Study Title: Identifying and addressing critical social, ethical, and behavioral factors associated with COVID-19 testing and vaccination among Spanish speakers

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Background, Rationale and Context

Significance

Latinx communities in the US are disproportionately affected by COVID-19.[5-7,33] Latinx (a gender-inclusive term[34,35] that we use to refer to Hispanic/Latino populations in the US) persons comprise 18.5% of the US population and as of June 19, 2021, comprised 28.8% of US COVID-19 cases.[36] Latinx persons are 2 times more likely to contract COVID-19 than their non-Latinx White counterparts, 2.8 times more likely to be hospitalized from COVID-19, and 2.3 times more likely to die from COVID-19.[1] These disparities are even more profound among Spanish speakers and Spanish-speaking immigrants.[1-7]

Ongoing testing and vaccination are critical to effective control of the pandemic; however, complex issues contribute to low rates of COVID-19 testing and vaccination within Spanish-speaking Latinx communities.[5-8,37] Factors that pose challenges to testing and vaccination include poverty, limited resources, and institutional and structural barriers (e.g., discrimination and limited transportation). Latinx persons may: lack access to culturally congruent information about COVID-19 testing and vaccination, including eligibility and how to access these services; believe they are not at risk for COVID-19; worry about missing work due to a positive test result or vaccine side-effects; and assume that they have to pay for a test or vaccine. Other challenges include fear of engaging with government systems (including public health) and of the long-term health implications of testing and vaccination. These barriers are even greater among those who do not speak English, are undocumented, and/or live in mixed-immigration status households.[2,5-7,37] Our community-based participatory research (CBPR) partnership's preliminary research identified additional barriers, including: misinformation about testing and vaccination communicated through Spanish-language TV and social media and within social networks by word-of-mouth, and distrust in the test or vaccine (e.g., not believing that they will get the real vaccine as has happened in Latin America[38,39]; published[2,40] and unpublished data).

A profound need remains to understand the social, ethical, and behavioral implications (SEBI) of COVID-19 testing and vaccination interventions within Spanish-speaking Latinx communities.[2,5,7,33,41-43] COVID-19 testing and vaccination are strongly influenced by social, ethical, and behavioral factors at the individual, interpersonal, institutional, community, and policy levels.[44] While some of these multilevel factors are beginning to be explored, there is a great need for further empirical studies that focus on Spanish-speaking Latinx communities. The heterogeneity of the Latinx population is well established,[34,35,45,46] and Spanish speakers experience markedly different barriers from other Latinx persons due to a range of factors such as more pronounced economic challenges, lower levels of acculturation, and heightened fear and mistrust of government systems (including public health). Furthermore, Spanish-speaking Latinx persons in the US may be undocumented and/or live in mixed immigration-status households[35,47,48] and thus face unique challenges to testing and vaccination.

Peer navigation has potential to increase COVID-19 testing and vaccination within Latinx communities. Natural helping (e.g., peer navigation and lay health advising) is potentially effective in addressing health issues in underserved and vulnerable communities.[11,15,16,24,27,28,49-62] Peer navigation

harnesses relationships and networks to help individuals engage with prevention or care services. Peer navigators have advantages over other strategies because they can reach those who are considered "hard-to-reach" with carefully personalized messaging and support. As trusted community members, peer navigators can be the first people turned to for assistance. Effective peer navigators are part of the networks in which they work, in terms of self-identity, socioeconomic status, and lived experience; understand community needs and strengths and what is meaningful to members and communities; communicate in the language of members; and incorporate culture to promote positive behaviors.[12,15,16,21,24,28,51,53,59,60,62,63] As our partnership has learned, peer navigation strategies can be sustainable, as peer navigators often continue their work after a study and funding end.[23,64]

mHealth can also be a powerful tool to reach Spanish speakers. Spanish speakers have high rates of social media use, including Facebook, Instagram, and texting, for acquiring health information,[46,65-72] and this use extends to COVID-related information.[2,42,73,74] These rates are related to increased proliferation of mobile devices, including among Spanish-speaking Latinx persons.[75-77] Mobile devices support apps, including **Facebook**, which is the most commonly used social media platform.[78] Because of its ubiquity and frequency of use, Facebook holds promise as a platform for health promotion.[9,79-83] Facebook also has a direct messaging feature that allows users to communicate one-on-one and to a group. **Instagram** has also grown its user base and features. In addition to supporting photo and video sharing, Instagram offers a direct messaging feature, and Spanish speakers in our research recommend that we use this app in intervention implementation.[12,70] At the same time, **texting** (including through messaging apps such as WhatsApp) continues to increase dramatically in all age groups and can be a powerful health promotion tool because it is widely available, inexpensive, and instantaneous, and can be effective at promoting behavior change.[10,84-89]

Because the health-related views of Latinx persons are strongly influenced by trusted social network members[42,73,90] and because Spanish speakers are active users of social media, combining peer navigation with mHealth holds particular promise for increasing COVID-19 testing and vaccination within Spanish-speaking Latinx communities. Moreover, studies suggest that Latinx persons report increased willingness to be tested and vaccinated,[91,92] indicating that focused support that addresses barriers and builds on facilitators could be highly effective. For example, in a recent national survey, eagerness to receive vaccination was more pronounced for Spanish-speaking Latinx persons than English-speaking Latinx persons (27% vs. 11%), but Spanish speakers reported greater information gaps and uncertainty about how orwhere to seek vaccination.[92]

