**RESEARCH PROTOCOL AND STATISTICAL ANALYSIS PLAN**

# Localized mHealth approach to boosting COVID-19 testing and vaccine literacy, access, and uptake among women with criminal legal system involvement

**NCT05582746**

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## RESEARCH STRATEGY

### SIGNIFICANCE

***Public health problem:*** The COVID-19 pandemic has disproportionally impacted underserved populations [11, 12]. A particularly vulnerable population is women leaving jails, prisons, and community-based criminal legal supervision[13]. Of all the developed nations, the United States has one of the largest numbers of women with ongoing criminal legal system involvement (CLSI). A study by ACLU shows that women's incarceration has grown at twice the pace of men's incarceration in the last decades and that most women are held in jails, not prisons.[14] Women with CLSI often come from marginalized communities, have complex trauma, mental health, and drug problems.[15,16] Because of their situation, they are less likely to have stable employment, health insurance, or a linkage to primary care once they leave jail. They often have low education, low health literacy, and low self-efficacy in navigating the medical system and are less likely to engage in disease preventive behaviors.[17]

The COVID-19 pandemic has compounded and complicated the problems these women face when leaving criminal legal supervision. Eighty percent of the largest COVID-19 outbreaks occurred in U.S. jails and prisons[18]. Though people leave these facilities every day, COVID-19 testing or vaccine is not integrated into release plans (or for many facilities, confinement plans). Incarcerated women risk exposure while detained, and most of these women return to communities strongly impacted by COVID-19. Some jurisdictions have reduced or eliminated bail, and are releasing detainees to home arrest or community supervision[19]. A significant portion of these women are ill-prepared to deal with the pandemic and even less prepared, under these conditions, to conform to recommended COVID-19 mitigation practices, including testing and vaccine.

The COVID-19 vaccine is a breakthrough in this pandemic.[20] (ref). While the rollout of vaccine in the U.S. was rapid, exceeding expectations, uptake has been lower than it needs to be to achieve herd immunity.[21] Even with mass availability of COVID-19 vaccines, one in three Americans has said they will not get the COVID-19 vaccine[22], and the pace of COVID-19 vaccination has been slowing down nationwide. Recent reporting suggest that the U.S. may not achieve herd immunity because of vaccine hesitancy and low uptake.[21] As we monitor uptake of vaccine in our country's local jails, we are seeing vaccination uptake rates below 50% in most jails, but with some outliers.[5] People with CLSI, that is, those in prisons, jails, under community supervision, or recently released, experience the highest rates of COVID-19 – five times that of the general U.S. population.[1] Incarcerated persons also have three times the risk of death from COVID-19.[1] Early data about vaccine uptake tell us that they will also be the least likely Americans to accept vaccine.[1]

Given low anticipated rates of vaccine uptake among people with CLSI, **the need for continued COVID-19 testing in communities with low vaccine uptake is critical.** Imagine a woman, recently out of jail, homeless, and sharing a room in a house with an acquaintance: if she says she has symptoms, manages to get tested, and then finds she's positive for COVID-19, she'd would risk getting kicked out of her immediate source of shelter and safety. Would she choose to get tested considering these consequences? From a scientific perspective, we know so little about how people are making decisions about COVID-19 testing in a post-vaccine world, one and a half years into the devastation of a pandemic where rates of fatigue, employment, family, and housing instability are high. We know that families bringing their children with COVID-19 symptoms to clinics are hesitant to get tested when offered, owing to fears about prolonged quarantine and implications for employment.[23,24] Families would rather forgo testing decisions than disrupt employment, education, or childcare routines. For women with CLSI, the precariousness of their housing, employment, romantic, peer, and criminal-legal circumstances will make testing decisions even more difficult. It is in this context that we work to understand women's testing attitudes and practices; their vaccine hesitancy and beliefs, and immediately work to facilitate understanding and utilization of both. We propose a two-year study to rapidly assess (Aim 1), build and push (Aim 2), evaluate and disseminate (Aim 3) an mHealth intervention to boost COVID-19 testing and vaccine literacy, access, and uptake among women with CLSI in three cities.

***Health disparities population:*** This application is highly responsive to the RADx-UP Phase II call for research that tests interventions to reduce COVID-19 disparities among underserved populations and understands testing behaviors in a climate where vaccine is available.[7] People with CLSI are disproportionately socioeconomically disadvantaged (only between 1-30% of women have full-time employment after jail,[25] and the system of mass incarceration has targeted a disproportionate share of racial and ethnic minorities (Black women are 1.8 times as likely to be incarcerated; with Latinx women 1.3 times as likely as White women[3]). To that end, the population of women with CLSI, the focus of this application, meets the criteria for a health disparities population outlined by NIMHD.[2] It is also worth noting that much of the conversations on mass incarceration and COVID-19 are about men. The needs of women, who comprise 15% of the CLSI population (but are two million strong annually), are often overlooked. This study focuses on their unique needs and risks

in this pandemic. The study is intersectional in its focus – addressing COVID-19 disparities while simultaneously confronting the intersecting oppressions of CLSI, racism, poverty, and gendered experiences of violence, housing instability, incarceration, and health.

***Opportunity:*** Our team has a unique opportunity to **both study and immediately intervene** on promoting COVID-19 testing and vaccine literacy, access, and uptake using mobile health (*mHealth*) technologies (text and Web)[8] to provide information and engage women with community-based criminal legal system involvement in three geographically, socio-politically, and culturally different cities: Birmingham, AL, Kansas City, MO/KS, and Oakland, CA. We are positioned to embed the proposed study into an existing evidence-based women's health literacy online intervention platform (www.shewomen.org, 2R01CA181047) for women leaving jail. We are also well positioned to push the mhealth COVID-19 testing literacy intervention to over 500 women we have already recruited to our tri-city cervical health study of women with CLSI (R01CA226838), for which we have an 82% retention after one year of follow-up.[9,10] The benefit of our tested health literacy framing is that it addresses knowledge, beliefs, self-efficacy and confidence navigating the complex realities of the lives of women with CLSI.[26,27,28] We will engage the women as stakeholders to study regional and individual differences in COVID-19 testing attitudes, practices, and uptake in Birmingham, Kansas City, and Oakland. We will use findings to adapt and integrate a tailored and scalable COVID-19 testing and vaccine literacy mHealth intervention, and then push the intervention to women in the three cities, as well as make it available nationwide to CLSI women through promotion in jails, halfway houses, and non-profit organizations, to encourage COVID-19 testing, address COVID-19 vaccine hesitancy, and to boost COVID-19 literacy.

