Evaluating Public Health Interventions to Improve COVID-19 Testing Among Underserved Populations

PROTOCOL; STATISTICAL ANALYSIS; INFORMED CONSENT FORM

NCT05270694

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PROTOCOL

Using a community-based approach, we engaged participants from vulnerable communities in a cohort study focused on at-home COVID-19 testing. Participants received in-person instruction on testing and were provided with at-home COVID-19 test kits while answering monthly surveys on testing use and behavioral factors. By following a community engaged model we aimed to build trust and understanding in order to engage these vulnerable communities both effectively and ethically.

Setting and Participants

We conducted a longitudinal cohort study of at-home COVID-19 testing from March 2022 - November 2023, with recruitment focused on Portland, Maine. We aimed to engage a roughly equal number of participants from the immigrant, housing unstable, and low-income/uninsured communities. Individuals were eligible to participate if they were aged >=18 years and either: 1) an immigrant; 2) currently unhoused or had a history of chronic homelessness; or 3) received services through Portland Public Health (specifically the Portland Community Free Clinic [PCFC], Sexually Transmitted Disease [STD] Clinic, or Needle Exchange). The MaineHealth Institutional Review Board approved the protocol.

Intervention

All participants attended an individual in-person enrollment session with research staff in which they were consented, learned to perform a COVID-19 test, completed a baseline survey, and received five at-home COVID-19 tests. Participants then received five at-home COVID-19 tests every eight weeks for 48 weeks (30 tests total), regardless of whether they used all previous tests; this constituted the "testing program." Participants received their test kits either by mail or in-person at community partner sites or another location selected by the participant to ensure accessibility.

Measures

The baseline survey included study-specific questions regarding COVID-19 test use and behavioral factors (i.e. risk perceptions, attitudes, norms), as well as the RADx-UP Common Data Elements (CDEs), a set of standardized questions used in National Institutes of Health (NIH) funded COVID-19 research to build a repository of COVID-19 data (details of the CDE are shown in Appendix A). Participants then completed a brief survey every four weeks on COVID-19 exposures, symptoms, and their use of COVID-19 tests. Every eight weeks participants completed a longer survey that included additional questions on behavioral factors around COVID-19 testing. The initial eight-week survey also included questions adapted from the validated National Institute on Drug Abuse (NIDA)-Modified ASSIST survey regarding substance use behaviors. In total, each participant completed one baseline and twelve follow-up surveys over the span of 11 months.

NIH translation services translated all recruitment and survey materials into seven languages (Somali, Arabic, French, Kinyarwanda, Lingala, Portuguese and Spanish) representing the top languages spoken by patients of GPH. We securely hosted and stored the surveys on a REDCap database, and distributed the REDCap survey link to participants over email, text, or WhatsApp. If requested, research staff also administered the surveys over the phone or in-person. Participants who did not respond to a survey were sent a reminder email/message up to three times over six days; on day seven they were called by research staff. Participants were considered lost to follow-up if they missed completing three consecutive surveys and could not be reached. Participants

could receive up to $250 in grocery gift cards for their participation in the study: a $50 gift card at enrollment, $20 gift cards every eight weeks for completing surveys, and $40 gift cards for reaching the half-way point and end of the study.

The primary outcome was "desired testing behavior score." In every survey, participants were asked whether, in the last month, they had a close contact exposure to a known case of COVID-19 or experienced symptoms concerning for COVID-19 (reporting yes/no to a list of twelve symptoms), indicating an instance where testing was CDC recommended. Following these questions, participants were then asked if, in the last month, they had taken a COVID-19 test. The "desired testing behavior score" was then calculated as the proportion of surveys in which a participant reported taking a COVID-19 test when they reported an indication to test. For example, if a participant reported a symptom and/or exposure in five of their surveys but only reported testing in three of those surveys, then their desired testing behavior score was 3/5, or 0.6.

Independent variables examined in the analysis included vulnerability groups, behavioral factors, and demographic variables. The four dichotomous vulnerability groupings included: 1) immigrants 2) unhoused or history of chronic homelessness 3) low-income and/or uninsured and 4) substance use. We also calculated a "vulnerability score" for each participant indicating the number of vulnerabilities each participant identified with. The five behavioral factor scores related to COVID-19 testing and illness, measured using 5-point Likert scale questions, were: 1) confidence in ability to use tests 2) perceived severity of illness from COVID-19 3) perceived usefulness of testing 4) norms around testing and 5) commitment to testing. Additionally, we analyzed seven demographic characteristics: age, sex, race, employment status, education level, COVID-19 vaccination status, and self-reported health status.