This research is **significant** because Spanish-speaking Latinx communities carry disproportionate burdens of COVID-19 and have lower rates of testing and vaccination. However, there is limited understanding of the SEBI of testing and vaccination, and thus, a dearth of effective interventions to increase testing and vaccination within this population. Our study will fill these gaps through a better understanding of the individual, interpersonal, institutional, community, and policy factors influencing testing and vaccination and the testing of a Spanish-language intervention, known as *NuestraSaludSegura* (*Our Safe Health*), that integrates peer navigation and mHealth to increase testing and vaccination.

Innovation

This study is innovative in several ways:
1) We focus on a distinctly underserved and vulnerable population – the Spanish-speaking Latinx population – who encounter multilevel barriers to COVID-19 testing and vaccination in the US.
2) This study is proposed by a well-established partnership that has been exploring multilevel factors influencing health and developing and testing interventions designed to promote health equity within Spanish-speaking Latinx communities using authentic CBPR for two decades.[15,16,18,19,21,24,26,62,93-104]
3) Our community partners and collaborators cover the entirety of NC, allowing us to capture a wide range of experiences and settings (e.g., urban, rural, and suburban) and increasing generalizability.

4) This study collects formative research designed to increase our understanding of the SEBI of COVID-19 testing and vaccination and immediately translates this understanding to *NuestraSaludSegura*, a novel intervention designed to increase testing and vaccination within Spanish-speaking Latinx communities.
5) The *NuestraSaludSegura* intervention harnesses the complementary strengths of peer navigation and mHealth to increase COVID-19 testing and vaccination. The underlying evidence for these strategies is emerging, and to our knowledge, they have not been applied in combination within general Spanish-speaking communities.
6) The intervention leverages social media via existing platforms that Spanish-speaking Latinx persons already use (e.g., Facebook, Instagram, and texting). Thus, the behavior change focuses on testing and vaccination behaviors, not the antecedent behavior of downloading, learning, and using a new "app", which some mHealth strategies rely on for implementation.
7) We also include a novel strategy to dissemination that our partnership has developed. Designed to be low burden for attendees, our theory-based community forum brings together community members, partners, and other stakeholders to review study findings and develop next steps for practice and research.[95,100,105]

Approach

CBPR. CBPR has been identified as a critical approach to increase health equity and reduce disparities among underserved and vulnerable populations.[16,26,94,103,104,106-118] Blending the lived experiences of community members, the expertise of service providers and public health practitioners, and sound science can develop deeper and more informed understandings of health and yield interventions that are more relevant, more culturally congruent, and more likely to be effective and sustained, if warranted.[10,15,16,26,93,94,118-126] Furthermore, recruitment and retention rates may be higher, measurement may be more precise, data collection may be more acceptable, data analysis and interpretation of findings may be more accurate, and dissemination may be more likely than when using approaches that do not blend these multiple perspectives.[94,111,117-119,126-129]

The partners proposing this study have worked together for >18 years and have had many successes that, in part, we attribute to CBPR.[26,96,103] We have engaged in intensive decision-making about all aspects of this study, including the qualitative methods (i.e., in-depth interviews and focus groups), the intervention strategies (i.e., peer navigation and mHealth) and evaluation methods (i.e., the longitudinal group-randomized trial design), and dissemination plans. We will continue to use CBPR throughout this study. Our partnership is not study-specific; members join and leave, and be more or less involved, but the partnership remains.[10,11,26,96,100]

The proposed study. We have created a conceptually integrated CBPR study that includes systematic data collection on the multilevel factors that influence COVID-19 testing and vaccination; refinement of an efficacious intervention that uses complementary theory-based strategies (i.e., peer navigation and mHealth); intervention implementation and evaluation using a longitudinal group-randomized trial design; and dissemination of findings. This is an ambitious study, and we have allocated sufficient effort and delineated clear roles and responsibilities among study team members and community partners to ensure we accomplish the Aims. As a community member noted, "*We can't wait. COVID is hurting our community right now! We must do things that change these trends now!*"

Catchment area. We will conduct this study across NC. NC has more than 1 million Latinx persons, many of whom are immigrants,[139] and the COVID-19 experiences of its Latinx population reflect experiences nationally, increasing study generalizability.[140,141] In NC, compared to other racial/ethnic groups, the rate of COVID-19 infections has been higher within the Latinx community and fewer Latinx persons have been vaccinated.[142]

Study-specific steering committee. This study will be guided by a study-specific steering committee. This committee will be comprised of representatives from the Latinx community, community-based organizations, and academic research institutions. We expect to have ~15 committee members. Our team has much expertise with facilitating study-specific steering committees.[26,103,143] The committee will meet monthly to provide guidance on measurement; recruitment and retention; intervention refinement; and interpretation of findings. We will continue to use the "70%-consensus rule" to encourage consensus decision-making by asking if each committee member can support a decision by at least 70%.[101,128]

Objectives

Aim 1: Collect, analyze, and interpret exploratory qualitative data to expand our understanding of the SEBI of COVID-19 testing and vaccination within Spanish-speaking Latinx communities. We will conduct 50 individual in-depth interviews with health providers (including administrators, clinicians, community health workers, and safety-net clinic staff) and with representatives from Latinx-serving community-based organizations; and conduct 6 focus groups with Spanish-speaking Latinx community members (total number of focus group participants=60).

