu vaccine will be eligible to participate in the study. Two student volunteers will be at each clinic for the recruitment process during flu season (between October and December depending on volunteer schedule availability). A volunteer will approach any parent(s) in the waiting room prior to their schedule appointments to recruit for the study regardless of gender or race/ethnicity.

For the retrospective chart review, there is minimal risk involved to participants. All protected health information will be de-identified prior to data analysis and publications; subject identity will be known only to the study staff. Subjects who participated in the initial arm of the study will be included in the chart review to determine further demographic data and whether the child received the flu vaccine.

Informed Consent

Signed informed consent will be obtained from the parent/guardian for the parent's participation in the study and for permission to access EMR data for their child. A study volunteer not actively involved in the child's medical care will obtain the informed consent. The informed consent will be obtained in person in the waiting room of the outpatient pediatric clinic prior to the scheduled clinic visit.

A Study Information Sheet will be provided to the study volunteers when they orient to their roles on this project, including that they may be asked to be interviewed by Dr. Giles following their participation. They will be told this is voluntary, and will have no bearing on their grade. Immediately prior to their interview, Dr. Giles will again review the study information sheet with the study volunteer, and ask for permission to proceed with the interview. No written consent will be obtained from the study volunteer.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. All of the individual participant data collected during the trial, after deidentification, will be available. The Study Protocol, Statistical Analysis Plan, and Informed Consent Form will also be available. All data will be available beginning 9 months and ending 36 months following article publication. The study team intends to share with researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals may be submitted up to 36 months following article publication. Subject identifying information will be destroyed three years after study publication by removing the dataset from REDCap, consistent with data validation and study design, producing an anonymous analytical data set. Direct data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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