VIEWS ON COVID-19 AND VACCINATION STUDY PROTOCOL

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1. Title

If We Build It, Will They Come? A Pilot Study to Develop and Test Messages to Maximize Uptake of Coronavirus Vaccine When Available.

2. External IRB Review History*

N/A

3. Prior Approvals:

N/A

4. Objectives*

This study aims to develop evidence-based messages that effectively mitigate concerns of people at risk for not being vaccinated against COVID-19, with the ultimate goal of maximizing vaccine uptake in vulnerable populations when a COVID-19 vaccine becomes available. To achieve our goals, we will accomplish two objectives:

(1) Gain an in-depth, current understanding of factors influencing vaccine hesitancy in vulnerable populations.

(2) Develop and test messages that effectively address concerns of vaccine-hesitant subgroups at risk for declining to be vaccinated, providing an evidence base to inform future outreach efforts.

5. Background*

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has rapidly instigated a global pandemic. As of this writing, there are approximately 65 million documented cases of infection worldwide, and over 1.5 million deaths. In the United States (US), coronavirus disease 2019 (COVID-19) has disrupted the economy, overwhelmed healthcare system, led to widespread school cancellations, and caused more than 274,000 deaths since March 2020. A vaccine against COVID-19 is widely viewed as the key to controlling the pandemic and enabling a return to “normal” life. Vaccine development is proceeding at an unprecedented pace with 10 vaccines currently in phase 3 trials. Experts have projected that a safe and effective vaccine may be available by mid-2021. At the same time, a growing body of evidence indicates that a significant proportion of adults in the U.S. may not accept vaccination against COVID-19. Even more alarming, COVID-19 vaccine hesitancy (refusal or reluctance to accept a vaccine) appears to be increasing as the vaccine approval process becomes increasingly politicized. Just as efforts to develop vaccine production and delivery capacity have been undertaken in advance of having a proven effective vaccine, parallel efforts are needed to identify effective messages and communication strategies to overcome COVID-19 vaccine hesitancy.

Our team recently surveyed a nationally representative sample of approximately 1,000 adults in the United States and found that only 57% intended to be vaccinated when a coronavirus vaccine becomes available.[1] This percentage was even lower among people who identified as Black or Hispanic (39% and 43% respectively), those with a high school education or less (46%) and those in the lowest income groups (49% of those reporting a household income of $30,000 or less, compared to 72% of those reporting a household income of $100,000 or more). We asked those who indicated they would not or might not get vaccinated for their reasons and found that some individuals may be willing to be vaccinated if provided specific information about the vaccine such as side effects and effectiveness. Others expressed generalized skepticism, fear and distrust of vaccines, with some even referring to anti-vaccine conspiracy theories. Our findings are consistent with an extensive body of research documenting that people often do not behave rationally and highlight the urgent need to proactively develop and test interventions to maximize vaccination rates when a coronavirus vaccine becomes available.[2-6] To address this need, our goals in the present study are to create and test targeted messages to address the concerns of subgroups of people at risk for not being vaccinated, with the ultimate goal of maximizing vaccine uptake when a vaccine for COVID-19 becomes available. We will accomplish this by working with an existing online panel of volunteers, which will allow efficient, focused data gathering. Results of the first round of the survey will provide a nuanced, current description of how vulnerable adults perceive the coronavirus and forthcoming vaccines, which will be used as the basis for developing messages and communication strategies. In the second round, we will test different versions of messages intended to reduce vaccine hesitancy and support uptake. This project will ultimately result in a set of tested, evidence-derived messages about vaccination for COVID-19. We will make these messages available, together with evidence how these influence members of vulnerable populations' understanding of vaccination, and disease risk, as well as intent to be vaccinated. The messages will be freely available for use by organizations and providers seeking to improve communication about a coronavirus vaccine.

6. Inclusion and Exclusion Criteria*

Inclusion Criteria.

- Adult (age 18 and over) who are members of an online panel (Prolific). Members of this panel joined the panel specifically to receive invitations to participate in research surveys and similar activities.
- Able to complete an online survey in English.

Exclusion Criteria.

- None

Children

This study will not include children. The study is restricted to adults aged 18 and over.

Prisoners

We will not knowingly conduct research on prisoners, however it is possible that prisoners are members of the existing internet research panel.

Pregnant Women

It is possible that data will be collected on pregnant women as they may have enrolled for the existing internet research panel which we will use.

Non-English speaking subjects

Participants will need to be able to complete an online survey in English. Due to the nature of the study (internally funded) we will not have the capacity to translate the survey into other languages.