***Preliminary studies and health literacy intervention framing:*** In May-June 2020, we surveyed study participants in Kansas City, Birmingham, and Oakland exploring their sources of information about COVID-19. Out of the 335 participating women, 82% said that they get information from the TV, and over 55% said that they get COVID-19 information from social media.[29] Only 15% of them talked with a medical provider about COVID-19. When asked about the source they trust the most, television ranked first (over 40% of respondents), followed by information from a medical provider (only 10% of respondents). Media represents the women's primary source of information; thus, their risk of exposure to misinformation is real and current. In interviews we conducted in March 2021 with CLSI women from Kansas City, vaccine hesitancy was driven by low COVID-19 literacy as well as by anti-vaccine attitudes from family and friends.[30]

In a paper on how criminal justice-involved women navigate COVID-19, based on a series of semi-structured interviews we conducted with 35 women enrolled in our ongoing studies, we report that women were anxious, frightened about the pandemic, and lacking general knowledge about the virus.[31] A few women across the sites mentioned that "they heard that COVID-19 was part of a larger government conspiracy, like retribution against the U.S. for the killing of an Iranian leader." [31] When we checked in with our women this past year, we found that COVID-19 made already bad living circumstances even worse (see table). Half of the women sought COVID-19 testing in the past year, and knowledge about COVID-19 varied. The women reported doing well at COVID-19 mitigation, though admittedly 80% reported housing problems made worse. Knowledge was variable: with 28% of women saying that taking vitamins can prevent the spread of COVID-19, but most (over 90%) knowing that a person can have COVID-19 but show no symptoms.

| **COVID-19 Experiences among CLSI Women in Tri City Cohort, N=408 (number of women who answer COVID-19 specific questions)** | |
|---|---|
| Age (avg) | 43.7 |
| Race | |
| Black | 60% |
| White | 28% |
| Latinx only | 4% |
| Healthcare providers cancelled in-person medical appointment | 39% |
| Healthcare providers conducted telehealth appointments | 58% |
| Tested for COVID-19 | 49% |
| Positive COVID-19 test | 8% |
| Sheltered in place under state order | 82% |
| Practiced social distancing | 94% |
| Able to wash hands or soap | 95% |
| Wears masks | 98% |
| Laid off from job | 33% |
| COVID-19 made worse | |
| Housing/finding a place to stay | 80% |
| Getting medical care | 97% |
| Getting medicines or prescriptions | 91% |
| Making money | 93% |
| Paying rent, utilities or other bills | 97% |
| Getting enough to eat | 83% |
| Personal or family relationships | 76% |
| Level of stress | 93% |
| Alcohol use | 91% |
| Drug use | 85% |
| Interpersonal violence | 77% |

When the COVID-19 vaccine was initially available, we engaged the women in studies about vaccine intentions.[30] Among 25 women interviewed in Kansas City, we found that the women have complacency, that is their perceived risk of vaccine-preventable disease is low. The women have low confidence, that is their trust in the effectiveness and safety of vaccine is low (which will no doubt be exacerbated by news coverage of problems with vaccines). Finally, we found that

misinformation abounds – rumors about some vaccine doses being placebos and conspiracy theories about where the virus comes from and state secrets (ref). We found that 53% were explicitly not willing to get vaccinated; an additional 8% said maybe; and 12% said only if it was required for work or for family reasons.[30] For women with vaccine hesitancy, embracing COVID-19 testing as an alternative to the vaccine in order to have a relatively normal social life and protect their loved ones may be an acceptable alternative, if they know about the benefits of testing. For CLSI women that have been vaccinated, education is needed for them to understand the importance of COVID-19 testing post-exposure if symptoms develop. Interventions to promote COVID-19 testing and vaccines to this population will have to address health education and mitigate mistrust, misinformation, conspiracy theories, and bridge the large gap between the women's concerns, discomfort, and their eventually uptake of both COVID-19 testing and vaccine.

We have successfully leveraged a health literacy framework to reach the target audience of women with CLSI. We used this framework (targeting knowledge, beliefs, self-efficacy, and confidence navigating health systems – our operationalization of health literacy) to increase cervical health literacy over time and improve cervical cancer screening tests rates.[27] We have also used this framework to expand our work across multiple outcomes, using health literacy as an underpinning of interventions to reduce cervical and breast cancer risk, sexually transmitted infection risk, and bolster women's reproductive goal planning (ref). We are confident based on two prior health literacy R01s for reaching CLSI women that a health literacy intervention framing is an effective way to reach women with CLSI and address their barriers to health promotion. We will leverage this same framework to develop COVID-19 literacy content, which will expect in turn, to boost testing and vaccine literacy, access, and uptake. The table below shows a sample operationalization of health literacy as it applies to the present subject matter.

| **COVID-19 Vaccine Literacy Intervention Content** | | | |
|---|---|---|---|
| **Knowledge** | **Beliefs** | **Self-Efficacy** | **Confidence** |
| COVID-19 transmission<br>COVID-19 risk, mitigation<br>COVID-19 vaccine risks/efficacy/safety<br>COVID-19 testing in a vaccine environment | Hesitancy about vaccine efficacy, safety, utility<br>Beliefs about testing in a vaccine environment<br>Mistrust about government, health care, or other institutions<br>Trust in media sources | Incarceration/drug use/ homelessness/ transportation/ financial/ other barriers to testing and vaccine appointments | Confidence navigating COVID-19 testing, vaccine appointment booking |

The content, of course, will be revised and improved upon after critical and robust data are collected with stakeholders as part of the proposed study (**Aim 1**). Once we complete data collection with CLSI women as stakeholders, we will use the intervention content to develop the COVID-19 module for the mHealth intervention (**Aim 2**). The platform for mhealth intervention already exists through another ongoing project (www.shewomen.org, 2R01CA181047), which will save both resources and time, in our effort to quickly build an intervention to reach CLSI women in a timely manner. We will then rapidly push the intervention to an existing cohort of women (R01CA226838), whom we are in the second/four years of follow-up, giving us ready-made-access to a cohort. This will also save resources, time, and effort, and allow us to intervene directly with our high risk and high need population and assess our impact on COVID-19 testing and vaccine literacy, access, and uptake (**Aim 3**).

Based on our prior work with CLSI women, mHealth strategies are an excellent way to keep in touch and push just-in-time content. During the pandemic, we were forced to close field sites and stop any in-person follow-up visits. Even prior to the pandemic, telephone follow-up surveys were conducted with 60% of participants. Post-pandemic, we conducted 95% of those surveys over the phone, with the remaining over email or mail correspondence. The majority of our women use text messaging regularly and can access the Web on their phones. Our ongoing RCT (N=70 participants completed) of an mHealth intervention on reproductive health, and reproductive goal planning shows this modality is feasible for delivering information and engaging participants. Specifically, we found that 81% of women who initiate are able to complete the intervention. The average time for completion of one module, for example on sexually transmitted infections, took 19 minutes, whereas cervical cancer took 13 minutes to complete. We estimate the proposed module on COVID-19 testing and vaccine will take on average between 15 to 20 minutes to complete. This time for intervention completion, combined with text message information about any new COVID-19 mitigation news (e.g. boosters, vaccine for children, new testing recommendations, testing locations, etc.), should result in about 30-60 minutes of total formal engagement over the duration of the study.

What we propose will be brief, but targeted messaging intervention from verified sources, delivered in an adequate lay language and using spokespersons that are relatable and familiar, and can be trusted, which has been proven effective in changing targeted behaviors.[32,33] Our intervention design also draws on lessons

learned from evidence-based interventions to improve vaccination uptake among adults, for example a meta-analysis conducted in 2021 on public response to health messages encouraging vaccination.[34] Our mHealth intervention allows participants to attend to the information at their own pace, while ensuring that they are prompted to complete the module. To avoid unidirectionality and promote engagement, they will be able to use an asynchronous messaging component to ask questions and receive answers from the research team. There is no question that such an intervention is necessary for a population with likely low uptake of both testing and vaccination, especially when that population is not the explicit target of most public health messaging. To the critique of whether the intervention is sufficient, we don't know. We hypothesize that the intervention will be effective at boosting COVID-19 testing and vaccine literacy, access, and uptake, and the goal of this study is to test that hypothesis. One advantage of this approach is the ability for nimbleness, that is, being able to adapt in real-time to new information about the pandemic and being able to push that new information out to women using the proposed intervention platform. Another unique advantage is the scalability of such an intervention, and its ability to be made widely available to all CLSI women in the United States.