Aim 2: Refine and test *NuestraSaludSegura* to determine its impact on COVID-19 testing and vaccination among Spanish-speaking Latinx persons using a group-randomized trial design. Integrating our successes with peer navigation and mHealth strategies with other relevant COVID-19 studies and Aim 1 findings, we will refine and test the *NuestraSaludSegura* intervention. We will enroll 20 peer navigators, known as *Navegantes*, who represent 20 unique social networks, and 8 unique members from each social network for a total of n=160 social network members. After baseline data collection, we will randomize *Navegantes*, coupled with their social networks, into intervention and delayed-intervention groups (10 *Navegantes*; 80 social network members per group). We will train and support intervention-group *Navegantes* to increase COVID-19 testing and vaccination services within their social networks. We will evaluate the intervention by comparing changes in testing and vaccination from baseline to post-intervention follow-up between groups. *We hypothesize that intervention group will demonstrate increased COVID-19 testing and vaccination*.

Aim 3: Develop and disseminate practice, research, intervention, and policy priorities and recommendations to increase COVID-19 testing and vaccination among Spanish-speaking Latinx communities in the US. We will conduct an empowerment theory-based forum with Latinx community members and other community members and representatives from community-based organizations and universities to develop and disseminate priorities and recommendations based on study findings.

Methods and Measures

Design

Aim 1:

We will conduct **individual in-depth interviews** with two categories of participants from across NC: (1) Health providers (including administrators, clinicians, community health workers, and safety-net clinic staff), who have planned, managed, and/or conducted COVID-19 testing and/or vaccination activities for Spanish-speaking communities; and (2) Representatives from Latinx-serving community-based organizations. We also will conduct **focus groups** with Spanish-speaking Latinx community participants.

Aim 2:

We will refine and test the *NuestraSaludSegura* intervention, integrating our previous successes with peer navigation and mHealth strategies with other relevant COVID-19 studies and Aim 1 findings. We will then recruit, enroll, and collect baseline data from 20 *Navegantes* (peer navigators) and their social network members (n=8 unique social network members per *Navegante*) from across NC. *Navegantes* (coupled with their social networks) will be randomly assigned to: intervention or delayed-intervention groups (10 *Navegantes*; 80 social network members per group). Intervention-group *Navegantes* will be trained and supported for 6 months of implementation in Years 1-2; delayed-intervention group *Navegantes* will be trained in Year 2. CBPR partners emphasized that a delayed-intervention comparison design is the most equitable, acceptable, and ethical.

Assessment of intervention efficacy. We will use a longitudinal group-randomized trial design with 2 arms (intervention and delayed-intervention) to evaluate the impact of the intervention. Quantitative outcome data will be collected from each *Navegante* and their 8 enrolled social network members at 2 time points: (1) baseline (*prior* to randomization and *Navegante* training) and (2) immediate post-intervention (6 months after the *Navegantes* in the intervention group are trained).

In-depth interviews. After post-intervention follow-up, we will conduct in-depth interviews with each *Navegante* in the intervention group (N=10) to explore and better understand their implementation of the intervention, their natural helping behaviors, and other lessons learned.

Aim 3:

The translation of findings into action is a CBPR hallmark,[16,26,30,93-95,97,99,100,105,111,129,137,143,190-193] and we have developed an empowerment theory-based[100,169,194,195] and highly collaborative process to do just that.[95,100,166] We will organize and conduct a bilingual community forum to translate findings into practice, research, intervention, and policy priorities and recommendations.

Setting

The study will take place in community settings (e.g., community organizations) across NC.

Subjects selection criteria

- **Inclusion Criteria**

  Aim 1:

  To be eligible to participate in the in-depth interviews as a health provider, a participant must (a) be employed at a clinic, health center, or other organization that has planned, managed, and/or conducted COVID-19 testing and/or vaccination activities for Spanish-speaking communities; (b) be ≥18 years of age; and (c) be willing to participate. To be eligible to participate in the interviews as a Latinx-serving community-based organization representative, a participant must (a) be affiliated with a Latinx-serving community-based organization, (b) be ≥ 18 years of age, and (c) be willing to participate.

  To be eligible to participate in the focus groups, a participant must (a) self-identify as Hispanic/Latinx, (b) be Spanish speaking, (c) be ≥18 years of age, and (d) provide informed consent.

