Understanding Factors Influencing COVID-19 Testing and Vaccination in Immigrant, Low-income and Homeless Populations, and Testing Targeted Interventions, Aims 1 and 2a/ Addendum to add 2b/3: [3U54GM115516=05S2 RADx-UP]

Introduction/Summary & Background

The COVID-19 pandemic has disproportionately affected people from minority, vulnerable and disadvantaged communities.[1-4] There are likely a variety of reasons for this, including longstanding differences in the experience of marginalized populations in health care and other settings, fears about economic consequences of being diagnosed with COVID-19 and being asked to quarantine, concerns about contact tracing, housing density, work exposures, and differential burden of underlying comorbidities.[5,6] These populations in the US are at a higher risk of acquiring COVID-19 because of poverty, occupation, lack of protective equipment at work, use of public transit, living in multigenerational housing, access to quality healthcare, and both fear and reality of legal repercussions for many immigrants.[1,3,7-9] In general, socially vulnerable populations, many of whom are essential workers, are more likely to acquire COVID-19 and to die from it should they contract it.[3] Despite greater risk of being infected and dying of COVID-19, those in minority, at-risk, and disadvantaged communities are less likely to get tested and vaccinated[10].

Research Focus & Specific Aim Statement(s)

We have a unique opportunity to collaborate with our community partners to create and evaluate the impact of a public health intervention in the area of Cumberland County, Maine, to provide outreach, testing, and vaccination education to a large community of immigrants from sub-Saharan Africa, the Middle East, and Central America, higher-risk low-income people accessing a public health facility (with a sexually transmitted infections clinic, needle exchange, and a free clinic), and individuals experiencing homelessness. We will use qualitative methods to understand beliefs about, and knowledge of COVID-19, and barriers and beliefs about testing and vaccination. We do not have a specific hypothesis. Rather, our research is focused on understanding the current state in our specific populations of interest. In future work (Aim 2b and 3 will be submitted separately, see Cover Letter), we will use what we learn to inform a community-developed and based intervention to engage immigrant, low-income, and homeless communities in testing and vaccine education, and evaluate the impact of this intervention on testing and vaccination uptake in these communities.

Our Aims for this protocol are:

Aim 1. To understand patient perceptions of, fears about, and experiences with COVID-19 testing and vaccination, including booster vaccination in our immigrant, low-income, and homeless populations. We will specifically explore cultural beliefs and attitudes, concerns, barriers, perceived stigma, and bias, expectations, and preferences around COVID-19 testing and vaccination. We will also ask for suggestions for helping their communities avoid COVID-19 infection and be open to and have access to COVID-19 testing and vaccination. *We will accomplish this aim* by conducting semi-structured interviews with individuals from immigrant, low-income, and homeless communities, and also key informants who work closely with these community members.

Aim 2a. To use the data from Aim 1 to develop and pilot test public health messaging in our immigrant, low-income, and homeless populations, and to develop a strategy for a testing program.

We will accomplish this aim by working closely with our community partners to understand the findings, barriers and suggestions from Aim 1, collaboratively develop messaging around COVID prevention and a strategy for an acceptable community-based testing program based on these data and CDC communication tools, and then iteratively refine the messages based on the feedback we receive from community partners and CHW who work with these communities.

(NOTE: no COVID testing will be done until Aim 2b and Aim 3 are approved, which are not part of this protocol)

Significance

To address disparities in Covid testing and vaccination, we need to understand the beliefs and barriers to accepting testing and vaccination among disadvantaged populations, including homeless, low-income, and immigrant populations.

Innovation

Our proposed work is innovative because we will use qualitative data from diverse immigrant, homeless and low-income at-risk populations regarding COVID-19 attitudes and beliefs to build public health strategies to improve testing and vaccine acceptance in diverse, at risk populations within Cumberland County, Maine. We will contribute to evidence base regarding the effectiveness of this public health messaging in immigrant and low-income at-risk communities.

Community Partnerships

Our community partners are very interested in the proposed work and will be integral collaborators on this work. We will hold monthly team meetings with our community partners to get input on all aspects of the proposed research, including recruiting participants and interpreting findings. Our partners are: Greater Portland Health, Prosperity Maine, the Preble Street Resource Center, The Portland Public Health STD clinic & Needle Exchange, and The Portland Community Free Clinic. We also have a relationship with Portland Public Health Minority Health, although they are not one of the four key community partners in this project. We do expect we will work with their Minority Health CHW during the key informant interviews and also as we design our messaging campaign.

Methods

Setting. We will conduct this work in greater Portland, ME, in Cumberland County- population 295,000. The percentage of county residents living at or below the poverty rate is 7.8%. Cumberland County has large immigrant communities from sub-Saharan Africa, Central America, and the Middle East (particularly Iraq and Syria), approximately 6% of the population; approximately 500 individuals experience homelessness on any given night, the sexually transmitted disease clinic serves 3,300 clients annually, and an active needle exchange program exchanging over 199,000 syringes annually.

Methods to Accomplish Aim 1

Overview: We will interview a minimum of 40 individuals from our communities of interest to participate in in-depth semi-structured interviews. This includes 6 unique immigrant populations, recruited through Greater Portland Health and Prosperity Maine. We will also include individuals from 4 other groups: those seeking care at the Preble Street Resource Center or Preble Learning Collaborative homeless health clinic, STD clinic, Needle Exchange, and The Free Clinic: See Table 1, and conduct a thematic analysis of the interviews. Although our minimum planned interviews are 40, if we do not reach thematic saturation in the analysis we will continue to conduct interviews within specific community groups, up to a total of 80, as needed.

Table 1. Study Population Community Group	Number of Interviews
Somali immigrants	4
Latinx immigrants	4
Angolan immigrants	4
Iraqi and Syrian immigrants	4
Burundi and Rwandan immigrants	4
Democratic Republic of Congo immigrants	4
Needle Exchange	4
Free Clinic	4
Sexually Transmitted Infection Clinic	4
Preble Street Resource Center (homeless)	4
Total N	**40**

Participant Recruitment: We will recruit adults aged 18 and older, and all genders. Participants will be recruited with the help of the CHWS employed at Greater Portland Health), team members at the Preble Street Learning Collaborative, team members at Preble Street Resource Center, team members at the STD Clinic and Needle Exchange, team members at the Portland Community Free Clinic, and team members at Prosperity Maine. Interested patients and clients of these organizations will be referred to study personnel on site to obtain more information about the study. If they agree to participate, the interviews will be performed by study staff. Interested participants will also be referred to study personnel by phone. Participants will be given a phone number at CORE they can call to participate in the study and leave a private message.

