You & Me COVID-free

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Purpose of the Study

This is an observational, direct-to-participant sub-study that distributes at-home, self-administered, SARS-CoV-2 antigen testing kits to people in designated communities. Duke will be in charge of the coordination of the sub-study. Adults and children living within the pre-identified communities will be invited to take part in the substudy, provided they meet the inclusion criteria. Potential subjects will self-identify by actively choosing to seek further information about the study via REDCap or by calling the DCRI Call Center. They will be able to participate via REDCap or through the DCRI Call Center. The study will be called You & Me COVID-Free Research Study.

Background & Significance

In the US, > 4 million people have been infected with the SARS-CoV-2 virus and >400,000 died. Infections and deaths, however, have disproportionally affected historically marginalized populations. Early in the pandemic the focus has been on testing to identify symptomatic individuals to reduce morbidity and mortality from infection. As public health measures have scaled up mitigation strategies are increasingly being considered to reduce community spread of infection. The availability of rapid tests for detecting SARS-CoV-2 presents opportunities for rapid, frequent and low-cost at-home testing in asymptomatic populations as part of a broader mitigation strategy that includes protective measures (masking, social distancing, increased hygiene) and contact-tracing and isolation. With 50% or more of infections resulting from pre-symptomatic or asymptomatic transmission, at-home testing may offer an effective option for screening and for breaking chains of transmission. Rapid antigen tests are relatively inexpensive and therefore can be used frequently for detecting infected individuals who are asymptomatic, pre-symptomatic and without known or suspected exposure to SARS-CoV-2. However, even with antigen tests, the implementation of community level testing will be challenging, with an impact that is still to be determined.

The public health crisis of the COVID-19 pandemic continues to rage on across the US. Novel mitigation strategies and community level public health interventions are critical to stop the spread of this virus. One of these interventions is frequent, low-cost, rapid-result, at-home viral screening of asymptomatic and symptomatic individuals. The goal of frequent home testing is to identify SARS-CoV-2 index cases early, trigger isolation and quarantining precautions, and ultimately decrease community transmission. The Centers for Disease Control, through coordination with public health departments, is conducting a public health intervention of frequent home testing, completed in a timeline needed to address the pressing need in high-risk communities. This intervention of home testing requires intentional engagement and a clear recognition of risk. Within pre-selected communities, CDC will distribute at-home, self-collect/self-testSARS-CoV-2 tests with instructions to complete regular testing irrespective of symptoms or exposure history. Previous at-home testing studies have generated inconclusive results, in part due to multiple factors including inadequate community engagement strategies to promote uptake and consistent testing in the target population as well as limited testing and prevention knowledge, attitudes and behavior. This cohort sub-study in a subset of the population will explore the community and human behavior factors in response to at-home testing. Participants in the public health intervention who meet eligibility criteria will be invited to participate in the sub-study, consented, and asked to complete questionnaires aimed at evaluating self-reported social interactions, behaviors, and

health system utilization in response to results from the at-home SARS CoV-2 antigen test. This sub-study will provide participant level behavioral information essential to understanding the relationship between large scale at-home testing and community transmission during the SARS-CoV-2 pandemic and relevant for implementation of public health interventions in future pandemics.