Aim 2:

To be eligible to participate in the *NuestraSaludSegura* intervention as a *Navegante*, a participant must (a) self-identify as Hispanic/Latinx, (b) be Spanish speaking, (c) be ≥18 years of age, (d) provide informed consent, and (e) report having been vaccinated against COVID-19 (because *Navegantes* serve as role models). Access to a smartphone will not be an inclusion criterion. We have some flexibility to provide smartphones and data plans for *Navegantes* without them, though given smartphone proliferation (and our past research experiences), this will likely be unnecessary.

To be eligible to participate in the intervention as a *social network member*, a participant must (a) self-identify as Hispanic/Latinx, (b) be Spanish speaking, (c) be ≥18 years of age, and (d) provide informed consent.

- **Sample Size**

Aim 1:

We will conduct **50 individual in-depth interviews** for a total number of 50 interview participants and **6 focus groups** with 8-12 participants each for a total number of 60 focus group participants. We will screen participants to ensure we obtain representation by: gender, documentation status, and those with and without experiences of COVID-19 testing and vaccination. As it is difficult to predict **saturation**[144-150] *a priori*, we have flexibility to expand the number of interviews and/or focus groups if warranted. Project members working with the qualitative data will meet regularly to discuss emerging themes and determine if saturation has been reached.

Aim 2:

Sample size calculations are based on a follow-up adjusted baseline (or ANCOVA) model. We estimated the sample size needed (20 *Navegantes* and 160 social network members) by performing calculations in nQuery v8.7.

Interventions and Interactions

Aim 1:

Interviews will be digitally recorded. While interviews and focus groups can be conducted remotely via telephone and videoconferencing platforms (e.g., Zoom and WebEx), we will conduct them in-person if possible based on the current CDC recommendations. Safety precautions (e.g., personal protective equipment) will be followed as indicated. Dr. Rhodes and an infectious disease epidemiologist published guidelines for safely conducting community-based and community-engaged in-person research during COVID,[151] which have been adopted by multiple Clinical and Translational Science Award hubs throughout the US and by CDC research teams.

The in-depth interview and focus groups guides. These guides will be structured to gather *descriptive* "deep"[152] qualitative data. An initial low-literacy assessment will collect demographic data. Guides will be developed iteratively with the steering committee and in consultation with the RADx-UP Coordination and Data Collection Center (CDCC) and consortium through ongoing literature review; brainstorming of domains and constructs; and drafting, review, and revision of potential questions. Because this Aim is

exploratory and designed to be **inductive**, the framework is subject to revision. This Aim's outcome will be a better understanding of the SEBI of COVID- 19 testing and vaccination among Spanish- speaking Latinx persons. Interview guides will adhere to best practices (e.g., creating non-leading/open-ended questions, ordering from general to specific, maintaining neutral tone, and depersonalizing behaviors by third-person-ing questions) to elicit knowledge, descriptions of experiences, opinions, and values.[98,146,150,153-156]

Aim 2:

The original intervention and its refinement. The bilingual *weCare* intervention serves as a foundation for *NuestraSaludSegura*. *weCare* is based on the social cognitive and empowerment theories and social support[9,10,28,168-170] and harnesses peer navigation and mHealth.[9-14] The objectives of *weCare* (i.e., to increase care engagement and improve health outcomes among vulnerable persons with HIV) align with the objectives of *NuestraSaludSegura* (i.e., to increase testing and vaccination among vulnerable persons disproportionately impacted by COVID-19). Thus, the refinement process will be efficient and include revising the *Navegante* training and mHealth messages. The study team and the steering committee will conduct the refinement in parallel to Aim 1, integrating findings from other relevant studies([e.g., 69,171,172]) and from Aim 1 as they emerge. Specifically, we will review the theoretical underpinnings of the intervention and anticipated outcomes of *NuestraSaludSegura* and refine the training, including the mHealth messages, to build *Navegante* capacity to increase COVID-19 testing and vaccination within their social networks. This process is designed to expedite the translation of Aim 1 findings into intervention, which is a hallmark of CBPR[94,113] and a priority of our partnership given the burden of COVID-19 within Spanish-speaking Latinx communities.

Each *Navegante* will serve as a health advisor, opinion leader, and community advocate and use in-person and/or virtual (through Facetime or Zoom) individual and group activities and mHealth (using Facebook messenger, Instagram direct messaging, and text messaging) to communicate and provide social support within their social networks during the 6-month intervention. The *Navegantes'* approach is personalized to each social network member's needs and priorities. **Table 1** provides an abbreviated summary of *Navegante* activities and examples of activities operationalized.

Based on our partnership's history training peer navigators,[15-28] we currently have a *Navegante Training Manual*, which will guide the 4-session interactive training of the *Navegantes*, including sections on effective facilitation, how to prepare for training, session checklists, and all training activities and materials. This manual will require refinements related to COVID-19. We also will develop a *Navegante Resource Guide* that will provide details about COVID-19 testing and vaccination across NC (e.g., local providers and services and eligibility information) that *Navegantes* can refer to as they work with their social networks after training.

