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INTERVENTIONAL RESEARCH PROTOCOL

(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  NJ HEROES TOO (New Jersey Healthcare Essential Worker Outreach and Education Study - Testing Overlooked Occupations)

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- **Protocol Version and Date:**
  V5.0 10/21/2021

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1.0 Research Design

1.1 Purpose/Specific Aims

A. Objectives

NJ HEROES TOO (New Jersey Healthcare Essential Worker Outreach and Education Study Testing Overlooked Occupations) proposes to approach underrepresented minority healthcare workers (HCW) who will act as ambassadors to help expand testing in their households and extended networks. In Aim 1, using qualitative methods we co-design, develop and implement an innovative, HCW-centric outreach intervention strategy to engage Black and Latinx minority HCW and their communities. We explore community perceptions about COVID-19 testing, treatment, and vaccination to design COVID-19 testing materials and messages that are culturally tailored to address concerns of Black and Latinx minority communities. In Aim 2, we conduct a mixed methods study to evaluate the effectiveness and cost of: (1) the HCW-focused outreach intervention strategy versus (2) standard community engaged outreach, working with community based organizations (CBOs). We will explore contextual factors (individual, family, and community) affecting COVID-19 testing implementation outcomes and scalability. The primary outcome is uptake of COVID-19 testing in the targeted populations. We propose testing with the novel Rutgers Clinical Genomics Laboratory/RUCDR saliva test, the first FDA-authorized diagnostic test using saliva to detect SARS-CoV-2 for non-invasive, home based self-testing. We hypothesize that a participatory outreach strategy approach focused on identified index HCWs will mobilize quicker uptake of testing within community settings than best-practice CBO recruitment approaches. We also hypothesize that recruitment through index HCWs will be more successful for hard to reach participants compared to a traditional CBO approach. The strategy focusing on HCWs could easily be expanded to other front-line and essential workers, making the strategy generalizable and sustainable.

B. Hypotheses / Research Question(s)

Aim 1: Co-design, develop, and implement an innovative, user-centered HCW outreach intervention strategy to engage Black and Latinx minority communities while assessing pre-implementation COVID-19 testing context. Phase 1 includes an iterative, theory-guided formative evaluation process involving a needs assessment using target population interviews and stakeholder input through advisory committees to understand the COVID-19 testing context and inform design and implementation of the intervention.

Question 1A: What are the most acceptable and easily understood ways to present materials and messages to HCWs, as well as, their family members and networks?
Question 1B: Are the same messages appropriate for Black and Latinx minority communities?
Question 1C: How can available intervention materials be best adapted to optimize acceptability to Black and Latinx minority communities?

Aim 2: Conduct a mixed methods study to evaluate the effectiveness and cost of a HCW focused outreach intervention strategy versus standard community engaged outreach to explore contextual factors (individual, family, and community) affecting COVID-19 testing implementation outcomes and scalability. In Phase 2, lower-income index HCWs (from our cohorts, as well as, the Visiting Nurse Association, and Parker Health) serve as ambassadors to offer testing to their “spheres of influence” (households/contacts).

Hypothesis 2A: A participatory outreach strategy approach focused on identified index HCWs will mobilize quicker uptake of testing within community settings than best practice, community recruitment approaches.

Hypothesis 2B: Recruitment through index HCWs will be more successful for hard to reach participants compared to a traditional community based organization approach.
Question 2A: What are the costs of implementing NJ HEROES TOO for healthcare and community organizations?
Question 2B: What lessons have we learned about implementation and opportunities for sustainment?

1.2 Research Significance

COVID-19 in New Jersey

With a population of 8.9 million people, New Jersey (NJ) is the 11th largest in the US, and is the most densely populated, with 1,215 persons/square mile (compared to California [256], Texas [113], Florida [410], and New York [413]). Population density likely contributes to COVID-19 transmission.[1,2] As of Aug 3rd, there were 188,466 cases and 15,921 deaths from COVID-19 in NJ, the 2nd highest per capita death rate in the USA (after New York). NJ has the 2nd highest proportion of state residents who were in fact positive (2.0%) after New York (2.1%). Based on CDC estimates, moreover, there are likely 3-10 people who are truly positive for every test-confirmed positive. Thus, the incidence of COVID-19 in NJ is likely to be between 6% and 20%.