7. Study-Wide Number of Subjects*

N/A; this is not a multi-site study.

8. Study-Wide Recruitment Methods*

N/A

9. Study Timelines*

Individuals who are members of an online research panel will be invited to complete an online survey. The survey will take approximately 20 minutes to complete. Because the topic (COVID-19 vaccine hesitancy) is rapidly changing, we may re-contact some participants to allow longitudinal data collection. Participants will be notified that they may be invited to respond to additional studies; participation in each survey will be voluntary. Invitations to a second survey will be distributed through the online panel platform, and will not require participants to provide any identifiable information to the research team. We anticipate completing this study in one year.

10. Study Endpoints*

Primary endpoint: Intent to be vaccinated against COVID-19.

Secondary endpoint: Predictors of intent to be vaccinated against COVID-19, including knowledge, attitudes, and beliefs about COVID-19, vaccines (in general), and a COVID-19 vaccine.

11. Procedures Involved*

Participants will be recruited from an existing online research panel (Prolific). Prolific verifies participants at the time they register with Prolific and assigns participants a Prolific study ID. Prolific will post the invitation to our survey to the dashboard of eligible participants registered on their site. The survey title, duration, and payment amount will be displayed in the dashboard of eligible participants, as well as a link to the online survey. Surveys will be programmed in Research Electronic Data Capture (REDCap) - an online survey application. Participants' survey responses will be collected anonymously.

If a participant elects to respond to the survey, they will be taken to a REDCap survey. The survey will include questions that assess participants' intent to be vaccinated when a COVID-19 vaccine is available, as well as participants' knowledge, beliefs, and attitudes about COVID-19, vaccines in general, and a COVID-19 vaccine.

In one section of the survey, we will ask participants to imagine they are at a routine follow up visit with their primary care provider. Participants will be randomized to several brief, hypothetical messages from their provider regarding vaccination after which participants' intent to be vaccinated will be re-assessed. See table 1 for questionnaire domains and sample items.

Table 1. Sample Survey Domains and Items

Sample Domains	**Sample Items**
Personal risk I – disease overall	What is your **best guess** as to whether you will get the coronavirus within the next **6 months**?
Vaccination intent	When a vaccine for the coronavirus becomes available, will you get vaccinated?
Message testing	Imagine that you are seeing your doctor for an annual physical exam. Near the end of the appointment, your doctor says, "We have the COVID-19 vaccine available today. **I've taken a careful look at the studies and the results are very impressive.** They show that it's very safe and very effective. This is the best way to **protect yourself** from this virus. I recommend you get it."
Risk Beliefs	The COVID-19 pandemic is a hoax.
Knowledge of COVID-19	If 100 people your age were infected with COVID-19, about how many would need to be hospitalized?

Attitudes towards vaccine - general	Vaccines are one of the most important medical advances ever developed.
Attitudes towards COVID-19 vaccine specifically	The COVID-19 vaccine has been developed too quickly.
Vaccine knowledge	Vaccines don't work against viruses.
Vaccination norms and values	Most of the people I know will get vaccinated against COVID-19.
Personal experience with COVID-19	Have any of your friends and family members have become very ill or died of COVID-19?
Vaccination behavior (past and future)	Thinking back over the past 5 years, how many of those years did you get a flu shot?
Demographics and other characteristics	Age, gender, education, etc.

Participants will receive a small payment as recommended by the panel vendor, valued at approximately $3.00 to $3.50 for a 20-minute survey. The final amount will depend on the final estimated survey completion time and an hourly rate selected to maximize participation and the number of participants. The hourly rate range required by the survey vendor is $6.50/hr-$12.50/hr). Payment will be made directly by the online research panel to participants after survey completion.

12. Data and Specimen Banking*

No specimens are being collected as part of the research. We will maintain a limited dataset for analysis at the completion of the study.

13. Data Analysis and Management*

Data will be stored on University of Massachusetts Medical School computers and/or Meyers Primary Care Institute computers. We will not collect any information that will allow us to identify participants. All contact with participants will be via the online vendor, which has assigned a unique study id to each participant.

We will examine response distributions of each variable and associations between variables (e.g., correlations between perceived personal risk and tendency to engage in protective behavior).

We will test the impact of different communication strategies that providers might use to recommend COVID-19 vaccination using t-tests, chi-squares, and regression models to compare vaccination intent according to which message participants received. Appropriate statistical tests will be chosen depending on specific variables and their distributions.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects*

The proposed study involves no more than minimal risk to participants.