We will refine our *weCare* library of theory-based sample messages[10] that *Navegantes* can tailor and use to meet the specific needs of each social network member. We have much experience with mHealth message development to improve health outcomes.[9,10,12,14,29,99,135,173] A critical component of *NuestraSaludSegura* is the "connection" between the *Navegantes* and social network members. Growing evidence suggests that in-real-time, personalized, and bidirectional social support and problem solving provided by a peer using mHealth may be more successful in changing behaviors among populations facing many multilevel barriers to change than other technology-based approaches, such as software applications providing automated messages.[12,14,29,174-176] In our research to better understand the mechanisms underlying *weCare*, we discovered the importance of participants "knowing the person behind the messaging" and perceiving that this person cares about them.[12]

Table 1. Activities of *Navegantes in the NuestraSaludSegura intervention*

Activities	Examples
Raise awareness of the ongoing need for COVID-19 testing and vaccination	*Navegantes* increase consciousness among their social networks about the need for testing and vaccination to slow the spread of COVID-19, state and local rates of testing and vaccination and among Latinx populations, and the importance of taking action.
Provide information and referrals	*Navegantes* provide information about local providers of COVID-19 testing and vaccination services (e.g., testing and vaccination sites near a social network member's home or workplace, days and hours of operation, and whether an appointment is needed and how to make one).
De-mystify the process of seeking COVID-19 testing and vaccination	*Navegantes* explain what to expect when accessing COVID-19 testing and vaccination, including where to go, how to get there by public transportation (or where to park if in a car), the presence of security, sign-in processes, what information will be requested (e.g., if staff will ask for identification or insurance information), availability of interpreters or Spanish-speaking staff, what steps are involved in the testing or vaccination process, and how long the process will take (e.g., turnaround time for receiving test results and required observation period after receiving the vaccine).
Reframe and bolster norms and expectations	*Navegantes* highlight how the benefits of COVID-19 testing and vaccination are linked to social network members' priorities (e.g., protecting the health of their families and communities and facilitating the ability to gather with others safely).
Share announcements and reminders	*Navegantes* share announcements with social network members about upcoming testing and vaccination events.
Troubleshoot and problem solve SEBI of COVID-19 testing and vaccination	*Navegantes* help overcome stigma related to COVID-19 and build trust around testing and vaccination (e.g., addressing concerns about immigration status and confidentiality). N*avegantes* brainstorm options for overcoming barriers related to transportation (e.g., if a COVID-19 testing or vaccination site is not on a bus line and a social network member does not have a car or a driver's license), schedules (e.g., conflicts between work schedules and testing or vaccination site hours), and other challenges (e.g., concerns about the potential impact of a positive COVID-19 test result or vaccine side effects on the ability to work).
Support communication with providers and staff	*Navegantes* talk through ways to effectively communicate and share concerns with providers and staff at testing and vaccination sites. *Navegantes* may remind social network members to bring a list of questions, symptoms, or information about potential COVID-19 exposures when going to get tested or vaccinated.
Support other prevention behaviors	*Navegantes* provide guidance on recommendations for other prevention behaviors (aligning with current CDC guidelines), including mask use, social distancing, and potential need for booster vaccination.
Provide feedback to providers and staff	*Navegantes* meet with providers and staff at COVID-19 testing and vaccination sites to provide feedback for multilevel changes to improve accessibility for Spanish-speaking Latinx communities.

Baseline and immediate post-intervention assessment. We will develop a Spanish-language assessment to collect data at baseline and immediate post-intervention (6 months post-baseline), based on Aim 1 findings, other relevant studies describing factors influencing COVID-19 testing and vaccination, our previous successes with peer navigation and mHealth strategies, and the theories underlying the intervention. **Table 2** outlines *draft* measurement priorities identified by our partnership while preparing this application. To ensure data harmonization, we will use the RADx-UP Common Data Elements and PhenX toolkit (https://www.phenxtoolkit.org/). The assessment, including final selection of measures,

will be created using an *iterative* process by partners, including consultation with the RADx-UP CDCC and consortium

Table 2. Measurement priorities

Outcome variables	**Primary: COVID-19 testing and vaccination** including ever being tested, ever being vaccinated, being up to date on recommended doses, and number of doses received
Demographic variables	Age and date of birth; birthplace; ethnicity/race; language use; current living situation; zip code; marital/partner status; family structure (e.g., children); educational attainment; current employment; financial status; immigration status; pregnancy status; insurance status
Symptoms	COVID-19 symptoms and exposure to assess need for testing
Potentially mediating variables	Awareness and knowledge about risk, testing, and prevention of COVID-19; intentions and readiness for COVID-19 testing and vaccination; perceived COVID-19 testing and vaccine access; knowledge of how to access testing and vaccination services; service use self-efficacy; perceived barriers to services; usual source of care; skills and self-efficacy to communicate effectively with providers; provider trust; history seeking and using prevention and care services; self-efficacy to overcome barriers; perceived provider discrimination; stigma related to COVID-19; social support; community attachment; perceived impact of positive test on job security; access to transportation
Other variables	Intervention acceptability; satisfaction with participation in intervention; interactions with *Navegante* and social network members regarding COVID-19 testing and vaccination (*to assess contamination*)