STATISTICL ANALAYSIS

We performed a descriptive analysis to characterize demographics and vulnerability status of the participants. We also stratified by vulnerability group to describe differences across groups. We examined whether COVID-19 testing behavioral factors differed by vulnerability group by using two-sample t-tests to perform difference testing between group and non-group for each behavioral factor score.

We performed bivariate linear regressions to assess the association between desired testing behavior and each vulnerability, behavioral, and demographic factor. Factors significantly associated with desired testing behavior in the bivariate regressions were then included in a multivariate linear regression; the vulnerability score was also included, despite non-significance in bivariate analysis, as the previous literature and earlier qualitative analysis in our community indicated these categories have a strong relationship with testing. A linear relationship was confirmed by a plot of residuals against the predicted values. There was no evidence of multicollinearity, as assessed by tolerance values > 0.1 and VIF values <10. The assumption of normality was met, as assessed by visual inspection of the Q-Q plot. Analyses were conducted using STATA version 17.0.

	Human Research Protection Program Institutional Review Board **Consent to Participate in a Research Project and Authorization to to use and Disclose Protected Health Information (PHI)**	

STUDY TITLE: *Understanding Factors Influencing COVID-19 Testing and Vaccination in Immigrant, Low-income and Homeless Populations, and Testing Targeted Interventions, Addendum for Aim 3*

PROTOCOL NUMBER or Research Summary Date: *December 22, 2021*

CONSENT VERSION DATE: *September 06, 2022*

HOSPITAL OR INSTITUTION: *MaineHealth*

INVESTIGATOR: *Dr. Kathleen Fairfield*

PHONE NUMBER: *207-661-7611*

SUBJECT'S NAME (printed):_____

Throughout this consent form "you/your" will be used to refer to either you or your child/the participant.

Part I: Key Information About this Research Study

You are being asked to volunteer in a research study. You do not have be in this study. Even if you do agree, you can still leave the study at any time without any penalty, without giving a reason, and will still be able to continue your medical care as usual. Withdrawal or refusing to be in the study will not affect your relationship with MaineHealth, Greater Portland Health, Preble Street Learning Collaborative, the Portland Community Free Clinic, or the Preble Street Resource Center in anyway.

Why is this study being done? This research is being done as a collaboration (working together) between MaineHealth, the NIH, and RADx-UP to address disparities (differences) in Covid testing in underserved populations, to evaluate public health messaging campaigns focused on Covid, and to remove barriers to testing by offering it at strategic locations in these communities.

What is the NIH and RADx-UP??

The NIH stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. The NIH funded (provided financial support) for the RADx-UP program.

RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP, we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

Why are you being asked to be in this research study? You are being asked to take part in this study because you receive care and/or services at one of our partner locations or their affiliates (organizations that we work with), such as: Greater Portland Health, Preble Street Learning Collaborative, the Portland Community Free Clinic, or the Preble Street Resource Center.

How many people will take part in this study and how long will it take? This study will include approximately 150 study participants at MaineHealth and through our partner locations.

How long will you be in the study and how much time will it take up?
We think you will be in the study for about 12 months. The first visit will last about 1 hour. After your first visit, you will be asked to complete surveys each month for a year. The surveys will alternate between a short survey (about 5 minutes) and a longer survey (about 20 minutes).

What will you be asked to do?
If you decide to join this study, we will ask you to complete rapid COVID nasal swab testing when you have had an exposure to someone with COVID-19 (a "close contact") or when you have symptoms that could be consistent with COVID-19, for the year you are involved in the study. The testing kits will be free of charge to you, and will be mailed to you. You will be asked to complete a survey about your results and any symptoms, at home every month. If you test positive, information about you will be sent to the Maine CDC and may also require contact tracing (this is routine and mandated by the state).

If you are currently experiencing homelessness, you will be invited to complete your testing for close contacts or symptoms at the Preble Street Learning Collaborative or Greater Portland Health on the day of the walk-up testing clinic. Study staff will be available to assist you with the surveys.

We will gather data (information) from you directly through surveys.
Examples of the information that we may collect from you or other places include, but not limited to:

• We will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history.