To ensure that participants have access to current, accurate information about the coronavirus, we will provide the web address to the main Centers for Disease Control (CDC) website (https://www.cdc.gov/), which contains information and resources related to the coronavirus pandemic.

We will await review and approval by the Institutional Review Board of the University of Massachusetts Medical School prior to the initiation of any study activities.

We will not receive or request information that would allow us to identify participants. We will have only their responses to the survey questions, and their Prolific study ID (which consists of a string of approximately 20 numbers and letters). We will never have access to a key which would allow us to link the Prolific id to participants' name, email, address or phone number. All data will be collected electronically via the Prolific online platform and REDCap. All computerized data will be kept on secured computers or networks. These data will be accessible only to research staff, using confidential usernames and passwords. Published data will not contain any individual identifiers.

15. Withdrawal of Subjects Without Their Consent*

Because our data collection from participants will occur via survey, we do not anticipate the need to actively withdraw participants. Participants whose response is very incomplete or shows significant signs of inattention to the survey, highly contradictory responses, or nonsensical text in response to open ended items will be omitted from analyses.

16. Risks to Subjects*

Potential Risks to Subjects

The proposed study poses minimal risks to the study subjects. The risks that do exist fall within three categories: a) risks associated with participating in research surveys; and b) risks associated with the research content area. Our procedures for protecting against such risks are described below.

Risks Associated with Participating in Research Surveys. Subjects will be recruited to participate in online surveys. It is possible some participants will perceive these as be time-consuming or frustrating to complete. Our procedures for protecting against such risks are described below.

Risks Associated with the Research Content Area. We recognize that the content of the survey (i.e., reaction to the coronavirus and its dangers) may be emotionally sensitive. Our procedures for protecting against such risks are described below.

Adequacy of Protection Against Risks

Informed Consent

All participants will be provided with the essential elements of informed consent prior to the start of the survey as approved by the IRB. Participants will be informed that participation is voluntary and that they may discontinue participation at any time without consequence. Participants may decline to participate in the study or refuse to answer certain questions.

The first page of the REDCap survey will include the following introductory paragraph:

> You are being asked to participate in a research study. Participation involves responding to an online survey about COVID-19. We think it will take approximately 20 minutes to complete the survey. You will be paid $3.50*. The survey is anonymous. The research team will never see your name, email, or any information that would allow us to identify you. Participation is voluntary and you can leave the study at any time. If you have any questions about the research, you may contact Kimberly Fisher via email [study email@umassmed.edu]. By continuing, you are consenting to take part in this research study.

IRB Approval

Recruitment methods, standard informed consent procedures, and the entire study protocol will be reviewed and approved (or deemed exempt) by the University of Massachusetts Institutional Review Board to ensure the protection of human subjects. The study will not begin until IRB approval/exemption is obtained. The study will continue to be monitored and reviewed by the IRB for the duration of the study if not exempt.

Vulnerable Subjects

We will not target any specific vulnerable population for this study. Children will not be included. It is possible that a pregnant woman may participate, but we reiterate that the study involves only participation in an anonymous online survey, with no more than minimal risk.

Protections Against Risk

Minimizing Risks

The training and monitoring of all study staff performance in accordance with an IRB-approved study plan will be the responsibility of the Principal Investigator. All efforts will be made to minimize risks and participant inconvenience.

Risks will be minimized by 1) ensuring participants are informed of the study activities in advance; and 2) providing participants with resources to contact if they have any questions or require assistance.

Protection for Risks Associated with Participating in Research Surveys

Subjects will be recruited from an existing internet panel to participate in online surveys. The online research panel has been established with the explicit intent to engage members in completing online surveys, and **all participation is fully voluntary**. For the present study we will keep estimated survey completion time to 25 minutes or less. Participants will be informed of the estimated completion time in advance so that they may consider it in deciding whether to participate.

Participants will be informed that participation is voluntary, and that they are free to not respond or to terminate involvement at any time.

Protection for Risks Associated with Potential Loss of Confidentiality

All persons collecting, or handling data are trained in human subjects' procedures, confidentiality and privacy protection. All investigators and project staff are required to receive and complete IRB and HIPAA training.

Protection for Risks Associated with the Research Content Area

We recognize that the content of the survey (i.e., the coronavirus pandemic) may be emotionally sensitive.

Content of Surveys/Questionnaires. Items will be modeled on existing survey instruments and items. Our study team includes a psychometrician with extensive item writing experience as well as expertise in health literacy and communication (Kathleen Mazor EdD) and a critical care pulmonologist (Kimberly Fisher MD) with expertise in having difficult medical discussions (e.g. physicians, healthcare communications researchers). Participants will be free to skip any question they are uncomfortable answering. We will provide reputable resources for information (e.g. the CDC website) for participants to turn to for unanswered questions.