Semi-structured interviews: Our open-ended questions are based on preliminary observations about testing concerns from a webinar hosted by the Maine CDC and the City of Portland's Minority Health Program in June of 2020, CHW experience in immigrant communities, specific concerns in homeless population in Portland, and the at-risk individuals who receive care at STD Clinic, needle exchange program, and the Free Clinic, though communication with health care providers in these clinics during the course of the pandemic. We have information that some people avoid testing because of reports of concerns about the cost of testing, long waits for results, being asked to quarantine away from family, or fear of not being able to work. The guide will be further refined by the study team, with input from our Community Advisory Board. We will field test the instrument in prior to beginning data collection, and expect it will change over time as is standard in qualitative research. Our goal will be to keep the interview length to under 30 minutes. However, depending on answers and details provided while sharing their experiences, interviews can continue up to 60 minutes. The Interview Guide for participants is included as a separate document.

Procedure: We will have a researcher to conduct interviews on site when our community partners have space for us to interview clients. Team members from the community partners will let potential participants know we are conducting interviews on site that day, to learn about their experiences with COVID, and will introduce anyone interested in participating to the research staff who will have access to a private room.

Interpreter services (using one of two language lines used by MaineHealth) will be called as needed, and paid for from grant funds. We have asked the IRB for an alteration of consent. The interviewer will then review the script (Patient Information Sheet) inviting them to participate, and after permission, begin audio recording the interview. At the conclusion of the interview, the participant will receive the $20 incentive (gift card). No identifiers will be collected, except age, sex, and which demographic group (table 1) the

participant belongs to, so that we can collect a minimum of 4 interviews from each group. We will also offer the option of participation by phone or ZOOM call. If a potential participant chooses this, the Community Partner will give them the Patient Information Sheet_Option2_Phone/ZOOM, and a phone number to call at CORE, in order to sign up to participate. The participant name, phone number, and address will be collected and maintained in REDCap for scheduling and in order to mail the incentive after the interview is completed. After the incentive is mailed, the identifiers will be destroyed. Interviews are expected to last 30-60 minutes, with some variability based upon the provided responses.

Audio recordings will be professionally transcribed and uploaded to MAXQDA for analysis. After analysis, audio recordings will be deleted.

Key informant Interviews:

We will also elicit information from key informants in these communities (staff from the community partner teams and/or community health workers (CHW)). We would include up to 40 key informants, with a goal of 2-4 from each of the representative demographic groups. We will conduct these interviews in person or via Zoom, and record them for transcription and analysis. Interviews recorded via Zoom will be transcribed using the platform's audio transcription feature. During the interviews, we will not collect any identifiable information from key informants aside from which demographic group they work with. The key informants will not receive any incentive for their time as they are employed by the community partners with which the research team is contracting. They would learn about the opportunity to participate from the community partner that employs them via email, with all participation being voluntary. See the document Recruitment Email for Key Informants. The Interview Guide for Key Informants is included as a separate document.

Analysis: All semi-structured interviews conducted using interpreters will be verbally translated to English by the interpreter during the interview, the English segments be professionally transcribed. Interviews conducted in English will be professionally transcribed directly. With assistance from MAXQDA, we will conduct a thematic analysis[11] of transcripts, focused on identifying themes relevant to COVID-19 testing and vaccination within and across groups of participants. We will triangulate our analysis, in order to increase our scope, depth and grounding.[12] Two research team members will independently identify themes, then meet to compare and cross-examine alternative interpretations. If needed, we will conduct additional interviews to reach thematic saturation as noted above.

Methods to Accomplish Aim 2a

Overview: We will use the themes identified from the interviews in Aim 1, the community health worker model,[13] and the health beliefs model to develop a strategy for communication and engagement around vaccination and testing and for implementing testing in the communities of interest.[14] All public health communication around COVID-19 vaccination and testing will follow CDC recommendations.[15] We will engage our community partners and Community and Scientific Advisory Board and the Maine CDC throughout this process.

Trusted Community Health Worker Intervention: The minority health CHWs and the staff at our at-risk partner sites are cultural brokers, and as such they are trusted in the communities in which they reside and work. Community health workers are aware of key contextual factors beyond language in their communities, including culture, immigration status, and acculturation.[13] CHWs from immigrant groups already serve as key sources of information for their community, as they often serve as interpreters and accompany people to medical visits. Many of them have medical training, having been health care workers in their home country. Staff at our care sites for other vulnerable community members serve in a similar fashion. Providers for homeless health at the Preble Street Learning Collaborative help connect clients with primary

care, social services, and housing.[16] Staff at the STD Clinic, needle exchange and the Free Clinic also connect clients with similar services, and serve as trusted brokers for connection to health care. In this manner these community members serve as important role models and teachers around health behaviors such as accepting new health recommendations. The CHWs and staff from our community partner sites will communicate informally and formally with community members in a number of settings. This model is known to improve adoption of healthier behaviors, and to decrease health disparities.[13]

Intervention development. Informed by findings from Aim 1, we will collaboratively develop messaging (based on CDC tools and adapted for our communities) and a dissemination strategy, and plan (but not execute) a community-based testing program.

To collaboratively develop the intervention messaging and dissemination strategy, we will conduct "problem and solution tree" sessions. Problem and solution trees are a participatory process for outlining the different factors contributing to a problem and developing potential solutions (i.e. interventions) collaboratively with stakeholders.[17] The problem is drawn as the trunk of the tree, contributing factors are drawn as the roots (i.e. "root causes"), and branches/leaves as the potential solutions. Our goal is to use the problem and solution tree approach to *translate* the qualitative findings from Aim 1 into a "menu" of potential messages and dissemination strategies. The sessions will be conducted with various types of participants, all of whom have experience working with our populations of interest, such as our community partners, CHWs, key informants who were engaged in Aim 1, and potentially others. Community partners and potential participants will be emailed in advance to invite them to a session and provide them with all the information they need to decide if they would like to participate (see the document Invitation Email for Problem/Solution Tree Sessions). Interested participants will then be provided a summary report of the qualitative findings from Aim 1 (no identifying information will be included, results will be high-level synthesized findings). The sessions will take place over ZOOM, or another video conference platform, and will be facilitated by one of our team members. The session will include a discussion around defining the problem (e.g. low rates of COVID-19 testing among unhoused populations), followed by a brainstorming of "why" this problem exists (identifying all the different factors that contribute to the problem and leveraging the qualitative findings to help explain the "why"), and then a brainstorming of potential solutions to address each root cause (i.e. potential messages and dissemination strategies). See the document Problem/Solution Tree Session Agenda. Sessions will be recorded in order to adequately capture the rich, brainstorming conversations but recordings will only be viewed by study team members. We will then take the co-developed ideas from the various sessions and design a holistic intervention with elements that will focus on all three vulnerable populations and elements that are specific to certain populations for both a general and tailored intervention.