***What is known and what remains to be known:*** We know 1) Women leaving jails and prisons will bear a far greater share of COVID-19 morbidity, given that jails and prisons are sites for the country's largest outbreaks and given the disproportionate representation of socioeconomic disadvantage and racial/ethnic minority status among women with CLSI (both known correlates of disparities in COVID-19); 2) Hesitancy for taking COVID-19 vaccine is high, and uptake remains low among people with CLSI – with less than half of this population currently expected to get vaccinated. Testing will be critical to mitigating spread of COVID-19 in unvaccinated groups; 3) Main information sources currently used by CLSI women run a high risk of exposing them to information that may increase their vaccine and testing hesitancy; 4) Few, if any, interventions are being designed to specifically target this group; 5) We have a proven health literacy framework and mhealth intervention platform that we can use for a just-in-time intervention to mitigate women's concerns and boost COVID-19 testing and vaccine uptake.

What remains to be known is 1) While hesitancy is great, we know so little about CLSI women's *access* to testing and vaccination, which is a center for debate in the "hesitancy" literature (ref). Our study presents an opportunity to study the intersection of access issues with hesitancy, mistrust, literacy, and uptake of both testing and vaccine. 2) We don't know how testing and vaccine beliefs vary across women of different racial/ethnic groups and geographic regions. Anecdotally we are finding that women in Oakland, where state policy and perhaps culture are much for COVID-19 mitigation progressive (early and prolonged protective orders, like mask mandates, and normalization of vaccine), compared to Birmingham and Kansas City, are more willing to get vaccine. But we don't have systematic data measuring these differences. We know nothing about how any women in this population feel about testing in a vaccine environment, at all. This study will allow us understand beliefs and practices. 3) While data will emerge about ongoing testing and vaccine uptake in jails and prisons, probably few researchers are following the high risk but often overlooked group of women with CLSI. This group is far more populous than women in actual jails and prisons, but perhaps more or equally at risk for COVID-19 morbidity and mortality, given the precariousness of their housing, living, family, drug, and mental health situations. We have the fortunate opportunity of access to an existing cohort of 508 women in three cities for whom we have demonstrated excellent retention rates (upwards of 82% after more than a year). 4) We don't know what kind of interventions work to boost COVID-19 testing and vaccine uptake. The health communications community (refs) has some ideas about what will work and has employed various public outreach strategies (refs). But there is an immediate need for efficacy information about tailored interventions for high risk populations to boost COVID-19 testing in a vaccine environment, especially those that can be easily tailored to specific audiences and can be quickly scaled up to encompass larger populations. This study will provide those data, which will no doubt have utility for this pandemic, for future pandemics to come, and for boosting testing and vaccine in an extremely understudied population.

***Summary of significance:*** Interventions focused on women leaving CLSI that address COVID-19 testing and vaccine literacy are needed, especially as new viral variants are discovered and the need for boosters and potentially annual inoculation has become increasingly likely. Ongoing testing in an environment where we expect one-quarter of Americans to never get vaccinated will be critical, especially among those groups at greatest risk of exposure and least likely to get the vaccine. Our intervention will happen at the most appropriate moment to build adequate, evidence-based knowledge about COVID-19 testing and vaccine barriers, and help shape sound COVID-19 literacy that will hopefully also equip women with skills to filter misinformation. As part of this proposal, our content management system (CMS) for the existent mHealth intervention will be upgraded to be able to send timely messages about testing protocols, vaccine safety, availability, and any coming changes in guidance over the next two years. Given that our study population has

the least access to medical innovations and the most distrust of those innovations (especially the pandemic and vaccines), we would be well-positioned to adapt to changing pandemic realities to offer information from a trusted source, information that they can understand and relate to. Our proposed study is significant in that we will intervene on COVID-19 health disparities among an extremely vulnerable and overlooked population – women with CLSI. Findings can be used to push out this and similar interventions to marginalized women, most of whom have access and are regular users of mobile technologies in this pandemic and in future ones.[35,36]

## INNOVATION

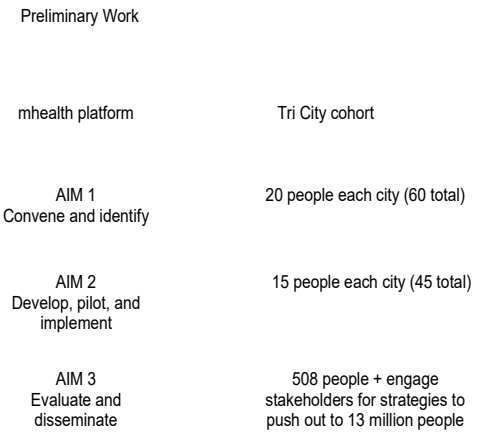
This study is innovative in the following ways: 1) Understanding COVID-19 testing attitude and practices in a vaccine environment will be critical. This study will foster understanding of what goes on with women with CLSI to effectively address the highly mobile population that circulates between jails and communities. Two million of these women leave jails and prisons every year. What we learn from the women will inform what we do for the 11 million men who leave jails and prisons annually. 2) This proposed intervention can be built onto existing interventions (like we propose to do) to increase speed of implementation, rapid uptake, and impact. Further, we are adjusting the mHealth approach to meet the needs of marginalized populations and leveraging a health literacy framing that we have already proven effective with our population. 3) The proposed intervention is designed to be adaptable to local contexts – at a minimum three cities in the proposed application, but with solid plans built into evaluation to disseminate rapidly to the field and broader population of people with CLSI. 4) We integrate participants as stakeholders throughout the grant period, not only soliciting feedback at every step, but also budgeting time for stakeholders as research assistants. Stakeholder feedback on development (**Aim 1)**, implementation (**Aim 2)**, and evaluation and dissemination (**Aim 3**) will be critical not only to developing an effective program for the population, but also to building something sustainable.