Design & Procedures

This is an observational, direct-to-participant sub-study that distributes at-home, self-administered, SARS-CoV-2 antigen testing kits to people in designated communities. This sub-study focuses on gathering participant-level data to evaluate behavioural determinants of home testing and socio-behavioural mechanisms of SARS-CoV-2 community transmission. As part of the public health intervention, households will receive test kits and included in them will be information about the REDCap surveys and a QR code to facilitate access. Only after the participants have received the testing kits, will they be offered the option to participate in this sub-study. Once registered, if the participant wants to be a part of the sub-study, eligibility criteria will be verified ande-consent will be obtained through REDCap. Push notifications will be programmed using Twilio for adherence to taking surveys. For participants who provide consent to the sub-study, the app will also feature the ability to report the results of their test results, and respond to surveys and questionnaires. As an alternative to REDCap, participants can participate in the study via phone interviews conducted by a centralized study call center. Home test kits will include a QR code for the REDCap surveys and a toll-free number to the DCRI call center/eConsent for those interested in participating. Using scripted interview guides, call center staff will be ready to explain study participation, obtain verbal consent, administer study questionnaires including soliciting test results, and issue phone reminders for participants who chose not to use REDCap. Using NIH Tier-1 Common Data Element (CDE) measures, the surveys and questionnaires will collect data on demographic characteristics, medical history and health status, SARS-CoV-2 testing and symptoms, social interactions, knowledge of prevention strategies, and infection risk, and attitudes towards vaccines.

Participants will be asked to complete a front-door questionnaire to determine interest in completing the study. After completing the swab test, they are asked to take a baseline survey (20 minutes to complete), then 28 days later they are prompted via text and email to take the end-of-study survey (about 1 minute to complete).

Selection of Subjects

In order to be eligible to participate in this study, an individual must sign and date informed consent form. There are no exclusion criterias if inclusion are met. Community selected is Merced County, CA.

Subject Recruitment and Compensation

Through partnership with CCPH, the United Way of Merced County, CA was identified as the lead Community Partner to spearhead the enrollment of this substudy. Using materials created by the study team, they will introduce to study subjects in their region. They hope to enroll approximately 100,000 subjects by providing free COVID-19 test kits, and asking participants if they will answer questions in a

survey for a chance to recieve a gift card. If participants would like to answer survey questions, they will follow a QR code to access REDCap and will be guided through the eConsent process. Participants may be compensated via Amazon gift card (up to $60) as detailed in the consent form.

If a participant is interested in the sub study, they will either call the DCRI call center to verbally consent or will click a link to access REDCap. If they would like to learn more, they will be taken to the consent form, will fill that out and then will complete surveys. If they have questions either through REDCap or website about the sub study, they will be directed to call the DCRI call center to have their questions answered. The compensation schedule is listed in the consent forms as follows:

If the particpant chooses to be part of our study, they will be asked to complete survey questions, and will complete surveys after testing. Combined, the three surveys (1 short survey, 1 detailed survey, and, 28 days later, 1 final short survey) will take about 20 minutes to complete:

For pre-consent survey: Participant has a 1 in 10 chance of receiving a $10 gift

For post-consent surveys: Particpant will be provided gift cards worth up to fifty dollars, and will be paid according to the following schedule:
$25 after you complete Survey 1
$25 after you complete Survey 2
There is no travel time or lost wages incurred as there are no study visits.

Participants will have access to the You and Me COVID-free website, https://youandmecovidfree.org/.

Risk/Benefit Assessment

Study-related risks include potential loss of confidentiality but steps will be undertaken to minimize this risk. There are no interventions involved in this study. The benefit of this study is to learn testing impact on reducing the community spread of the infection, however there is no direct benefit to participants.

Data Analysis & Statistical Considerations

The approach to analysis will be primarily descriptive. Demographics, questionnaire data, and testing results will be reviewed and summarized using graphical techniques and summary statistics. Where applicable, exact method confidence intervals will be computed around point estimates. Trends over time will be evaluated graphically. The proportion of participants adhering to social distancing guidelines after a positive vs. negative test result will be compared using tests of proportion clustered by participants with various levels of intra-participant correlation. Stratified analyses by test or week number will also be performed. We will explore the associations between positive test results and critical behavioral measures using mixed modeling techniques to account for the participant and household correlations. Analyses will be conducted using SAS (SAS Institute, Cary NC) and R with R Studio (R-project). Point estimates with 95% confidence intervals will be reported. The analysis will be done for applicable study populations as described above, and stratified by participant demographics of

interest (e.g., age, gender). There will be a comparison of the proportion of participants that report adhering to social distancing guidelines after positive vs. negative test result.