Lastly, we will pilot test and iteratively refine the messages and dissemination strategy based on feedback we receive from our community partners, the CHW, and Community and Scientific Advisory Board as part of our clinical program development. We will iteratively revise the messaging strategy, and seek further feedback until the research team, community partners, and Advisory Board believes we have developed a systematic strategy for messaging. (Note that Aim 2b will be submitted under a separate protocol, as that focuses on testing).

The research team will employ careful note-taking at meetings of the monthly meetings with community partners, CHW, and Community and Scientific Advisory Board. These notes will be used for both program development and program evaluation. This information will supplement the Key Informant Interview data.

Additional Human Subjects Protections Data Collection and management

When conducting interviews with participants, if a participant is >89 years of age, their age will be documented as “>89” rather than their exact age. In addition, their age will be redacted from the transcription.

Recordings will be coded by study staff using a Study ID and kept in a password- protected file by study staff. Coding will only include interview number (assigned sequentially), interview location, and date. This is necessary for assurance of accuracy of transcriptions. In-person interviews with participants will be recorded and audio recordings will be sent for professional transcription. If a participant chooses to conduct an interview by phone or ZOOM, the same procedures will be followed for audio recordings. The participant name, phone number, and address will be collected and maintained in REDCap for scheduling and in order to mail the incentive after the interview is completed. After the incentive is mailed, the identifiers will be destroyed. Interviews with key informants will by coded by interview number (assigned sequentially), interview location (or if by Zoom, the demographic population the key informant works with), and date. The key informant interviews will be conducted via Zoom will be saved as audio-only and sent for professional transcription. Here is the language from the webpage which describes Zoom cloud security (https://zoom.us/trust/security):

Any potentially identifiable information incidentally given by participants will not be included in the transcripts. Transcripts will be accessible only to study staff and kept behind the MaineHealth firewall.

Study staff will not retain any of the original recordings; they will be deleted upon completion of data analysis. It is important that we hold on to recordings until after analysis to confirm accuracy of the transcriptions.

Anticipated Risks and Benefits

Disclosure of the identity of participants tied to their recording is the only possible risk to participants. However, we are taking many steps to assure that this will not occur. No PHI is being collected.

Recordings will be kept in a password- protected file by study staff. We will pay for a transcription service to transcribe all recordings where applicable, and any potentially identifiable information incidentally given by participants will not be included in the transcripts. Transcripts will be accessible only to study staff and kept behind the MaineHealth firewall.

Study staff will not retain any of the original recordings; they will be deleted upon completion of data analysis. It is important that we hold on to recordings until after analysis to confirm accuracy of the transcriptions.

Sharing results

We will share our findings, in aggregate, with public health entities in New England, including the Maine CDC, our community partners and with our population health leaders within MaineHealth and Maine Medical Partners.

Potential problems

We anticipate possible problems such as lack of participation, lack of trust and willingness to share experiences, and participants’ comfort with meeting format (in-person vs zoom). We hope to overcome

these by working closely with trusted community partners who are known to the participants. Also allowing for in-person interviews, particularly for people experiencing homelessness and those accessing public health services (STD clinic, needle exchange) will be valuable in overcoming these barriers.

Project Timeline

	Sept	Oct	Nov	Dec	Jan	
Pilot and Finalize Interview Guide	X					
Recruit Study Participants	X	X				
Conduct Interviews	X	X				
Analyze Data		X	X			
Create & Adapt Messages & engagement strategy			X	X	X	
Refine & Evaluate Strategy				X	X	X
Community Partner Meetings	X	X	X	X	X	X

Understanding Factors Influencing COVID-19 Testing and Vaccination in Immigrant, Low-income and Homeless Populations, and Testing Targeted Interventions, Addendum for Aims 2b and 3: [3U54GM115516=05S2 RADx-UP]

Introduction/Summary & Background

This is an amendment to the initial application to include 2 additional Aims and describes our work and collaboration with the National Institutes of Health and the Duke Clinical Research Institute based upon our grant award.

Research Focus & Specific Aim Statement(s)

The work described here is an amendment to an exemption application, for Aims 1 and 2a, to include Aims 2b and 3. The additional aims will use what we learn from Aims 1 and 2a to inform a community-developed and community-based intervention to engage immigrant, low-income, and homeless communities in testing and education, and evaluate the impact of this intervention on testing uptake in these communities. This protocol includes key elements from our collaboration with the National Institutes of Health (NIH) and the **RADx-UP** program (Rapid Acceleration in Diagnostics in Underserved Populations). RADx-UP is a health research program launched by the NIH to learn more about COVID-19 disease. The Duke Clinical Research Institute (DCRI) is a research group chosen by the NIH to combine the data collected from all national site locations taking part in RADx-UP studies.

This project is extremely time-sensitive and has public health importance because currently it is very difficult for underserved populations to be tested for COVID in the Portland area if they are not able to do drive-up testing. Because our homeless, low-income, and immigrant populations are typically on foot, there is a critical and immediate need to offer free walk-up testing at key sites in Portland where they already receive health care or public health services.

Our Aims for this protocol are:

Aim 2b. To use the data from Aims 1 and 2a to develop, pilot test, and implement a walk-up, COVID-19 testing program to increase testing uptake in our immigrant, low-income, and homeless populations. *We will accomplish this aim* by working closely with our community partners to develop a walk-up testing program and to continuously evaluate its effectiveness. We will also conduct RADxUP surveys at the community testing sites to the degree that we are able, for people accessing walk-up rapid testing there, which is an expectation of RADx-UP funding.

Aim 3. To evaluate the impact of a public health messaging and testing program developed in Aim 2b on rapid COVID-19 testing uptake. *We will accomplish this aim* by following a community cohort of 15 members each, from 10 community groups, conducting surveys every other month from 3 months before the messaging campaign begins to 9 months after, to evaluate changes in knowledge, attitudes, and testing participation over time. This cohort will also participate in a home testing program for Covid-19. *We hypothesize* that knowledge about testing and willingness to participate in testing will increase after exposure to our public health messaging and with access to home COVID-19 testing.

Significance

To address disparities in Covid testing in underserved populations, we need to evaluate public health messaging campaigns focused on Covid, and remove barriers to testing by offering it at strategic locations in these communities.