## APPROACH

***Overview:*** We propose a two-year study to rapidly assess (Aim 1), build and push (Aim 2), evaluate and disseminate (Aim 3) an mHealth intervention to boost COVID-19 testing and vaccine literacy, access, and uptake among women with CLSI in three cities. The table below lists aims and describes corresponding research activities, outcomes, and benchmarks. The accompanying figure shows the foundation of preliminary work, access to the population, and new proposed study aims. In general, Aim 1 employs a stakeholder-informed design to collect information from women with CLSI in three cities about COVID-19 testing attitudes, practices, and uptake. Aim 2 builds an intervention using a proven health literacy framework for

| **Aims, Activities, Outcomes, and Benchmarks** | | |
|---|---|---|
| **Activities** | **Outcomes** | **Benchmarks for success** |
| ***AIM 1.*** *Convene a stakeholder group of women with CLSI to serve as partners in identifying regional and individual differences in COVID-19 testing attitudes, practices, and uptake in three distinct geographical regions of the U.S.* | | |
| • Finalize IRB protocol/approvals/data collection instruments<br>• Convene stakeholders (participants) from each site (20 each from KC, BHM, OAK)<br>• Conduct interviews with stakeholders (20 each from KC, BHM, OAK)<br>• Analyze and summarize interview data in consultation with stakeholders | • Themes related to COVID-19 testing, attitudes, practices in a vaccine environment | • Report with findings from Aim 1 presented to intervention design team |
| ***AIM 2.*** *Develop, pilot, and implement a COVID-19 mhealth intervention for women with CLSI that responds dynamically to local, cultural, and access differences in testing, and evolving public health recommendations.* | | |
| • Develop the scripts for video/animation segments for the COVID-19 training (knowledge, testing and vaccine) modules based on Aim 1 data, preliminary studies, and literature<br>• Produce the video/animation files for the COVID-19 training modules<br>• Programming for the COVID-19 training modules<br>• Programming for the delivery of tailored (localized) content<br>• Develop the protocol, changes to the U.I. and administrator dashboards, and program the upgrade to the SMS and email systems.<br>• Recruit 45 women (15 from each site) to pilot test the modules.<br>• Conduct initial pilot testing with 45 women for the COVID-19 module<br>• Refine content of modules/timing<br>• Finalize the structure and content of the online intervention<br>• Activate the pilot tested modules for delivery to the entire cohort (N~500 women) | • User interaction, acceptability and useability of COVID-19 testing and vaccine literacy module | • Mhealth COVID-19 module developed, tested, and implemented with CLSI women in Kansas City, Birmingham, and Oakland |
| ***AIM 3.*** *Evaluate the impact of an mhealth intervention on COVID-19 testing and vaccine literacy, access, and uptake among women with CLSI over time.* | | |

| | | |
|---|---|---|
| • Verbal consenting of 508 existing tri-city participants to new COVID-19 study (expect 95% acceptance rate)<br>• Baseline (pre-intervention) survey conducted<br>• 1, 12-month (post-intervention) follow-up surveys conducted<br>• Quarterly phone/text/drop-in check ins to maintain contact with participants, update information, and boost retention<br>• Meeting with participant stakeholders to plan dissemination<br>• Meeting with researchers and professional networks to plan dissemination/diffusion of intervention | • COVID-19 test completion, testing and vaccine literacy, access, and uptake | • Pre- and post-intervention findings about CLSI women's COVID-19 testing and vaccine literacy, access, and uptake<br>• CLSI stakeholder, researcher, and practitioner plan for dissemination/diffusion of intervention to broader population of CLSI people |




women with CLSI using an mHealth modality, also built specifically for women with CLSI. While we are submitting this application as a clinical trial (it met all four NIH criteria for clinical trials), we employ a simple pre/post intervention design, collecting baseline data before intervention implementation and post-intervention follow-up for the entire sample. Given the emergency of the COVID-19 pandemic and need for immediate effective testing interventions in a vaccine environment, we felt it would be unethical to use a randomized study design and withhold a low risk, potentially beneficial intervention from high need women.

***Team:*** Due to the multi-site nature of this study and the needed expertise spanning criminal legal systems, health, COVID-19, stakeholder engagement, health literacy, health communications, mHealth, and mixed methodology, we have a large but close team. MPI Ramaswamy has been collaborating with most team members for as long as a decade. MPI Geana is a specialist in health communication with expertise in underserved populations; Ramaswamy and Geana built an mHealth women's health literacy intervention together (2R01CA181047), and their work has generated several papers. Co-Is Lorvick, Cropsey, and their staff members have been working with Ramaswamy on the tri city cohort study since 2017 (R01CA226838). Together they have a seamless system for collaboration and success, with both studies resulting in half a dozen papers in press. They are committed to working together for the proposed project. Ramaswamy brings on long-time colleague and CDC Advisory Committee on Immunization Practices member, Dr. Kevin Ault; racism, mistrust, and history professor, Dr. Jason Glenn; stakeholder engagement specialist and mentee, Dr. Sharla Smith; infectious disease doctor and COVID-19 jail expert, Dr. Alysse Wurcell. Methodologists and long-time collaborators of Dr. Ramaswamy include statistician Co-I, Dr. Jaehoon Lee and qualitative Co-I, Dr. Amanda Emerson. Existing project managers from previous studies will spend a portion of their time on this newly proposed project. An additional benefit of the team structure is the inclusion of paid time for stakeholder research assistants – that is women with CLSI – who will be hired at each site to get formal work experience in research and contribute to the research process, and importantly, dissemination of findings for the study. Because RADx-UP projects are encouraged to support early stage investigators (ESIs), specifically targeting diversity in research and practice, we would like to note that 50% of investigators/staff (9/18) are faculty and staff who identify as people of color. Three of the ESIs on this application identify as persons of color.

***Timeline, syncing with ongoing studies, and impact:*** The table below shows the timeline of proposed study aims against the backdrop of ongoing studies. From a feasibility perspective, we are taking advantage of having both the cohort to whom we plan to push the intervention to (ongoing cohort study below) and the platform with which to design the intervention (ongoing mHealth intervention). This allows us to work fast, which is critical in this pandemic. We propose a two-year study to rapidly assess (Aim 1), build and push (Aim 2), and evaluate and disseminate (Aim 3) an mHealth intervention to boost COVID-19 testing and vaccine literacy, access, and uptake among women with CLSI in three cities. By incorporating the proposed study onto existing ones, we save resources on development, investigators and staff, in order to build something quickly that we expect will have significant public health impact (get high risk women into COVID-19 testing and vaccine) and have utility for the future (as ongoing COVID-19 testing and vaccine boosters are needed[37]) new pandemics emerge, and as we try to build the science of vaccine uptake among women with CLSI – a science that is needed but almost non-existent.

**Study Timeline: Overlap with Ongoing and Proposed Studies**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| *Ongoing* ***ACCESS TO THE THREE CITY COHORT*** R01CA226838, 2018-2023 Tri-City Cervical Cancer Prevention Study among Women in the Justice System | | | | | | | | | |
| | *Ongoing* ***PLATFORM FOR mHEALTH INTERVENTION*** 2R01CA181047, 2019-2024, Sexual Health Empowerment for Jail-Involved Women's Health Literacy and Prevention | | | | | | | | |
| | | | | *New Proposed* ***mHEALTH COVID-19 LITERACY INTERVENTION TO WOMEN IN THREE CITIES*** U01MDXXXXXX, 2021-2023 | | | | | |
| 2018 | 2019 | 2020 | 2021 | 2022 | | | | 2023 | |
| **STUDY ACTIVITES** | | | Pre | Y1 Q1 | Y1 Q2 | Y1 Q3 | Y1 Q4 | Y2 Q1 | Y2 Q2 | Y2 Q3 | Y2 Q4 |
| IRB approval | | | X | | | | | | | | |
| **Aim 1** Convening of stakeholders and collection of preliminary data | | | | X | | | | | | | |
| **Aim 2** Development, pilot testing, and implementation of intervention | | | | X | X | | | | | | |
| **Aim 3** Evaluation of intervention impact and dissemination planning | | | | | | X | X | X | X | X | X |

***Sampling, recruitment:*** We will use convenience sampling for this study – in that we will recruit from the TriCity cohort (ref). Based on our prior experience, we expect 95% of women to accept participation in the new study. The sample currently available includes 108 women in Kansas City, 166 women in Birmingham, and 234 women in Oakland (ref). The Kansas City sample was originally recruited in jails (seven years ago) but has now been community based since (with some periodic local reincarceration). The Birmingham sample was recruited two years ago in a community corrections program. The Oakland sample was recruited through probation offices and in working with local reentry organizations, four years ago. We have maintained contact and excellent retention rates one and two years later across sites – at 82%.