• We will ask you for your Social Security number (SSN) as part of the secure confidential survey at the beginning of the study on an ipad. This is not required. If you agree, we will use your SSN to help us link your data with other data, such as your electronic health record and Centers for Medicare and Medicaid Services, among others. We will not share your SSN with anyone or use it for any other purpose. You may choose not to provide your SSN and still be able to take part in this study.
• We will ask you information about COVID-19, including information about any symptoms (a change in your health) and test results. If you had a positive COVID-19 test, we will ask information about contact tracing (people who may have come in contact with you while you had COVID-19). We will ask about your medical history and if you have or have not had vaccines and why.
• We will ask you information about your health, education, family, home, relationships, and social life, among others.
• We will ask you to fill out confidential questionnaires and surveys in order to collect the information above.

What are the risks or discomforts that are possible from being in this study?
The risks involved with participation in this study are low and may include:
- Accidental disclosure of information. We will prevent this by using a secure database to store your information.
- Nosebleed from testing. This is unlikely; however, we will provide instructions to you and assist you if needed.
- Anxiety from false positive test results. This is unlikely. You will be provided with instructions and you will have contact information for the study team if you have questions or concerns.
- Fatigue (tiredness) from completing any long surveys

What benefits to you are possible if you participate in this study?

The possible benefits you may experience by being in this research are:
- Access to free rapid Covid-19 testing for one year.
- There is an expected benefit to society (our community) from detecting Covid infections and learning about what people think about Covid testing.

If you say no to being in this study, do you have other options for your condition? You may get COVID testing elsewhere if you do not take part in the study. The study team can give you a list of places that offer testing, or you can talk to your care team about other options.
Will being in this study cost you anything?
You will not be charged for any tests or services that are required by the research. The rapid COVID test kits will be provided to you free of charge.

Will you be paid for being in this study? A $50 gift card will be given during the first visit after completing the initial survey. For those who choose to receive their survey by email or mail, we will mail you a $20 gift card for each completed longer survey (sent every two months).

If you complete your survey onsite, you will receive your gift card following completion of your survey (regardless of how many questions you answer). Those who maintain their participation in the study until the half-way mark (6 months), will receive an additional $40 gift card and those who maintain their participant until the end (12 months), will receive another $40 gift card.

See the payment section in Part II of this form for additional information.

If you decide to be in the study, the researchers will tell you about any important new information that is learned during the course of this study, which might affect your condition or your willingness to continue participation in this study.

Part II. Additional Information and Details

A description of this research study will be available on http://www.Clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

IF I AM BEING COMPENSATED FOR BEING IN THIS STUDY
Please check the appropriate box:

__ You are a U.S. Citizen or Resident Alien. If you are paid $600 or more a year from MaineHealth, your social security number and amount paid will be reported to those in charge of taxes (IRS) and you may have to pay taxes on this money.

__ You are a Nonresident Alien. For tax purposes, all payments made to you, including those for your participation in this study, are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by MaineHealth.

___ If you do not wish to be paid for your participation in this study, please initial here: ____

HOW CAN I WITHDRAW FROM THIS STUDY?
You can always choose to stop participating in this study. If you want to withdraw please contact the Investigator listed at the top of this form.

For the information collected prior to your withdrawal the information will continue to be part of the data and included in the final analysis for this research. No new information will be collected.

WHAT WILL YOU DO WITH MY DATA?
MaineHealth will keep your data securely in a local database, and this data will be shared at scheduled intervals (about every 3 months) with RADxUP. This database will include your name, address, date of birth, and contact information to allow us to follow up with you. Your data will be protected at MaineHealth as it will be stored in a private database called REDCap, available only to the study team. After the initial survey, we will store your answers separately from your idenfying information, and link it only with a Study ID. This includes surveys you will fill out every months about results of Covid tests you do at home.

RADx-UP will also keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies.

The DCRI will build two RADx-UP databases (systems that hold electronic information).
The first database will only hold information that can identify you (called identifiable information). This information includes your full name, address, phone numbers, email,birthdate, social security number and medical record number..

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team at MaineHealth, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.