Innovation

Our proposed work is innovative it will contribute to evidence base regarding the effectiveness of public health messaging and rapid Covid testing in immigrant and low-income at-risk communities.

Methods

Setting & Community Partnerships. We will conduct the aim 2b work in greater Portland, ME, in Cumberland County and the aim 3 work in greater Portland, ME as well as the greater Lewiston and Auburn, ME area in Androscoggin County. The aim 3 work will include the greater areas of Lewiston and Auburn in order to reach more members of the immigrant community for the cohort. We will work with the same community partners for both aim 2b and 3, one of whom has a physical office in both Portland and Lewiston.

Our community partners will be essential to helping us to reach the local underserved population and to develop testing sites. The 3 clinical partners who will host walk-up testing sites are: 1) Greater Portland Health (which includes several locations in and around the greater Portland area), 2) Preble Street Learning Collaborative (which is a MaineHealth entity), and 3) The Portland Community Free Clinic. Also, Preble Street (a community resource distinct from the Learning Collaborative) is a Community Partner who will work closely with our team around clients experiencing homelessness to refer participants and offer testing. Preble Street works closely with local homeless shelters, and we will work in coordination with them to offer testing as needed to people experiencing homelessness where testing is not otherwise available. This may include outreach to homeless clients in local shelters or encampments where care and outreach is provided by our community partners. We have 1 non-clinical site, Prosperity Maine, assisting with referrals for participation and supporting the research team's development of public health messages.

Methods

Aim 2b. To use the data from Aims 1 and 2a to develop, pilot test and implement a walk-up, COVID-19 testing program to increase testing uptake in our immigrant, low-income, and homeless populations. *We will accomplish this aim* by working closely with our community partners to develop a walk-up testing program and to continuously evaluate its effectiveness. We will also conduct RADxUP surveys at the community testing sites to the degree that we are able, for people accessing walk-up rapid testing there, which is an expectation of RADx-UP funding.

Logistics of walk-up testing: We will work closely with our 3 clinical community partners to create and pilot test a COVID-19 testing program. We plan to have access for walk-up testing for COVID using rapid COVID tests at each site. Any rapid test used will be either fully FDA approved or FDA approved under an Emergency Use Authorization (EUA), for example Abbott's BinaxNOW or BD Veritor. We are unable to specify the exact rapid COVID test that will be used due to potential issues with test procurement. Each site will operate for one half day (3-4 hours) each week, upon mutual agreement of the research team and the community partner site. We expect that the day would be the same each week (for example, Greater Portland Health might choose Tuesday morning for their testing time).

Participants:
This study will include adults (18 and over) of any sex, race or ethnicity. They will be people who typically receive clinical care at one of our community partner sites, or who do not have a usual source of primary care services. Any person who approaches study staff for participation that presents with signs or symptoms of significant illness (including non-COVID symptoms) will be referred to clinical services and/or emergency medical services per standard of care. Once treated, these patients may re-screen for participation.

No financial incentives will be provided for the walk-up test participants.

Workflow (document A, Workflow for Walk-up Testing): At each site we will have an EZ-up canopy or a covered area of the building such as a vestibule, a table, an iPad, (document B Welcome signage Walk-up Testing), and necessary supplies. The testing clinic will be staffed by a minimum of two people; a member of the research staff and a clinical staff member designated by the community partner (such as a medical assistant). Clients who are coming for a visit or specifically to access testing will be welcomed and asked via a standard script (document C, Walkup Testing Script) if they are interested in participating in a program offering free testing for Covid that day. Research staff will review the informed consent, and provide a copy to the participant. The staff will explain that in order to access the test, the participant will be asked some basic questions (not to include patient identifiers), while the test is processing.

Consent: We request a waiver of documentation of written consent. We anticipate that several members of the research team will speak other languages including Somali, Arabic, and Spanish. All members of the research team who would obtain consent in another language will be assessed prior to the study starting, by MMC Interpreter services, using a formal assessment of their conversational proficiency (Language Testing International's ACTFL OPI). Participants will review the consent form (document D, Consent for walk-up testing) that includes contact information for the study. The consent form will be translated into the following languages: Spanish, French, Kinyarwanda, Somali, Arabic, Lingala, and Portuguese. Additional language translation will be made if the Community Partner requests that we do so in the future.

The research staff will first enter a local REDCap dataset,(document E, REDCap Enrollment data walk-up Tests) record the date and location of the test (which community partner site), and assess whether the patient has symptoms of Covid or a known close contact using a brief series of questions.

The research staff will show the participant the signage with the instructions for self-collection of the nasal swab, per the manufacturer's instructions (document F, Signage Self Swab Instructions – this is an example for Abbott's BinaxNOW rapid COVID antigen test). The research staff will make clear that the swab only needs to be inserted approximately ½ to ¾ of an inch in each nostril, but this may slightly vary depending on the rapid COVID test used. The participant will hand the research staff (or community partner team member) the test swab, and the staff member will complete the needed steps to get the test results per the manufacturer's instructions. The test takes approximately 15 minutes to turn positive or negative, but this may slightly vary depending on the rapid COVID test used. While waiting for results, the research assistant will ask the client accessing testing to complete a questionnaire on the iPad which includes the required Common Data Elements from the RADx-UP program (document G, RADx-UP CDE without Identifiers), directly into a local REDCap dataset. For walk-up testing participants, we will eliminate identifiers from the questionnaire as follows: questions numbered 157-161, 163-169, 293-294. We will encourage the participant to continue answering the Common Data Elements questionnaire after their test results are back. The participant may stop answering questions at any time. Each entry into the RADx-UP REDCap dataset will generate a new participant Study ID, but as the participant will not be identified, they will not receive a copy of the Study ID for walk-up testing.

Assistance will be offered to all participants and, if needed, the research team member will enter the information for the person. If the person seeking testing does not speak English, and no staff that are present speak their preferred language, a phone interpreter will be offered and accessed on site. The participant will be asked to answer all questions, but advised to skip any questions they do not feel comfortable answering. As noted in the cover letter, the RADx-UP questions are exhaustive and we will determine during a pilot test of the first 10 participants whether it is possible to collect them all. If not, we will request an exception from the RADx-UP program leadership for our walk-up participants to obtain only a subset of the questions. We expect RADx-UP leadership will provide guidance for the questions to prioritize.