For recruitment, women will be invited to participate by study staff at the respective sites, with an IRB-approved verbal consent that reviews study procedures, risks, benefits, and the voluntary nature of participation. For the last year, given the pandemic, 100% of research activities occurred virtually, with 95% of interviews over the phone and 5% over email or postal service mail correspondence. Though our study field sites are opening up, we expect most recruitment will be over the phone. At the end of the verbal recruitment and consent process, the study staff member will ask the woman, “Would you like to participate in this study?” We used this exact same method to recruit women into the original tri-city cohort study, since those women were already participating in other studies at each site. The method was IRB-approved, effective, and resulting in 95% participation among all of those invited (ref). An advantage is that the study team, particularly the field staff, has remained the same over the last seven-10 years. For the present study, participants will know the person inviting them, thus having the benefit of familiarity with personnel and typical study procedures. For sustainability purposes, we will work with stakeholders in Aims 1 and 3 to better understand how to reach new potential participants in future dissemination activities.

We will tell women during the consent process that for Aim 1, 60 women will be randomly chosen to participate in interviews; and for Aim 2, that 45 women will be randomly chosen to provide feedback on an early stage of the intervention, but for Aim 3, that all women will be invited to participate. We will use a random number generator to select participants for Aim 1 and 2. If women complain during the consent process about unfairness and not being able to be selected for Aim 1 and 2 (which has not happened to us in the past), we will invite them to participate. Aim 1 and 2 do not mandate a random selection process for scientific reasons.

***Attrition and retention:*** For Aim 1 and Aim 2, we will keep recruiting until we reach our desired sample size. Because Aim 1 and Aim 2 only have one time point of participation, attrition is not an issue. For Aim 3, we expect 95% of the 508 women to agree to participate in study, resulting in a sample of 483 women at baseline assessment for this aim. Based on our ongoing community-based mHealth women’s health literacy RCT, where 81% of women who initiated the mHealth intervention completed it, we expect 391 to complete the intervention. Also based on our RCT, we are at 100% retention for the post-intervention follow-up, so we expect to retain all 391 women for the 1-month post-intervention follow-up. At the 12-month follow-up, we expect a final conservative attrition rate of 20%, based on our prior research activities following cohorts of women with community-based CLSI. Thus, the smallest expected N for the final sample will be 313 women.

Similarly, Aim 1 and Aim 2 should do not have retention issues, since activities occur at one point in time. For Aim 3, retention of participants for the post-intervention follow-ups will be accomplished through methods that our research teams have been using successfully for the last 10-20 years in our respective cities to achieve excellent follow-up rates with hard-to-reach samples, e.g. those with recent CLSI, drug users, and the homeless (refs tri city 68,69). These methods include supplementing existing participant contact information with names, addresses, phone numbers of participant, family members, friends; places of hanging out like bars, bodegas, street corners, or churches; places for usual drug or mental health treatment (with signed approval to contact these facilities), places of previous incarcerations, Facebook and Instagram handles. We

will employ quarterly check-ins during which we verify contact information of participants. Pre-COVID-19 we had field sites in Oakland and Birmingham (Birmingham is still open as it's a city site). We had also negotiated the rental of a field site in Kansas City. We anticipate that these will reopen in the next year, and all are located in places familiar to participants out in their community, which will further boost our attempts at long-term retention. Finally, this study has the benefit of part-time employment of "stakeholder research assistants," that is, women with CLSI. This approach should help us identify and test new strategies for retention.

***Intervention content and modality:*** The COVID-19 literacy module will be developed according to the most recent public information about COVID-19 testing and vaccine from the WHO, CDC, and ACIP, updated as new recommendations emerge and in consultation with our ACIP Co-I, Ault. MPI Geana produced an educational video podcast about the evolution of the pandemic during the acceleration phase, distributed through the online Treepple Health News video platform, as well as scripts for educational videos about COVID-19. Co-I Wurcell also produced COVID-19 education videos for the state of Massachusetts and local jails. These videos and scripts will provide a foundation for the COVID-19 literacy module. Content will include the topics listed in the table below. MPIs Ramaswamy and Geana and Co-Is and staff have published research on social and health care circumstances of CLSI women during COVID-19 using survey research[29-31]; perceived risk, attitudes, and behaviors related to COVID-19 and vaccine using open-ended interviews[31]; and trust in sources of information about COVID-19[30-31], that will provide the foundation for some of this intervention development. Semi-structured interviews with stakeholders in Aim 1 will provide the necessary localized knowledge about testing in a vaccine environment - *new information.*

These sources will inform the development of the COVID-19 literacy module that covers the following health literacy domains: COVID-19 knowledge about transmission, risks, testing recommendations, vaccine and side effects; COVID-19 beliefs about testing in a vaccine environment, hesitancy for taking vaccine, mistrust, media source trust; COVID-19 self-efficacy for engaging in strategies for protection, testing, getting to and completing testing and vaccine appointments; confidence in navigating institutions responsible for testing and vaccine administration. Operationalization of "literacy" as knowledge, beliefs, and self-efficacy follows the operationalization of content-specific critical health literacy as used in our previous and ongoing interventions for women with CLSI and is described in the significance section[26-28]. The table on the following page, shows sample segments for the mHealth module.

In addition to increasing their health and media literacy, we will build trust and rapport with women through the study. Given that marginalized women, often women of color, have the least access to medical innovations (vaccines) and the most distrust of those innovations (especially the pandemic), we would be well-positioned to adapt to changing pandemic realities to offer information from a trusted source. The segments will include the words of women in the target population, text, and video content to offer information, and interactive features like quizzes about testing and vaccine beliefs and maps to show how to find appointments.

| **COVID 19 Literacy Module (example)** | |
|---|---|
| Segment 1 | Cause, transmission and symptoms |
| Segment 2 | Disparities |
| Segment 3 | Testing matters! Testing attitudes and beliefs |
| Segment 4 | Vaccine matters! How vaccine works, efficacy, safety, side effects |
| Segment 5 | Why women are hesitant, myths and facts |
| Segment 6 | Which institutions to trust? |
| Segment 7 | Trusting sources of information |
| Segment 8 | Overcoming barriers to testing and vaccine |
| Segment 9 | Appointments, transportation, fear, stigma |
| Segment 10 | We are in this together. Spread the word! |

We will also integrate a media literacy segment in the COVID-19 literacy module with a focus on two major areas of media literacy: misinformation and disinformation. Media literacy is a complex construct, but at its core, it focuses on the ability to "access, analyze, evaluate, and produce both print and electronic media."[38] Although we will not address the "produce both print and electronic media" component in this training, we will address critical thinking about sources of information, how to identify disinformation, and about sharing erroneous information on social media, as an essential part of stopping its dissemination. With this segment, we aim not only to create an aware audience but also to empower these women to actively play a role in curbing mediated misinformation and disinformation, especially among their highly vulnerable communities.