***Navegante* training and support**. The *Navegante* training will be designed to increase knowledge and build skills as *health advisors*, *opinion leaders*, and *community advocates* in person and/or virtually and through mHealth. Navegantes will be trained to use a version of the "ask-advise-assist" model to provide guidance and help others and will be given a wallet-sized reminder card that outlines the steps, as we have done within peer navigation interventions in the past.[19,70] Trained *Navegantes* will then carry out helping activities to increase COVID-19 testing and vaccination within their social networks for 6 months. During this time, *Navegantes* will be supported and meet with study staff as a group (monthly) and individually (as needed) for social support, intervention planning, experience sharing, and problem solving in person, virtually, by phone, and/or by social media. As part of the process evaluation, they will submit monthly Activity Logs (described below) to document their work with members of their social networks.[(e.g., 20,50)]

How will the trained *Navegantes* increase COVID-19 testing and vaccination within social networks? Through informal individual interactions and more formal activities, *Navegantes* will fulfill multiple roles. First, as health advisors, *Navegantes* will raise social network members' awareness of the ongoing need for COVID-19 testing and vaccination and help them think through pros and cons and how to overcome commonly experienced barriers to accessing services. For example, a social network member may hesitate to seek testing because they fear disclosing their immigration status or do not trust providers. Thus, the *Navegante* will describe what is required for testing and how providers are required to maintain confidentiality. As opinion leaders, *Navegantes* will reframe and bolster norms and expectations about COVID-19, testing, and vaccination. *Navegantes* are taught the concept of reciprocal determinism from social cognitive theory[168] to illustrate how attitudes and behaviors are influenced by and influence one's environment. For example, some Spanish speakers may have fatalistic views about COVID-19; thus, a *Navegante* may reframe attitudes regarding COVID-19 to encourage testing and vaccination as taking control of one's health. Third, as community advocates, *Navegantes* will bring the voices of Spanish speakers to providers. *Navegantes* will participate in tours of local testing and vaccination site within their region, which will provide *Navegantes* direct experiences with accessing services that will help them support their social network members in using services, build relationships between *Navegantes* and providers, and provide opportunities for *Navegantes* to share feedback for process improvement (based on their own experiences, the experiences of their social network members, as well as Aim 1 findings) with providers over time.

Each *Navegante* will also conduct group activities in-person and/or virtually with their social network members including an initial meeting to "inaugurate" their role as a community resource. Study staff will

provide guidance to the *Navegantes* and assist them in conducting group activities. These activities will be documented on the Activity Logs (described below) that will provide important details for intervention evaluation, especially because not every social network member will attend each session.

In addition to in-person and/or virtual individual and group activities, *Navegantes* will use the mHealth platform(s) preferred by each social network member (i.e., Facebook, Instagram, and/or texting) to communicate directly with them during the intervention to plan activities and support use of COVID-19 testing and vaccination services. For example, *Navegantes* will use social media to remind social network members about group activities and problem solve attendance challenges. A *Navegante* and social network member may also communicate "in-real-time" via social media about the process of receiving COVID-19 testing and vaccination; for example, the *Navegante* may help the social network member navigate a clinic. The *Navegantes'* ability to provide immediate, efficient, and bidirectional communication is critical to overcome barriers to taking action and initiating service use.

Each *Navegante* will also use personalized Facebook and Instagram accounts for indirect communication (e.g., posting information about COVID-19 testing and vaccination events). In our *weCare* intervention, we learned that study-specific Facebook pages are less effective than accounts that function like a personal Facebook profile.[10] In addition to being low literacy, Facebook and Instagram posts will be engaging and informative. For example, graphics that illustrate the rates of COVID-19 testing and vaccination in different population subgroups can raise awareness of the importance of taking action. We will provide *Navegantes* with links to reliable sources, including CDC and state COVID-19 informational websites. *Navegantes* will also post informal and welcoming pictures and videos (recorded using smartphones) of local COVID-19 testing and vaccination services staff and facilities to demystify what it is like to access services and to increase self-efficacy to use services. While it is possible that not all participants use all social media platforms, given the current use of Facebook and Instagram, and their potential as low burden communication methods, these posts will be worthwhile. Furthermore, they may reach others who are not enrolled in this study. All posted information will be correct, consistent, and linked to the intervention's theoretical underpinnings; study staff will be available to help *Navegantes* think through their messaging.

Activity Logs. *Navegantes* will complete and submit monthly Activity Logs. Activity Logs aid in our process evaluation and serve as triggers for *Navegantes* to initiate activities.[20,50] They document whom the *Navegante* worked with for each activity (e.g., codes for those within and outside of the enrolled social network members); the type of helping activity; whether it was an individual or group activity (and the number of people involved); and whether, which, and how mHealth platforms were used. **Importantly, the Activity Log will allow us to assess the *Navegantes'* work beyond their enrolled social network members**. An innovation of this study is that we will be able to precisely describe what the *Navegantes* did and who was reached.

In-depth interviews with *Navegantes*. In-depth interview guide development and data collection with *Navegantes* will mirror the processes described above in Aim 1.