Our team includes an informatics engineer (to be named). The informatics engineer will upload the data from MaineHealth REDCap instance to the RADx-UP REDCap instance in intervals specified by RADx-UP. All RADx-UP survey data will be entered into REDCap directly at the testing clinics. The iPADs will be purchased using grant funding allocated for this project and used exclusively for this project.

Results (see also Document A, Workflow):
The participant being tested will be informed of a negative or positive result.

For a negative result, if the person has symptoms or had a recent close contact exposure to Covid, they will be informed that they should obtain a repeat test. We will instruct the participant to repeat the test in the proscribed number of days as per the manufacturer's instructions and per the FDA's EUA. We will provide the participant information on where they can go to obtain this repeat test free of cost, whether at our next available walk-up clinic or another location.

For a positive result, the instructions for quarantining (document H, Instructions for quarantine, Maine CDC) will be provided as well as instructions for home symptom management from the CDC (document I, 10 things to Manage Covid Symptoms). For any positive rapid tests, the community partner will report the required information to the Maine CDC. If the participant does not receive primary care at that site, the community partner (with the participant's permission) will attempt to contact the participant's usual source of primary care.

For participants experiencing homelessness: the Preble Street Resource Center or Greater Portland Health (who both provide care for people experiencing homelessness) will connect the client to a case manager for arranging quarantine housing for homeless COVID-19 positive persons. There is already a process in place for this, and quarantine rooms available, as well as a protocol for transportation. We will defer to our community partners for arrangement of these services as per their usual care.

Our goal is to conduct a minimum of 25 rapid tests on walk-up participants weekly across the 3 testing sites with our community partners. The research staff and community partners will communicate frequently during the first several weeks of testing to make adjustments as needed to the workflow. The first 4 weeks or 100 tests (whichever is shorter) will be considered the pilot period. We will monitor participant and staff comfort, workflow, wait periods, and volume of testing carefully during this period. At that point we will reassess the workflow and work closely with the Maine Medical Center IRB if any changes to the protocol are needed. We intend to continue walk-up testing until the funding is exhausted (no longer than 24 months). At that point, we will determine the state of the pandemic and work with our community partners and the Maine CDC to transition to their own testing program or identify other testing capacity locally.

Data Collection and Management (Aim 2b):
As described above, RADx-UP project includes required common data elements. A CSV file obtained from RADx-UP was used to create the REDCap data entry form locally. The participant may decline to answer any of the survey questions. All collected data elements will be directly entered by the patient (or, if needed, by the team member working with the patient) into REDCap. The research staff will keep a simple database in REDCap, as described above, (document E, REDCap Enrollment data walk-upTests), to gather basic data, without participant identifiers.

Methods

Aim 3. To evaluate the impact of a public health messaging and testing program developed in Aim 2b on rapid COVID-19 testing uptake. *We will accomplish this aim* by following a community cohort of 15 members each from 10 community groups, conducting surveys every month from approximately 3 months before messaging campaign begins to 9 months after, to evaluate changes in knowledge, attitudes, and testing participation over time. This cohort will also participate in a home testing program for Covid-19. *We hypothesize* that knowledge about testing and willingness to participate in testing will increase after exposure to our public health messaging and with access to home COVID-19 testing.

OLD Schema: 6 cohort surveys (“attitudes & testing survey”)+ 24 bi-weekly surveys (“testing survey”) + visit 1 RadxUP survey = 31 surveys total

	Visit 1 (Day 0)	Messaging Campaign	Month 3 – Survey 2 (+/- 2 weeks)	Month 5 – Survey 3 (+/- 2 weeks)	Month 7 – Survey 4 (+/- 2 weeks)	Month 9 – Survey 5 (+/- 2 weeks)	Month 11 – Survey 6 (+/- 2 weeks)	Month 12 (+/- 2 weeks)
Informed Consent	X							
RadxUP Survey	X							
Cohort Survey			X	X	X	X	X	X
Bi-Weekly Survey	Q2 weeks through to Month 12							

NEW Schema: 6 “attitudes & testing surveys” + 6 “testing surveys” + visit 1 RadxUP survey = 13 surveys total

	Visit 1 (Day 0)	Messaging Campaign	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Informed Consent	X													
RadxUP Survey	X													
Attitudes & testing survey				X		X		X		X		X		X
Testing survey			X		X		X		X		X		X	

NOTE: Aim 3 will be run concurrently with Aim 2b. We will begin recruitment at the same time our walk-up clinics are being started.

Recruitment: We will recruit the 150 people for the cohort study with the help of our Community Partners. Signage and flyers about the cohort study (document J, Cohort Recruitment Sign/Flyer) will be placed in the lobby of each partner site, and shared with staff members. People who access walk-up testing (Aim 2b) will also be invited to participate in the cohort study using this flyer until the cohort is filled. The information will be available in a 7 languages besides English (Spanish, French, Kinyarwanda, Somali, Arabic, Lingala, and Portuguese). Study staff will also periodically be available onsite at the community partner locations (in addition to during the walk-up testing clinics) to accept participant referrals from clinical staff. Community partners will not screen clients for participation; however, based upon already known information and the use of flyers, will refer clients to study staff. We are particularly planning to target Greater Portland Health for recruitment, for several reasons; they provide comprehensive care to all of the immigrant groups of interest, as well as people experiencing homelessness, and people who inject drugs. Greater Portland Health also serves primarily low-income populations, and has resources to allow for follow up testing and support as needed for people diagnosed with Covid.

We will further advertise for the study using the following strategies: meetings with staff members from MaineHealth clinics and other community organizations around Portland, Lewiston, and Auburn who also engage these populations; meetings with specific “gate keepers” such as religious leaders; flyering at public libraries, specific grocery stores, and immigrant-led businesses; advertising through community newsletters (such as Amjambo Africa – a local news outlet for the African community); requesting our Community & Scientific Advisory Board to spread the word through their networks, contacting city and county health districts to request they share the flyer on relevant listservs, and postings on websites and/or social media platforms (i.e. Facebook) run by MaineHealth or our community partners. We will also hold “outreach days” at Housing First locations, which are supportive housing apartment buildings for individuals who were previously unhoused. The Housing First programs in Portland are in collaboration with our community partner Preble Street. Study staff will coordinate with Housing First staff to schedule days and times to talk with residents about the study to see if they are interested in joining. We will also hold a few “outreach days” where study staff will set up a booth outside housing/apartment complexes that are predominantly rented by immigrant families so that interested residents can approach the booth and learn more about the study. Across all of these strategies, the only recruitment flyer used and shared with the various groups will be document J, but we may also use alternative formats of the flyer such as a larger poster version for waiting rooms or a shortened version of the flyer for the website or social media postings (see document W_Cohortrecruitment_socialmedia).