Finally, the mHealth application has been designed to simultaneously reach all participants with location-tailored pertinent information as it becomes available (such as COVID-19 vaccination opportunities and any new information about testing locations, or testing recommendations or boosters, for example).

***Web development and programming:*** The Center for Excellence in Health Communication to Underserved Populations (CEHCUP) from the KU School of Journalism and Mass Communications, will provide web development for the COVID-19 vaccine literacy module and segments, as well as the media literacy module. The Content Management System (CMS), which was developed by CEHCUP for the SHE-

Women website (www.shewomen.org), already can seamlessly integrate the COVID-19 module, once developed, which will benefit from the same platform and structure as current modules on women's health. Nevertheless, we will perform relevant improvements to all areas of the application to address the delivery of localized information and improve scalability. The administrative section will be enhanced to support the definition and management of new video components together with the related questions, permanent storage to the database, as well as reports designed to extract the data and make it available for review and further analysis. The participant section will be upgraded to support the display of the new video components, together with associated functionality to pause the delivery of the video, display overlayed questions, and provide explanations at set timestamps. We will also upgrade activity logging and recording of participants' answers to the database. We should note that for this particular group of women we have chosen an integrated, multimedia electronic vaccine literacy text-Web platform intervention system. Most women (76%) use text messages, and 80% have smartphones. We also know from follow-ups, that many women have “burner” type mobile phones, not permanent smart phones, which makes using a dedicated mobile app problematic, and some access the Internet through private or public computers, for which a mobile app would be useless. A web-based application provides the largest reach to a multitude of devices.

A content management system (CMS) is the foundation of the software platform that will be updated to support the current study and will provide seamless integration of SMS (text) messaging with the Web-delivered content. As one of the purposes of this research is to be the starting point for wider dissemination of this intervention, the technology we will implement should also serve as the core for future development. Considering both the characteristics of the target audience as well as the specific requirements of the project, the proposed CMS will 1) allow publication of content in various formats (text, audio, video); 2) asynchronous communication with users using various methods, starting with SMS messaging; 3) synchronous communication with users (e.g., chat); 4) integration with various social media channels for sharing of updates on testing and information vaccination (e.g. Facebook, Instagram); 5) track user interaction with the COVID-19 literacy content and automatically respond to certain user actions (e.g., send SMS reminders if the user does not open the content within a certain period of time), and 6) collect data using automated metrics (e.g., access logs, data usage logs) and survey-like tools. A dedicated administration dashboard will provide researchers with aggregated as well as individual data on website use, and allow full management of the CMS. User access to content will be PIN-protected, and data transfer will be encrypted. Because the underlying platform already exists via the SHE-WOMEN project, and some of the COVID-19 literacy information for the module has been already produced, we are leaving only six months to develop and pilot the Web module. While this is an aggressive timeline, we are well-poised to build on existing infrastructure/ access to participants to build and pilot. While content is developed (scripting, filming, etc.), upgrades to programming of the SHE-WOMEN web application will be performed to support the new content and study requirements. Based on our experience developing content for a women’s health literacy mHealth intervention, we are convinced this timeline is feasible (and necessary given the importance of pushing the intervention as quickly as possible).

***Procedures for getting participants to initiate mhealth intervention:*** We estimate an aggregated contact time of 30-60 minutes for participants enrolled in the program. This includes completion of the COVID-19 literacy training as well as engagement via text messaging, and asynchronous and direct communication with the research team through the website. However, because it is a text-Web intervention, accessing content will be dependent on user engagement with the platform. We will measure uptake of the intervention components as it relates to number of minutes participants actively engage with the content, and length of time for COVID-19 literacy module completion. Participants who successfully initiate the intervention will be sent texts to their mobile phone or email with a link to content on the SHE-Women website (www.shewomen.org). Content will be delivered through a mix of short videos of the health educators and standardized patient actors discussing content (available in mobile-optimized video as well as audio only format), interactive quizzes, and multimedia. We have found these content packaging and delivery methods to be highly engaging for women with CLSI (ref). Through automatic feedback from the website, the study manager at each site will monitor whether participants access content after receiving the text messages. If participants have not accessed content within 24 hours of receiving a text message prompt, they will be sent a second text message invitation. If participants still haven’t responded, they will receive a phone call from the site’s study manager, re-inviting them to access content for that day. In our ongoing RCT, we found that the average time from baseline to initiation of intervention was two days. The SHE-Women website also will have a tab available to live-chat with a health educator 5 days a week for 8 hours a day. This feature will be managed centrally at the Kansas City site (home of the MPIs). Participants will be able to send messages to the health educator through the SHE-Women website, if they are not able to live chat. The asynchronous messaging will be location-dependent and

will be automatically directed to each of the sites' research teams. This feature will be available in addition to standard text-message access to a health educator during business hours. We will add weekend or evening hours if necessary. Participants will be given a one-week window for self-directed completion of the COVID-19 literacy module. As soon as participants access all intervention content, the study manager at each site will be triggered to thank the participant and let them know that they will complete a post-intervention assessment in one month. The post-assessment will be offered to participants over the phone or through an electronic link to the survey. Participants will be sent any relevant COVID-19 information over text message throughout the study period, with uptake of these messages and user engagement (i.e. responses, live chats, emails, phone calls, etc.) documented. We are aware that knowledge about COVID-19 testing, prevention and treatment is a moving target during this pandemic, and that new evidence-based information may be available that may contradict, enforce, or supplement the initial COVID-19 literacy deliverable. If salient information requires, due to the modularity of the SHEWomen CMS, and the experience and relationships within the team, we can completely revise an existent segment, or produce and release a new segment in 48 hours or less, without interrupting or disrupting the intervention. The seamless integration of the text-messaging app within the intervention website automatically pushes notifications to all registered users every time a component of the COVID-19 literacy module has been changed or a new segment has been added. Furthermore, each study manager has the capability to compose and send SMS messages to its area participants, and a centrally managed option from the Kansas City site can send text messages to all participants enrolled in the intervention. This approach ensures that participants are constantly updated on information related to COVID-19 testing, vaccinations and any other coronavirus-related issues that are important for CLSI women.

***Pre-post study design and ethical considerations:*** We have chosen a pre-post design for evaluating the effectiveness of the intervention in this study. We are testing the hypothesis that relative to baseline COVID-19 testing and vaccine literacy, access, and uptake, after the intervention, participants' COVID-19 testing and vaccine literacy, access, and uptake increases. In other words, we will measure the outcomes of COVID-19 testing and vaccine literacy, access, and uptake at baseline; deliver the intervention to the entire sample; and then measure post-intervention outcomes at 1- and 12-month follow-up. While there are strong study designs for evaluating intervention effectiveness, like the gold standard randomized controlled trial, or a waitlist controlled design (which we have employed before for a low-risk intervention), we have determined that it would be unethical to withhold or make participants wait for a low-risk potentially high impact intervention of this sort. Based on what we know about women with CLSI – especially for those women in the community – they are rarely the target and recipients of educational interventions like this. Our analytic plan below describes the strategies we plan to employ to boost the rigor of the methodological approach to this study design. People with CLSI have three times the risk of death from COVID-19 compared to the general population. While our pre-post design is a scientific limitation, we have decided to proceed given the ethical obligation to participants and commitment to narrowing COVID-19 disparities.