Aim 3:

We will invite partnership members, organization representatives (e.g., providers and clinic and community organization staff), community members, and academic researchers, to review and discuss study findings. As a group, they will respond to 4 empowerment theory-based trigger questions that move from concrete ("What do you see in these findings?" "In what ways do these findings make/not make sense to you?") to action ("What can be done?" "What can we do?"). Based on the triggers, attendees will brainstorm specific strategies. Next, using a nominal group process,[21,95,100,105,196] attendees will define practice, research, intervention, and policy priorities for next steps based on 2 criteria (*importance* and

feasibility) [95,100,197-199] to ensure priorities have potential to decrease COVID-19 disparities. Examples of priorities that may emerge include social marketing/social media campaigns; clinical staff training to reduce perceived discrimination, better assess risk, and/or problem solve particular testing and vaccination access challenges experienced by Spanish-speaking Latinx persons; development of culturally congruent COVID-19 educational materials; and additional interventions (e.g., to reduce stigma) to increase adherence to recommendations.

Attendees will then divide into small groups based on the identified priorities, develop recommendations for carrying out those priorities, and present plans to the larger group of attendees. Action plans may include a timeline for next steps or a list of other individuals and organizations to engage. The forum also may identify priorities for future research and intervention development.

Outcome Measure(s)

Primary outcome measures are COVID-19 testing and vaccination, including ever being tested, ever being vaccinated, being up to date on recommended doses, and number of doses received.

Analytical Plan

Aim 1:

In-depth interview and focus group data analysis. We will analyze the qualitative data using constant comparison, a systematic approach to developing grounded theory[144,157] that is well-suited to uncovering participants' meanings and experiences. [144,157,158] It combines inductive coding with simultaneous comparison; initial observations are continually refined throughout data collection and analysis.[149,157,159] The goal is to identify themes, not to quantify participant experiences.[12,62,160,161] Analytical steps include:

- Interviewers will document post-interview and focus group impressions (e.g., content, process, and themes).
- Interviews and focus groups will be professionally transcribed and translated (if needed). Translation allows for simultaneous, collaborative analysis and iterative discussion of themes to yield more accurate findings.[162]
- Interviewers will verify transcripts by reviewing and correcting discrepancies while listening to the recording.
- Transcripts will be managed using the NVivo (Chicago, IL) and examined to identify and code domains for theme development.[145,163] This will begin with analysts reading the same 3 transcripts and writing memos (written records of the analysis process linked to the specific transcript). These represent conceptual, theoretical, and operational notes to help compare domains within and across interviews and focus groups and inform the initial analytical coding scheme.[144]
- The analysts will meet to develop a common coding system and data dictionary.
- All transcripts will be coded by at least 2 analysts (allowing for the addition of emerging codes).
- For data triangulation, analysts will develop, compare, then revise matrices that identify similarities and differences and explore emic and etic perspectives **within and across** participant categories (e.g., health providers v. Latinx-serving community-based organization representatives; health provider/organization representative interview v. Spanish-speaking Latinx community member focus group).[160]
- The CBPR partnership will review themes for validity (e.g., rigor, credibility, and trustworthiness).[97,164-167]

Aim 1 draws from a rich and thorough set of state-wide experiences that reflect millions of testing and vaccination encounters and the diverse perspectives of Spanish speakers and those who directly serve them across a wide range of settings. Thus, it will accomplish the most comprehensive qualitative assessment to date of SEBI of COVID-19 testing and vaccination among Spanish-speakers. Our results, in addition to informing Aim 2, will be important in their own right to inform other researchers and practitioners. Accordingly, results from Aim 1 will be shared as soon as available with RADx-UP CDCC and consortium.

Aim 2:

Hypotheses. *We anticipate that participants in the intervention group, relative to their counterparts in the delayed-intervention group, will demonstrate increased COVID-19 testing and vaccination.*

Quantitative data analysis plan. Data analysis will include **study group description** and **intervention impact evaluation**. *Study group description*. Frequencies and percentages for categorical variables and means, medians, standard deviations, and ranges for continuous variables will be tabulated to describe the sample. Reliability for measures will be estimated via internal consistency using coefficients alpha and omega.[178] Baseline intervention and delayed-intervention group comparisons will be performed. Correlation analyses will evaluate the associations between pairs of variables. Nonparametric statistics will be used when appropriate to evaluate significance of associations.

Evaluation of intervention impact. Data will be analyzed with an intent-to-treat approach.[179] Randomization at the social network level will likely balance cluster-level baseline characteristics; however, as randomization may not precisely balance these, and there may be differences in social network member characteristics after network randomization, inverse probability weighting using propensity scores will be explored to balance baseline characteristics (both network and individual) between arms[180] using best practices.[181] Balance on propensity scores between intervention groups will be assessed using standardized differences.[182] Propensity scores have been used in cluster RCTs.[183] We will evaluate the intervention impact by comparing rates of past 6-month COVID-19 testing and vaccination completion (*defined as complete dosage of approved vaccination: e.g., 2 Pfizer or Moderna doses or 1 Johnson & Johnson dose*) between intervention and delayed-intervention group social network members at immediate post intervention (6 months after the intervention group *Navegantes* are trained), adjusting for baseline rates. This ANCOVA approach has the advantage of being unaffected by baseline differences; if baseline rates, by chance, were different, the intervention effect would be overestimated by looking at change scores and underestimated by a follow-up score analysis. The ANCOVA approach gives the same answer regardless of baseline imbalance. Additionally, the approach generally has greater statistical power to detect an intervention effect than the other methods.[184] Statistical analysis will be performed using generalized linear mixed modeling[185] for binary outcomes (sometimes termed random-effects logistic regression). These models can assume a logit link for binary data (i.e., tested or vaccinated in past 6 months: yes/no) and allow for accounting for the within-group association of outcomes. If participants have repeated COVID-19 testing performed then an additional random effect for multiple testing will be considered, where appropriate. The generalized linear mixed model is an extension of general linear models that allows for non-independence of observations (e.g., within social networks).