Those interested in participating can sign up onsite at one of the community partner sites, call the research assistant directly to sign up (phone numbers are listed on the flyer - document J), or the community partner can provide assistance and call on their behalf to provide contact information for the research assistant to follow up. If the potential participant requests this assistance they would need to be in a room with the community partner as they call the study staff. This permission would be noted by the study staff in the participant’s research record. We will recruit in each segment of the populations of interest including people experiencing homelessness (or who previously were chronically homeless), people accessing public health services (at the Free Clinic, needle Exchange, and STD clinics), and immigrant groups (Table 1). Our goal is to reach 150 participants, ideally 15 from each population group. However, if we do not reach our recruitment goals from each population group, we will continue recruiting with the support of our Community Partners across groups to reach 150 total participants.

Losses to follow up: We will reach out to participants via phone call and/or text each time they do not complete a survey within the intended timeframe (i.e. within 1 week after the survey is sent). If we have participants who do not return three consecutive surveys, we will first reach out to them up to three times via phone (Document JJ, Phone Script for Non-respondents), approximately 1 week apart (with an interpreter as needed) and then mail a letter (Document JJJ, Letter to Non-respondents) to determine if they would like to continue in the study. For people experiencing homelessness, we will attempt to reach them through a phone call with our community partners who provide care for them (Document JJJJ, Script for Phone Communication to Community Partner). After these attempts, we will consider them lost to follow up. We will retain their data from previous surveys and testing. We will invite additional participants from the specific population group in the same manner via our community partners to keep a cohort of approximately 150 participants. When the original 150th participant enrolled reaches month 5 of the study timeline, we will no longer recruit to fill spots of participants who are lost to follow up or who withdraw.

Consent: For people who express interest in participation, a member of the research team will carry out the informed consent discussion, in person. The consent discussion will take place in a private room either at our community partner site where the participant typically receives care, at Maine Medical Center if the participant was recruited via Prosperity Maine and they receive clinical care at MMC, at another Maine Health location such as the CORE office building, or in the participant's home. We will only conduct the enrollment visit, which includes the consent discussion, at the participant's home when the participant specifically requests this due to transportation, childcare, or other challenges that they face with coming to one of the sites listed above. A research staff member will review the consent form (document K, Fairfield Aim3 MaineHealth Informed Consent), which will be translated into the participant's preferred language (Spanish, French, Kinyarwanda, Somali, Arabic, Lingala and Portuguese), with an interpreter as needed. The consent form includes an explanation of the goals of the study and the expectation of completing a rapid COVID test for symptoms or close contacts. Additionally, they are expected to communicate the results to the research staff, via brief emailed REDCap survey (or phone call) on a monthly basis, and complete the RADx-UP survey (visit 1 – i.e. at the time of enrollment) and an additional 6 surveys (via mail, phone call, in-person, or an email linked to a secure REDCap database), every other month as per the Schema above. A copy of the signed consent form will be given to the participant and the original will be kept in a locked file at CORE.

Testing:
At the time of enrollment, the study staff will explain to participants when and how they should be conducting home testing. They will be instructed to do a test at home approximately 5 to 7 days after any close contact with a person who has COVID-19. Close contact is defined as being within 6 feet for 15 minutes or more. They will also be instructed to do a test at home if they have symptoms of Covid, including fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. Also during the enrollment visit, the study staff will show participants how to collect a nasal swab and complete the rapid COVID test at home, per the manufacturer's instructions, and will provide them with informational materials about the test, such as the FDA provided fact sheet on that particular test and the product insert provided by the manufacturer. Each participant will also receive the written instructions for how to quarantine (document H, Instructions for quarantine, Maine CDC) and how to manage at home if they do test positive for COVID-19 (document I, 10 things to Manage Covid Symptoms). The participant will receive approximately 5 home test kits at the enrollment visit. We are unable to specify the exact amount due to supply chain issues with rapid COVID at-home tests. At-home tests can come in boxes of 5 tests and others in boxes of 2 (whereby we would provide 3 boxes for a total of 6 tests). The exact number of tests will depend upon which tests we can procure. Regardless, all participants will receive the same number of tests.

We will then mail the rapid COVID home tests to each participant approximately every 8 weeks (approximately 5 tests, as needed) and include a letter reminding the participant they are enrolled in this study and that is why they are receiving a box of tests (document S, Letter with mailed tests). The study team will maintain a record of all test kits mailed to the participants and expiration dates in the participant study record.

For participants experiencing homelessness, they will be invited to do COVID-19 testing at any of the three walk-up testing sites. Study staff who work at the walk-up testing sites will be aware of the 15 participants from the homeless community who are participating in the cohort study. We will be sure that the study team knows their names and identity and is able to distinguish them from the other walk-up participants for purposes of data capture. Study staff will enter test results and survey responses into REDCap (document L test result communication) for those 15 participants. The participants experiencing homelessness will have additional supports from either the Preble Street Learning Collaborative and Greater Portland Health sites, wherever they typically access care and services.

Positive tests:
People experiencing homelessness will be connected to a case worker onsite at the community partner to make arrangements for quarantine, using the same procedure described above under Aim 2b.

For other (housed) participants who test positive, at the time of enrollment (visit 1) they will be provided an informational sheet that describes what to do if they test positive (document T, What to do if you test positive) which outlines CDC guidelines and also gives information on treatment. The study team member enrolling the participant will go through the informational sheet with the participant to ensure the information is covered. This informational sheet will be revised, as needed, whenever CDC guidelines change or information on treatment changes. We will only use information from the following sources to revise the sheet: CDC, Maine CDC, NIH, and MaineHealth.

The Maine CDC will be informed of positive tests among the cohort participants by our research team. We have registered with the Maine CDC's REDCap system and have our own MaineHealth reporting link for positive test results. Since we collect identifiers from the cohort participants we will have the necessary information to complete the Maine CDC form (we ask community partners to do the positive test reporting at the aim2b walk-up clinics because our research team does not collect identifiers for that activity).