***Outcome measures:*** The table below lists outcomes, modality, and measures for each aim.

| Aim | Outcomes | Modality | Measures |
|---|---|---|---|
| **1** | COVID-19 testing, attitudes, practices in a vaccine environment | Semi-structured interviews | Prompts relating to attitudes and practices related to testing; difficulty accessing testing/vaccine or success stories; concerns heard from friends, family, news, social media, the streets; trust of government, health departments, pharmaceutical companies, corporations, doctors; perception of knowledge to make informed decision about testing and vaccine (acknowledging any regional differences) |
| **2** | Acceptability and useability of COVID-19 testing and vaccine mhealth module | Survey items and semi-structured interviews | Acceptability of mhealth intervention adapted from Sekhon et al (ref); usability scale adapted from Brooke (ref), open-ended questions developed by study team to assess limitations, opinions about least/most favorite parts, any other participant feedback |
| **3** | COVID-19 test completion, testing and vaccine literacy, access, and uptake | Survey items | COVID-19 test completion and vaccine access and uptake questions developed by study team (where, how many tests, results, vaccines, which, challenges/barriers/facilitators, side effects); COVID-19 literacy adapted from Roberto Biasio et al (ref), media use during COVID-19 survey by Fisher et al (ref), COVID-19 knowledge, attitudes, and avoidant behaviors survey from Center for Economic and Social research (ref); COVID-19 testing attitudes scales to be developed at study start (based on current scientific and media reports on attitudes about testing in a vaccine environment; vaccine mistrust and hesitancy scales, by Bogart et al (ref); attitudes about racism and mistrust by LaVeist et al (ref) |

***Validation of outcomes:*** As in our previous research, we will attempt to validate the self-reported outcomes of COVID-19 test completion and vaccine receipt. In our research on validating self-reported Pap tests among CLSI women (ref) we assessed medical records, semi-structured interview results probing about last Pap test recall, and a Pap test knowledge score based on a survey. We found that self-report of Pap

testing accuracy was associated with Pap test recall and Pap test knowledge scores. Thus, in all analyses of self-reported COVID-19 test completion and vaccine receipt, we control for COVID-19 literacy scores and run an analysis of the two-three questions about testing and vaccine recall to assess whether those factors should also be controlled for in analyses.

***Data collection and compensation:*** For Aim 1 we will conduct semi-structured interviews by telephone or Zoom, if social distancing is still necessary. We have been employing this method for qualitative data collection successfully during the pandemic. If we can safely interview in person we will do so at community-based field sites. For Aim 2, once we push the pilot content to participants, we will conduct feedback interviews over the telephone with participants, just as we have done previously to pilot test mHealth intervention content (ref), as well as analyzing website logs to understand pilot study's participants' interaction with the COVID-19 literacy module. For Aim 3, and in our ongoing cohort study we have been using an IRB-approved, secure, cloud-based data capture software, RedCap. In the majority of our follow-up of the tri-city cohort, 95% of interviews were conducted over the phone, by a staff member, with the staff member entering data directly into the RedCap database. In 5% of cases, we either emailed participants a link to the RedCap survey at their request or printed a copy and mailed it to them with return postage (in the case of participants who become incarcerated during the study). The RedCap platform has worked pretty seamlessly across the three city study sites for tracking needed surveys, doing quarterly check-ins, and conducting surveys with participants. We will continue employing this method for the present study. Quantitative data from website logs in the form of standardized reports (engagement time, module and segment completion times, number of logs, asynchronous interaction, correct answer to quizzes) will be retrieved and will complement the survey data.

We have always paid our research participants for their time. Less than one-third have stable employment, with many engaging in sporadic, under-the-table work to try and make ends meet. We have found in our combined decades of experience that compensating participants is necessary and appreciated. Participants for Aim 1 stakeholder interviews will be compensated $25; Aim 2 intervention completion will be compensated $25; Aim 3 quarterly check-ins will be compensated $10, and for each follow-up survey participants will be compensated $50. When participant stakeholders are brought together, they will also be compensated $25 for participation in feedback sessions on future dissemination, in addition to being invited to co-author reports, presentations, and papers with us. In our team's combined experience with multiple interventional and longitudinal studies with women with CLSI, this amount of compensation hits the sweet spot of being enough to retain participants over time, but not be so much as to coerce them to participate.

***Data analysis:*** Aim 1 data analysis will entail thematic analysis of semi-structured interviews supplemented by application of narrative inquiry techniques. The qualitative descriptive analysis will involve iterative coding, memoing, winnowing, and consensus-development around themes by analytic teams at each site and then across sites, led by the qualitative Co-I Emerson. Narrative inquiry of responses will address personal accounts elicited from women about encounters while trying to get tested or getting a vaccine, or stories about what peers and media are saying about testing and vaccines in their communities. Story-based interviewing allows for interpretation of meaning along formal and performative indices in addition to the more standard focus on repeated themes. We have used the narrative analytical approach in previous research and found that, with its extended units of analysis, the story-based technique renders visible nuances of perspective and experience that may be obscured in other qualitative methods (refs 47,48). For Aim 2, a descriptive analysis of survey items on acceptability and usability will be conducted and guide subsequent changes for interventions. Qualitative data will be analyzed using a thematic analysis across interviews and will be led by MPIs Geana (health communications/mHealth intervention expert) and Ramaswamy (jail health literacy intervention expert) to decide how and where to make changes in the final mHealth intervention. Aim 3 data analysis will include a series of quantitative assessments led by Co-I Lee. First, bivariate tests will be performed to examine the distributional properties of the survey data (COVID-19 test completion, testing and vaccine literacy, access, and uptake), website log data (usage of and interaction with the COVID-19 literacy module; i.e., intervention fidelity/dosage), and their correlations at each time point (0, 1, 12 months) within the sample, as well as in comparisons between participant subgroups (study sites, age, race/ethnicity, education, employment, etc.). Second, growth curve modeling (GCM) will be utilized to explore the changes in each outcome over the 13-month study period, while properly accounting for (a) the dependency of observations (e.g., autoregressive residual covariance), (b) the baseline characteristics imbalanced between dropouts and completers, and (c) other confounders (e.g., study sites reflecting policy climate/local promotion of testing and vaccine, age, race/ethnicity, education, employment, intervention fidelity/dosage). Third, hierarchical linear modeling (HLM) will be conducted to estimate the longitudinal impacts of COVID-19 literacy, attitudes, mistrust, hesitancy (independent variables) on test completion, vaccine access, and uptake

(challenges/barriers/facilitators, update [yes/no]; dependent variables). Site-specific effects will be identified in a follow-up subgroup analysis using data from the Kansas City, Birmingham, and Oakland subsamples. Lasty, a survival analysis will be conducted. Specifically, we will estimate the cumulative probability of taking COVID-19 test or vaccine over 12 months (i.e., survival function); and we fit Cox proportional hazards models to identify the factors (e.g., literacy, and demographic variables) that significantly contribute to the time to get vaccinated (i.e., survival time).

