Study Protocol

Title of Project: A Message Framing Intervention for Increasing Parental Acceptance of Human Papillomavirus Vaccination
NCT #: NCT03856437
02/10/2021

1. Abstract:

The overall goal of this project is to test the relative efficacy of gain- versus loss-framed messages in promoting adolescent HPV vaccination acceptance among African American parents. This project will provide useful insights into the design of psychologically targeted adolescent HPV vaccination messages for African Americans.

2. Subject Selection:

a. **Recruitment:** Participants will be recruited from online panels provided by survey companies.

b. **Eligibility Criteria:** Participants must meet the following criteria: 1) be at least 18 years old; 2) self-identify as African American; 3) be a custodial parent or caretaker of at least one child who has not initiated or completed the HPV vaccine series.

c. **Rationale:** African American women are more likely to develop cervical cancer and die from cervical cancer, a disease that can be prevented from the HPV vaccine. Understanding effective methods of communicating to African American parents about the importance of HPV vaccination is therefore critical.

d. **Enrollment Numbers:** We plan to enroll approximately 2,000 participants.

e. **Rationale for Enrollment Numbers**: A large sample size ensures adequate statistical power to detect even small effect sizes.

3. Procedures:

Participants will complete a computer-assisted survey. In the survey participants will first answer questions related to their beliefs about HPV and the HPV vaccine, as well as other background information. Then they will be presented with a gain-framed, a loss-framed, or a non-framed HPV vaccination message. After message exposure, they will answer questions related to their attitudes toward HPV vaccination, intentions to vaccinate their children, as well as other message response measures. The survey will take approximately 20 minutes. Participants will be compensated by the survey companies in accordance to their policies.

4. Risks:

There are no known risks associated with this research. Some participants may be uncomfortable answering some questions. All participants have the option of not responding to questions they do not wish to answer.

5. Benefits:

There are no direct benefits to participants. This research will result in an improved understanding of the design of effective educational materials about HPV vaccination.

6. Confidentiality:

Responses of the participants will be confidential. The questionnaires will not contain any questions that ask for information that could be used to identify the participants. The online survey will be anonymous. Only approved researchers will have access to the data collected. Data collected will be stored in a password-protected computer located in a room with limited access. All research data collected from this study will be stored for 10 years after the study and allow the research team to thoroughly analyze the data for research purposes only. The research data will be destroyed afterwards (removed from computer hard disks).

7. Consent Process:

Before the participants begin the study, they will be asked to read a consent form containing information on the purpose of the study, the procedures involved, confidentiality, and potential risks and benefits. It will also state that participants can withdraw from the study at any time if they feel uncomfortable with the survey. Participants will have the choice to continue with the study or not after reading the consent form.

8. Conflict of Interest:

There is no conflict of interest.

9. HIPAA Compliance:

N/A

10. Research Outside of the United States:

N/A

11. Research Involving Prisoners:

N/A