Surveys:
The first survey is the lengthy, required, RADx-UP survey with all the common data elements including identifiers (document GG_RADx-UP CDE_WITH_Identifiers). We expect that we will assist the participant to complete this in person at the time they sign the consent form and are enrolled in the study. However, if for some reason it is not possible for the participant to complete the survey at the time of enrollment, we will email them a REDCap link to the survey so they may complete at home. We will also ask the participant to complete the follow up survey at the time of enrollment (document M, Every 2 Month Survey of Cohort – Attitudes & Testing Survey), as this will act as a baseline measure. They will be informed that they can decline to answer any of the survey questions. All data are collected into a local REDCap instance and the common data elements will be uploaded periodically to the Duke Clinical Research Institute per their requirements. An incentive of a $50 gift card will be given during the first visit after completing the survey. At enrollment, the first entry into the RADx-UP Common Data Set in REDCap will generate a new participant Study ID. This study ID will be provided to the participant and used to link the participant's data, including the common data elements and all subsequent surveys and test results. (Note this information will be in a separate REDCap project from the Aim 2b walk-up participant information, which does not have a study ID, is not identified, and is not linked in any way).

We will send a total of 12 follow up surveys via an email linked to a local secure REDCap database for the cohort or the survey link will be texted or the survey will be sent by mail or done over the phone or in-person (whichever the participant prefers), over the course of 12 months (1 survey every month). The monthly surveys will alternate between the brief "testing survey" (document L, REDCap test result communication – Testing Survey) and the longer "attitudes & testing survey" (document M, Every 2 Month Survey of Cohort – Attitudes & Testing Survey). The participant will thus be sent 6 of each survey.

If a participant prefers a mailed paper survey, the research staff will send it with a stamped envelope with the return address completed (to the RADx-UP Study, CORE, 509 Forest Avenue, Portland), and will enter the data into REDCap upon receipt and destroy the paper copy immediately in a paper shredder at CORE. Participants may also elect to complete surveys via phone with the support of the research staff, who would enter the responses directly into REDCap. For participants who prefer to have the REDCap survey link texted to them, the text will be sent from a secure MaineHealth iPhone which was purchased for purposes of this study.

We may have participants, such as people experiencing homelessness or people who were recently housed, that prefer to complete their surveys in-person. Such participants may not have a phone, email address, or mailing address and hence, this is a necessary option. In this scenario, a research team member will work with community partners so that the participant is notified in advance of the day and time when they will be asked to meet to complete the survey. The research team member and participant will meet at the community partner site, or a location where the community partner provides services (such as a Housing First building). The research team member will provide the participant with a study iPad that has the REDCap survey for their particular study ID and ask them to complete the survey.

For cohort participants experiencing homelessness, they will be invited to complete their surveys (document M, Every 2 Month Survey of Cohort – Attitudes & Testing Survey; document L, REDCap test result communication – Testing Survey) with the research staff at a convenient time, at the Preble Street Learning Collaborative or Greater Portland Health, and will receive their incentive at the time they complete each survey.

Incentives:
We will mail the cohort participants an incentive in the form of a $20 gift card for each completed 2 month survey (unless homeless as described above) (document M, Every 2 Month Survey of Cohort – Attitudes & Testing Survey). In order to recognize sustained participation in the cohort, participants who complete surveys up to the 6 month mark will receive an additional $40 in gift cards and participants who complete surveys up to the 12 month mark (i.e. end of the study period) will receive another additional $40 in gift cards (see V_Letteraboutincentive). This means the total incentive amount possible is $250 ($50 enrollment visit + $20 * 6 surveys + $40 + $40 = $250). At the time of enrollment, we may also provide the participant a reusable bag to make it easier to carry all of the provided materials (i.e. COVID tests, FDA fact sheet, manufacturer information sheet, copy of signed consent form, $50 gift card). We may also provide a magnet that provides a "reminder checklist" of when each of their 2 month surveys will be due (document O_SurveyReminderMagnet).

Anticipated Risks and Benefits
Possible risk to participants include:

- Inadvertent disclosure of information. We will prevent this by using REDCap for all data storage, which requires two factor authentication. Paper copies of consents will be kept in locked file drawers in the offices of the research staff.

- Nosebleed from testing. We will minimize this risk by having appropriate signage about the depth of swab insertion. The Community Partner site has medical personnel available to support the participant with compression until the nosebleed subsides.
- Anxiety from false positive test results. We will provide clinical information to participants about false positives, but also ensure that they understand the need to quarantine pending confirmatory PCR testing.
- Fatigue due to survey length

Possible benefits to participants include:

- Access to free rapid Covid-19 testing.
- Societal benefits by decreasing the risk of infecting others with COVID-19
- Stronger relationships with public health services

Data Collection and Management (Aim 3):
As described above, RADx-UP project includes required common data elements. A CSV file obtained from RADx-UP was used to create the REDCap data entry form locally. The participant may decline to answer any of the survey questions. All collected data elements will be directly entered by the patient (or, if needed, by the team member working with the patient) into REDCap. As described above, all Survey data will also be collected in REDCap, or if mailed, entered into REDCap and written copies destroyed. Identifiable data will be deleted 3 years after publication.

Data will be uploaded periodically by our research team to the Duke Clinical Research Institute (DCRI); 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 participants. These data will be kept at the DCRI. The DCRI will not share these data with the NIH. Participant information including the participant social security number (if provided) will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and possibly electronic health record data (although the MaineHealth study does not collect electronic health record data), among others by the DCRI research team. For participants that agree, the DCRI will keep information that can identify the participant in order to contact the participant for future research studies. If the participant does not agree, this information will stay with the study team, as applicable. These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of this data at the DCRI will be able to see this information. The second database will not hold information to identify participants. It will hold all the nonidentifiable information the participants agree to give. Participants will be assigned a study code and participants will only be identified in this database by this study code. It will not contain PHI. DCRI plan to transfer and keep these non-identifiable data in a secure database for COVID19 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 non-identifiable data and cannot link the data back to the participant.

Sharing results/Publications

We will share our findings, in aggregate, with public health entities in New England, including the Maine CDC, our community partners and with our population health leaders within MaineHealth and Maine Medical Partners. As expected for all participating sites in the RADx-UP program, our site's data will be aggregated with the others by the Duke Clinical Research Institute.

Potential problems

We anticipate possible problems such as lack of participation, excessive interest in participation, and poor responses to the surveys. We hope to overcome these by working closely with trusted community partners who are known to the participants to disseminate an approved flyer (document N, Community Awareness Flyer), with the locations and times noted, either at their clinical care site, or through their usual communication methods such as their website, social media platforms and WhatsApp. If we have excessive interest in testing at certain locations for walk-up testing we will make every effort to add staff to accommodate them and will keep an updated list of nearby testing sites to refer people.

Project Timeline (testing begins as early as Dec 2021 and continues for the cohort for 12 months and for walk-up sites for 18 months unless RADx-UP continues funding).