The second database will not hold information to identify you. It will hold all the non-identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

Options to disclose identifiers:
I agree to let the Duke Clinical Research Institute (DCRI) collect the following **identifiable** information:

Name, address, contact information, and date of birth, as stated above:

_____ Yes _____ No
Initials Initials

I agree to let the DCRI collect **my Social Security number** as stated above.
_____ Yes _____ No
Initials Initials

I agree to let the DCRI collect my Medical Record Number as stated above.
_____ Yes _____ No
Initials Initials

I agree to let the DCRI collect **only** my zip code and no other **identifiable** information as stated above.
_____ Yes _____ No
Initials Initials

I agree to be contacted for future research as stated above.
_____ Yes _____ No
Initials Initials

We receive money from the National Institutes of Health (NIH) to do this study. NIH requires that we have a plan in place to share information we gain in this studyWe anticipate publishing the findings of this research and publishers often require that we have a plan in place to share the information we collect during this study.

Your information will only be shared in an anonymous way. Sharing research data helps to translate research results into knowledge, products, and procedures that improve human health. If you provide permission now to share your anonymized information with the database noted below, you may withdraw your permission later without any penalty or loss of benefit. The information will be withdrawn from the database. However, if the information has already been shared with other researchers that information will not be able to be deleted.

WHAT ABOUT CONFIDENIALITY AND PRIVACY?

We will take great care to protect the confidentiality of your data and ensure your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password. However, only study staff who need to see the data will have access to the data, and only to the data they need for research.
- We will take steps to protect your information from others that should not be able to see it.
- When your data are shared with other researchers, they will not have information that can identify you.

• When we are interacting with you, every effort will be made to protect your privacy. To do this, we will be sure that we have a private room when we help you with any of the surveys, and that we will use secure datasets for any surveys done by email.

This research is covered by a Certificate of Confidentiality from NIH. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Permission for the research team to obtain and use your patient health information

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How will the privacy of my patient health information be protected?

There are state and federal privacy laws that protect the use and sharing of your patient health information. By signing this form, you provide your permission, called your "authorization," for the use and sharing of patient health information protected by the Privacy Rule. Authorization includes allowing:

- Your health care providers to share your health information for this research study
- The research team to use and share your health information for this research study.

Health information about you that will be used or shared with others involved in this study may include your research record. Specifically, this will include *your name, address, phone number and/or email address, date of birth, Social Security Number (if you agree), medical*

record number, and information related to COVID exposure, symptoms, and/or testing. Your information may be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others. This may also include any new health information about you that comes from the research tests or procedures described in this consent form. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

The research team and people within MaineHealth who oversee and help administer research may see, use or share your information as needed for the research.

People outside of MaineHealth may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration, the Centers for Disease Control, or the National Institutes of Health), safety monitors, and other investigators and study sites in the RADxUP study.

We cannot do this study without your authorization to use and share your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and share your information only as described in this form; however, people outside MaineHealth who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and sharing of your information has no time limit. You may revoke (cancel) your permission to use and share your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. Send your request to: *Dr. Kathleen Fairfield, 509 Forest Ave., Portland, ME 04102.*

If you do cancel your authorization to use and share your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we shared before you wrote to the Principal Investigator to cancel your authorization.

Your decision to not sign this authorization will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records at MaineHealth.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury contact *Dr. Kathleen Fairfield* at *207-661-7637.*

For questions about your rights as a research participant, or to provide input, contact the MaineHealth Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 661-4474. Alternatively, you may provide comments or ask questions in the Human Research Protection Program Feedback section on our website at http://mmcri.org/ns/?page_id=17782 .

I have read, or have had read to me, the above information before signing this consent form. I agree to take part in this research study. I also give permission to use or share my personal health information for the purpose of this research. I have had the chance to ask questions. I have received answers that fully satisfy those questions.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

(Check applicable box below)
□ *Court-appointed Guardian*
□ *Health Care Proxy (advanced health care directive)*
□ *Durable Power of Attorney*
□ *Family Member/Next-of-Kin*

Witness to Consent of Subjects Who Cannot Read or Write
Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicted his/her consent and authorization for participation (check one box as applicable):
□ Making his/her mark above
□ Other means _____
(fill in above)

_____ _____
Witness for adults unable to read or write Date/Time

Study representative statement
I have fully explained in terms understandable to the subject all of the following: the purpose of this research, the study procedures, the possible risks and discomforts and the possible benefits. I have answered all of the subjects and his/her authorized representative(s) question to the best of my ability. I will inform the subject of any changes in the procedure or the risks and benefits if any should occur during or after the course of the study.

_____ _____
Signature of the Person Obtaining Consent Date/Time

_____
Printed Name of the Person Obtaining Consent

A signed copy of this consent form must be given to each subject entering the study.