

Study Protocol

Date: 7/31/2018

Title:

An Evaluation of Tailored Messages to Address Parental Questions About HPV Vaccination

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Study purpose and procedures:

The purpose of this study is to investigate mother's attitudes about vaccinating their 11-14 year old children against the human papillomavirus (HPV). Among mothers who do not plan to vaccinate their child, we will assess the influence of brief videos tailored to their questions and concerns.

Attitudes will be assessed through a Web-based survey administered by Survey Sampling International (SSI). The projected sample size is approximately 3,500, comprising mothers or female guardians of at least one child aged 11-14 who live in the United States. The survey will take no more than 20 minutes to complete. Mothers who indicate that they do not plan to vaccinate their children in the next year will be randomized to view brief videos tailored to their questions or concerns about HPV vaccination. The outcome of interest is intention to vaccinate. Mothers who have vaccinated their child or intend to vaccinate their child will be asked a separate set of questions relevant to this information.

Many of the survey items cannot be "skipped" because (1) the survey items primarily assess attitudes and beliefs, (2) the questions are not of a sensitive nature, (3) responses are anonymous, (4) participants have indicated their desire and willingness to respond to surveys such as this one by virtue of their enrollment as an SSI panel member, (5) there is no pressure for participants to complete the survey, and (6) participants may opt to withdraw from the survey at any time after beginning the survey.

Mothers who indicate that they do not intend to vaccinate their child against HPV will be asked about their questions or concerns regarding HPV vaccination (from a pre-populated list of common concerns). Mothers will be randomized to one of three arms: 1. A general information video; 2. A video addressing their top concern; or 3. One or more videos addressing all of their concerns. Each video is less than 50 seconds in length.

Inclusion criteria:

Mothers or female guardians will be eligible to participate if they have a child 11 - 14 years of age.

Protection of participants' privacy

SSI randomly invites panel members meeting the inclusion criteria listed above and provides them with a link to the survey. We will not be given any individually identifying information about respondents from SSI, and respondents will be assured that their responses will be kept anonymous. SSI does not link

identities to survey responses. Additionally, if a participant initially opts to participate in the survey but later opts to withdraw while in the process of completing the survey, all survey responses that they have provided up to the point of their withdrawal are automatically removed from the survey database. However, the participant's anonymized survey ID, survey beginning/end date/time, and variable indicating that the participant opted to withdraw from the survey will be recorded in the database, so that the researchers may accurately assess the number of participants who opted to withdraw from the study.

Recruitment:

Data will be collected from respondents via a web-based survey. 3,500 respondents will be recruited by SSI, which is an international survey response recruiting firm that has a panel of respondents who have volunteered to participate as survey respondents. SSI will be responsible for sending invitation emails to a random sample of panel members meeting the eligibility (inclusion) criteria. Panel members will be provided with a survey link. Upon visiting the survey link, they will be provided with an introduction page briefly describing the purpose of the study, what their involvement will entail, the confidential and voluntary nature of their participation, and study contact information.

Compensation:

Participants are not directly compensated by the investigators; rather, each respondent's name is entered into a quarterly drawing by SSI to win various prizes from SSI and respondents also receive points for each survey they complete, which can then be redeemed for various prizes (respondents' names are entered each time they complete a survey). Identities are in no way linked to survey responses and are never shared with the investigators. The proposed compensation arrangement is not excessive and is standard for survey companies such as SSI.

Data Analysis:

The effect of intervention group on intent to vaccinate will be evaluated with generalized linear models, adjusting for any baseline characteristics that are distributed unevenly (at $p < 0.05$).