***Power considerations:*** Aim 1 will have 60 participants total, that is 20 from each site. The goal for Aim 1 is not thematic saturation, but rather to collect enough information from stakeholders to supplement what is known in the health literacy and COVID-19 communication literature to develop the intervention.[39] Given on our prior research in developing health literacy interventions based on stakeholder interviews[30-31], 60 participants will be sufficient to meet our goals. If we feel that we don't have enough information to detect regional differences in stakeholders' feedback and believe that some may exist, we have the time and resources to ask more structured questions in this regard. Aim 2 will be piloted with 45 participants, 15 from each site. The goal of the pilot is to work out kinks in the mHealth intervention delivery, multimedia design, see which parts of the intervention are great, and which ones don't resonate, and to get feedback on what other areas of content need to be added in. In our prior research developing health literacy interventions[27], this sample is sufficient. We expect a complete sample of 313 participants for Aim 3 based on a 95% acceptance rate and 81% completion rate over the 13-month study period. Because there is little or no previous research that can guide power calculation for our Aim 3 investigation, we estimated minimum detectable effect size (MDES).[40] This approach provides an insight for the smallest 'true' effect for which this study can detect with $N$=313, 80% power, and Type I error controlled under 5%. The estimated MDES are small—$d$=0.15 for mean difference, $g$=0.08 for proportion difference, $\rho$=0.16 for correlation, and $f$=0.08 for GCM/HLM when 0.30 correlation is reasonably assumed among repeated measurements. These results suggest that this study will be adequately powered (> 80%) even when the 'true' effects of the intervention are small in this population.

***Potential problems and alternatives:*** The biggest potential problem is the aggressive timeline for Aims 1 and 2. For Aim 1, we are well-practiced in recruiting and conducting qualitative interviews with our sample. If this activity takes more than the three months allotted, we plan to continue data collection and analysis while simultaneously doing the work for Aim 2 on intervention development, especially considering that data analysis for the qualitative study in Aim 1 will happen concomitantly with data collection. Findings in Aim 1 will be integrated in real-time for Aim 2. Aim 2 also has an aggressive six-month timeline for mHealth module development (three months in common with Aim 1). Fortunately, we already have a dedicated website and SMS platform through which to deliver the intervention (www.shewomen.org). That website and SMS platform already has modules on cervix, breast, sexually transmitted infection, and reproductive goal planning developed and being tested in an ongoing RCT. Software programming starts from an existent structure that only needs to be upgraded, which is can be achieved within the dedicated timeline. The initial programming of the SHE-WOMEN website did took into consideration future upgrades, so we have created the adequate frame to ensure seamless integration of new modules. Therefore the structures and protocols already exist for development of an mHealth module, and software updates will be mostly conducted in the first three months (timeline common with Aim 1), leaving three dedicated months for content creation and pilot testing. While the activities for Aim 2 are substantial, we have done them all before and have a good sense of the time required to accomplish them. The primary concern with Aim 3 is retention, but this team has experience both with multiple studies of women with CLSI, but also with this exact cohort. The Kansas City women have been followed for 7 years; the Oakland women for 3 years; and the Birmingham women for 2 years. Based on this experience, our attrition estimates should be pretty accurate. And statistical power for determining intervention effectiveness is premised on some loss to follow-up. The final problem is the changing nature of COVID-19: whether that be disease patterns, outbreaks, new waves, new strains, new testing requirements, pauses in vaccine, the need for boosters, and changing information and levels of community trust. This is a reality of our times, and our work directly with stakeholders, and nimbleness in being able to adapt the mHealth intervention and push new information out to participants, should help us navigate changes during this pandemic.

***Dissemination:*** Due to the changing and urgent nature of the COVID-19 pandemic, rapid communication of findings relevant to the field is key. Between April 2020-2021 our team published nine COVID-19 manuscripts, produced three educational videos, two blog posts, co-authored a white paper as COVID-19 communication experts with an NIH team, wrote letters to our state governors, participated as expert witnesses in the COVID-19 decarceration efforts, vaccinated incarcerated persons, and worked directly with local health departments, jail health services, and local sheriffs to assist with providing mitigation and vaccine protocols, information, and as resources for questions. We anticipate staying fully engaged in both formal and informal

dissemination activities throughout the pandemic and (hopefully) post-pandemic period. Our formal manuscript plan is presented below. We engage stakeholders in multiple activities (Aim 1 data collection, Aim 2 and 3 data interpretation, and facilitate this by budgeting for stakeholder compensation for research activities as well as with full-time stakeholder research assistant positions in Kansas City, Birmingham, and Oakland). The latter activity will both ensure the rigor of findings prior to and during dissemination, but will also engage extremely marginalized CLSI women with formal employment opportunities. Of note is that half of our peer-reviewed manuscripts will be co-authored with participant stakeholders. We also plan to report findings in academic blogs, as authors of op-eds, through social media, presentations to NIH officials on findings, presentation at academic and local conferences, through our study website (www.kumc.edu/she), and in annual newsletters to participants in the three cities. We have also budgeted funds to support communications staff at University of Kansas Medical Center, University of Alabama Birmingham, and RTI Berkeley, to help boost dissemination and engage the broader media community.

| **Planned Peer-Reviewed Manuscripts** | |
|---|---|
| **Aim** | **Paper** |
| 1 | Regional differences in COVID-19 testing, attitudes, and practices among CLSI women in three cities (*co-authored with selected stakeholders*) |
| 2 | Development of a stakeholder-informed, just-in-time COVID-19 literacy mHealth intervention for women with CLSI *(co-authored with selected stakeholders)* |
| 3 | COVID-19 testing and vaccine literacy, access, and uptake among CLSI women (baseline, pre-intervention) |
| 1-3 | Working with CLSI participant stakeholders to design and assess outcomes *(co-authored with selected stakeholders)* |
| 3 | Facilitating access to COVID-19 testing and vaccine among women with CLSI (based on 12 months of follow-up data) |
| 1-3 | Doing public health intervention work during an ever-changing pandemic and information context |

Aim 3 has a dissemination planning component that features engagement of stakeholders at two levels. First, we will convene a group of CLSI stakeholders, similar to our methods in Aim 1, in order to explore diffusion of the intervention through the women's social networks. This would entail, for example, assessing whether and how the women would share the mhealth intervention link with their networks. Second, we will take advantage of Co-I Dr. Wurcell's COVID-19 in jails and prisons professional network, a group of about 30 jail doctors, public health researchers, and practitioners who attend monthly meetings. We will plan presentation of our work at these meetings and engage members in diffusion of intervention planning through their networks in the course of 2-3 meetings. Dr. Wurcell is also a board member for the Academic Consortium on Criminal Justice Health, and will use her network to facilitate panel presentations on study findings and engagement of the broader practitioner audience in years 2 and 3 of the grant. We also plan to reach out to other RADx-UP projects in our recruitment areas and beyond, and explore dissemination opportunities that are mutually beneficial, including sharing data with the Coordination and Data Collection Center. Finally, per our Resource Sharing Plan, we plan to make tested intervention materials open source for public access and use.

***Impact.*** Using these dissemination strategies, we hope to create an infrastructure so that the program and lessons learned from this study will be sustainable. The goal of testing the intervention is to demonstrate efficacy of these types of interventions in a very hard to reach and vulnerable population. The intersectional nature of mass incarceration, racism, and COVID-19 have already created profound disparities for an already vulnerable and often overlooked population of women. Once we have developed an easy to use mHealth intervention, we will have an opensource set of materials and technological platform available to the community of people working directly with people leaving the criminal legal system – a group of two million women who leave jails annually and another 11 million men. We have budgeted time, resources, and expertise necessary to disseminate findings and reach the broader population of people with CLSI and other marginalized members of our community with up-to-date information.

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