17. Potential Direct Benefits to Subjects*

There are no known direct benefits to individual participants from this study. Some participants may feel that participating contributes to scientific knowledge in general.

18. Vulnerable Populations*

Please refer to our answers to section #6. All study participants will be members of existing internet research panels.

19. Multi-Site Research*

N/A

20. Community-Based Participatory Research*

N/A

21. Sharing of Research Results with Subjects*

There are no specific plans to share results with study subjects; study procedures do not include any type of diagnostic testing.

All results shared in published research will be in aggregate or summary format and will not include identifiable information about participants. Published results will be available to the greater community at large, including study subjects.

22. Setting

The research activities will be conducted via email and an online survey, using an online research panel.

23. Resources Available

All research personnel listed on this study will read the protocol and receive the appropriate supervision and possess the appropriate experience (both higher education and related work experience) needed to fulfill their roles and complete their responsibilities for this study. All investigators and project staff are required to receive and complete IRB and HIPAA training.

The Principal Investigator will oversee all personnel and all research activities conducted within this study.

The Principal Investigator will have responsibility for the overall conduct of the project. She will have primary oversight of all study personnel. She will participate in the design and the execution of the study analyses and will be responsible for the reporting of study results. The Principal Investigator has extensive experience and expertise in survey methodology.

The Co-Investigator(s) will work closely with the Principal Investigator on all aspects of the design and execution of the proposed study.

The Programmer will perform a range of programming and data management activities essential to conduct of the project. S/he will develop study data bases, and perform analyses under the direction of the PI. Programmers at the Meyers Primary Care Institute all hold graduate level degrees and have vast experience working with survey data and other data for research purposes.

The Research Assistant will work under the direction of Principal Investigator, and co-Investigator to assist with all study activities. S/he will assist in managing the administrative

activities of the project. S/he will prepare materials for team meetings, and will facilitate communication between all project staff.

The Research Manager will train and supervise the Research Assistant and will provide guidance and oversight to the study on a day-to-day basis as needed. Research Assistant will receive individual supervision from the Research Manager and will have didactic group meetings with the Research Manager and other Research Assistants.

24. Local Recruitment Methods

All recruitment will be conducted via an online panel as described in #11 above.

25. Local Number of Subjects

We expect to recruit between 1000 and 3500 subjects via the online research panel (Prolific). We note that Prolific reports over 135,000 panel members as of this writing.

26. Confidentiality

The Meyers Primary Care Institute and the University of Massachusetts Medical School both have systems, oversight, experienced personnel, and an organizational culture that supports the appropriate use, access and storage of confidential information. All persons collecting or handling data are trained in human subjects' procedures, confidentiality and privacy protection. All investigators and project staff are required to receive and complete IRB and HIPPA training.

Data for all participants will be kept strictly confidential. All hard copies of research files will be kept in locked file cabinets or a locked file room. Participants will be assigned a code (Study ID) by Prolific (online research panel) to allow for information collection in such a way that the identity of the participants cannot be ascertained by the study team. We (the study team) will not have access to participant names, emails, or information that would allow participant identification. All computerized data will be kept on secured computers or networks. These data will be accessible only to research staff, using confidential usernames and passwords. Only de-identified data will be reported. All data will be used only for research purposes only; published data will not contain any individual identifiers.

Please also refer to section #14 for more information.

Data will be stored securely for use in future research analyses and grant proposals.

27. Provisions to Protect the Privacy Interests of Subjects

Surveys will be conducted online via a vendor (Prolific) who maintains a panel of volunteers who have expressed interest in participating in research. The vendor will not provide any identifiable information to the research team. The collection of sensitive information will be limited to information necessary to conduct the proposed research. Participants may skip any question they prefer not to answer or withdraw from the study at any time.

The research team will not access any protected health information.

28. Compensation for Research-Related Injury

N/A

29. Economic Burden to Subjects

N/A

30. Consent Process

The invitation and/or survey entry page will include the key elements of informed consent. Participants will have the opportunity to accept or decline the invitation. The subsequent actions of continuing to the survey and responding to questions will be considered evidence of consent to participate.

31. Process to Document Consent in Writing

We are requesting a waiver of written documentation of consent (e.g. signature). Since we will not be collecting names or email addresses of participants, signing a consent form could increase risk of loss of confidentiality.

32. Drugs or Devices

N/A

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