	2021		2022												2023							
	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug
Pilot walk-up testing		X	X																			
Recruit Cohort Participants						X	X	X	X	X	X											
Walk-up testing continues			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Mail test kits to cohort								X		X		X		X		X		X		X		
Send out monthly survey to cohort						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Community Partner Meetings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Understanding Factors Influencing COVID-19 Testing and Vaccination in Immigrant, Low-income and Homeless Populations, and Testing Targeted Interventions, Addendum for Aim 4: [3U54GM115516=05S2 RADx-UP]

Introduction/Summary & Background

This is an amendment to include one additional Aim that more deeply examines the financial impacts of the COVID-19 pandemic on the immigrant community in Portland, including the financial impacts related to COVID testing.

A major component of the originally proposed study was to collaborate with community partners to better understand and address disparities in COVID testing among underserved populations. The aim 1 qualitative research uncovered an important theme around the negative financial implications from testing positive for COVID due to lost income from quarantining/isolation. This theme was especially present in interviews with immigrant community members who work hourly jobs with no sick pay policy. One of the community partners engaged in the study, ProsperityME, is an organization that focuses on financial health and literacy for the immigrant community and was interested in this uncovered theme. As such, and in the spirit of community engaged research, we collaborated with ProsperityME to develop a new study aim that would build off the aim 1 qualitative findings and more deeply examine the financial impacts of the COVID-19 pandemic for the immigrant community.

Research Focus & Specific Aim Statement(s)

Our Aim for this protocol is:

Aim 4. To explore the financial impacts of the COVID-19 pandemic on the immigrant community, including financial impacts related to COVID testing, and the potential downstream effects of these impacts on health and social disparities. *We will accomplish this aim* by analyzing the aim 1 qualitative transcripts with a new coding lens focused on "financial impacts" *and* by conducting focus group discussions with ProsperityME staff to uncover their first-hand knowledge around the financial impacts their clients faced.

Significance

This research will provide important insights into other disparities caused by the COVID-19 pandemic for underserved populations, beyond health disparities alone. As requested by and in collaboration with ProsperityME, we plan to write-up the findings from this study aim in a "legislative brief" and coordinate a meeting with local and state-level government stakeholders in order to raise awareness and guide evidence-based solutions.

Innovation

Our proposed work is innovative as it explores broader impacts of the COVID-19 pandemic for an underserved population, which gives a deeper understanding of *why* we see disparities in COVID-19 testing and health outcomes; and also applies principles of community engaged research to ensure richer findings and more impactful application of study results.

Methods

Setting & Community Partnerships: We will conduct the aim 4 work in greater Portland, ME, in Cumberland County. We will work with our community partner ProsperityME, who we have already collaborated with on study aims 2b and 3.

Participants:
This study will include adults (18 and over) of any sex, race or ethnicity. The participants will specifically be ProsperityME staff who serve the immigrant community in Portland with housing assistance, workforce development, and other financial topics. We anticipate approximately 20 ProsperityME staff participants.

No direct financial incentives will be provided to participating ProsperityME staff. However, the focus group discussions will take place during the work day. The Executive Director of ProsperityME and program director agreed to host the discussions during the work day so this time could be covered for staff members who chose to participate.

Recruitment:
The ProsperityME program director will let staff know about this research study opportunity and explain its purpose on a staff-wide meeting. The program director will then follow-up with an email to let staff know what days and times were selected for the focus group discussions, and also state that this research study is voluntary and there is no requirement to participate (see document Recruitment Email for ProsperityME Staff). Staff who are interested in participating will be invited to respond to the email to let the program director know they are interested and which date they prefer to attend.

Focus group discussions: We anticipate conducting 2 to 3 focus group discussions (FGDs), with approximately 4 to 8 participants in each FGD. ProsperityME administrative staff will help coordinate the day and time for the FGDs so that the selected dates/times work for staffs' schedules. The FGDs will take place at ProsperityME's office location in Portland, in a conference-style room that will provide appropriate space and privacy for the discussion. We anticipate each FGD lasting approximately 1 hour. We will ask questions about the financial impacts of the COVID-19 pandemic in general for the immigrant community, financial impacts related to COVID testing, how financial impacts changed over time during the course of the pandemic, and what downstream/long-term effects ProsperityME staff are seeing on the financial health for clients and their families, if any (see document X, ProsperityME FGD Guide). The FGDs will be audio recorded upon consent of all participants. We will not collect participant names, but we will gather basic work history information from each participant to understand their level of experience working on financial issues with the immigrant community, including current job title, description of role, number of years working with ProsperityME, and past relevant work experience.

If a ProsperityME staff member wants to participate but is unable to attend the FGDs, we will conduct a separate interview with that staff member using the same set of discussion questions.

Consent: We have asked the IRB for an alteration of consent so that written signature is not required and instead we can seek verbal consent. ProsperityME staff will be provided a copy of the full consent form beforehand and given an opportunity to decline to participate (see Fairfield Covid CTR_ConsentForm_FGD_16Feb2023). The study team member facilitating the FGD will also review the consent form at the start of the FGD, answer any questions, and only begin the audio recording once all participants give their permission to do so.

Data Management and Analysis:

The data from the FGDs will include hand-written notes by study team members and the audio recordings. Hand-written notes will be typed up and the paper copy destroyed. Audio recordings will be transcribed and the transcripts uploaded to MAXQDA for analysis. After analysis, audio recordings will be deleted. All data/materials will be saved on a secure MaineHealth SharePoint site that is a specific site for this study and only provides access to IRB approved study team members.

Anticipated Risks and Benefits
The risks involved with participation in this study are low and may include:

(1) Accidental breach of confidentiality; that is, other people outside the research team could learn about the views and experiences that a participant shared during the discussion.
   - This could happen if one focus group participant shares what was discussed with others not involved in the study. We cannot prevent this from happening but the research team member facilitating the focus group will emphasize the importance of confidentiality at the start of the discussion when reviewing the consent form.
   - This could happen if a person not involved in the study gets access to the audio-recording or transcript and is able to identify a participant. We are taking several steps to ensure this does not happen. First, we will not collect any PHI. Second, all data (i.e. audio-recordings and transcripts) will be saved behind the secure MaineHealth SharePoint site where only study staff have access. Lastly, any identifiable information incidentally given by participants will not be included in the transcripts (i.e. transcripts will be de-identified).

(2) Stress from recounting financial and/or housing crises that your clients faced

There are no specific benefits for a participant in this study. However, there is a large social benefit as the findings from this study will help provide a better understanding of the financial impacts of the COVID-19 pandemic for the immigrant community in Maine. The findings may also be used to raise awareness among local and state government stakeholders.

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