The hypothesis that intervention and delayed-intervention groups differ in their prevalence, p, of COVID-19 testing or vaccination will be tested with the mixed-effects logistic model: $\mathbf{Logit}\,(p_{ij1}) = \beta_0 + \beta_1 Y_{ij0} + \beta_2\,\mathbf{INTVN} + \upsilon_i$, where p_{ij1} is the probability of testing or vaccination at immediate post-intervention for participant i in social network j, Y_{ij0} is 1 if participant i in social network j reports testing or vaccination at baseline and 0 otherwise, and, INTVN =1 for the intervention group and 0 for the delayed-intervention group. The random effect υ_j is the random effect for participants in social network j. The variance component for this random effect addresses the within-social network correlation. Under this model, β_2

corresponds to the difference in prevalence of testing or vaccination at immediate post-intervention between the intervention and delayed-intervention groups on the logit scale. This random-effects logistic regression model will be fit using adaptive Gaussian quadrature in SAS PROC GLIMMIX.[186]

This regression approach will allow us to produce estimates of prevalence and prevalence change additionally *adjusting for individual and cluster-level covariates*, which will be compared to unadjusted estimates. Individual-level covariates may include age, country of origin, employment status, and education level. Because there are only a small number of clusters (social networks), the literature advises that the number of cluster-level covariates should be limited to one or two key variables.[187,188] To assess the importance of covariates, we will use a backwards elimination model building approach, with primary consideration on assessment of confounding on the intervention-group difference. If confounding is present (defined to be greater than a 10% change in the regression estimate of the intervention-group effect), the confounder will be retained in the multivariable model. If many confounders are retained, alternative/sensitivity analyses will be conducted using propensity score weighting. All analyses will be 2-sided.[189] Note: While a better understanding of the relationships between members of social networks can be interesting, social network analysis is beyond the scope of this proposal based on our hypotheses and analysis plans.

Quantitative data collection/management. Assessment data will be collected by the study team in a safe and private location using audio-computer-assisted self-interview (ACASI) technology. We most recently used ACASI in our *weCare* intervention for English and Spanish data collection[9-14] and have worked out logistical details (e.g., data saving and backup) and ways to maintain participant interest. ACASI data collection overcomes challenges of literacy and will be conducted in Spanish. Saved ACASI files will be transferred using the Warehouse Manager to SAS data files for analysis and stored on a password protected secure server.

In-depth interview data analysis. Analysis of the data from in-depth interviews with *Navegantes* will mirror the qualitative data analysis processes described above in Aim 1.

Aim 3:

We will develop a final report of findings and practice, research, intervention, and policy priorities and recommendations to distribute to attendees, the RADx-UP CDCC and consortium, and others for whom the findings will be relevant (e.g., local and state-level health department leaders). We successfully used this approach previously to translate findings into action in a study of HIV disparities among sexual minority men. Subsequent actions led by forum attendees were (1) redirection of NC state prevention funds to develop safe spaces for facilitated group dialogue around intimacy and HIV risk; (2) a statewide conference to develop advocacy skills among community leaders; and (3) a new research partnership to explore the impact of immigration policy on healthcare use within Latinx communities.[26,100]

Human Subjects Protection

Subject Recruitment Methods

Aim 1:

In-depth interview and focus group participants for Aim 1 will be recruited through our partnership's broad networks of collaborators and community partners and by word-of-mouth.

Aim 2:

Intervention participants for Aim 2 can be recruited as a *Navegante* or social network member of a *Navegante*. Potential *Navegantes* will be recruited by being invited to an individual interview in which we will explore eligibility and personal, performance, and situational characteristics relevant to serving as a *Navegante*. We will then select *Navegantes*. After enrolling, each *Navegante* will be provided a script and recruitment materials to present to their social network members, explaining the study and asking them to contact staff using the study's toll-free number to enroll.

Informed Consent

Verbal informed consent will be obtained from each focus group participant, and signed informed consent will be obtained from each Navegante and each social network member participant. The investigators or other study staff will obtain informed consent in community-based settings before collecting data from participants.

Interview participants will be provided with a brief description of the study to review before deciding to participate.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed six years after closure of the study, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study. A limited dataset will be sent to the CDCC via a secure web portal. Data will be stored by the CDCC on protected, secure computer systems. Anyone with permission to see these data will have to use a password and multi-factor authentication.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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