COVID-19 Challenges for NJ Underserved and Socially Vulnerable Populations

Nearly 20% of those who have died of COVID-19 in NJ have been Black (18.5%) and Latinx (19.4%) and there is considerable overlap between the areas in the state with substantial COVID-19 cases, poverty, and under-represented minorities (URMs).[3-5]

Healthcare HEROES TOO: Nationally over 80% of healthcare support, service, and direct care workers are poor women and disproportionately people of color.

Nationally over 80% of healthcare support, service, and direct care workers are poor women and disproportionately people of color. For example, the national average earnings for home health aides and medical assistants range from $24,000-$33,000. Nationally, wages are so low that nearly 20% of home health aides and personal care aides live in poverty and more than 40% rely on some form of public assistance.[6] These low-income healthcare workers (HCWs) need support and their families and communities are at increased risk for COVID-19 exposure by virtue of multigenerational living situations. In the Northeast, NJ and NY are above the national level for multigenerational households (MGH). [7] In NJ, 50% of MGHs include a householder, their child, a grandchild, parent or in-law.[7] These social structures make a household-based strategy for improving testing important for HCW populations.

COVID-19 challenges facing outreach efforts for communities.

The devastation caused by COVID-19 in NJ and the limits on inter-personal interaction have imposed challenges to engaging diverse communities and healthcare stakeholders in translational and population health research.[8,9] Both the illness and the response have strained the limits of co-learning opportunities that are central to participatory and patient-centered approaches. Our community, HCWs, healthcare organization stakeholders, and research partners have identified a need for novel/effective virtual strategies that make use of community education, mass media, and social media to expand our continued outreach and engagement efforts. Programs are needed that work from relationships with trusted sources of information to build mutual respect, inform and educate, and provide opportunities for individuals, organizations, and populations to actively engage with COVID-19 testing education. Therefore, we propose NJ HEROES TOO as a potential outreach intervention strategy to approach URM HCWs identified as index individuals to expand testing in their households and extended networks.

1.3 Research Design and Methods

This project will proceed in two phases. Phase 1 consists of an iterative, theory-guided formative evaluation process involving a needs assessment using stakeholder interviews, evidence-based content review, pilot testing, and stakeholder input through advisory stakeholder committees to inform design and implementation of the intervention. Phase 2 will recruit HCWs and their family members from our ongoing

HCW cohorts, as well as, from the Visiting Nurse Association, Parker Health and staff from University Hospital Newark and Robert Wood Johnson University Hospital and compare their rates of COVID-19 testing with a community recruited control group. We will evaluate the effectiveness of a participatory outreach approach focused on identified index HCWs to test the hypothesis of whether it will mobilize greater uptake of testing within community settings than best practice, community recruitment approaches. We will additionally assess factors such as participant trust, health literacy, English proficiency, and patient activation that may impact testing in URM communities. Rapid cycle qualitative methods will explore other potential factors at the community and healthcare setting levels that may impact testing rates, as well as, assess which implementation approaches and strategies that are most effective in increasing the reach, access, uptake, and sustainability of COVID-19 testing.

A. Research Procedures

This project will not involve medical records, blood draws, or any physical contact with participants. All information is collected using the Rutgers Zoom secure platform or over the phone. Data collected will only consist of survey procedures, online focus groups, virtual (via Zoom) community conversations or key informant interviews, audio/video recordings from Zoom, and saliva samples provided by participants. No sensitive information will be collected.

Audio/visual Zoom recording will begin as soon as the moderator begins the Zoom session. The resulting mp4 recordings will be temporarily stored on a secure, encrypted, password-protected Rutgers server and uploaded to a transcription company, ADA Transcription, via a secure web portal. The transcripts will be returned to the research team through the same portal. The mp4 files will be destroyed after a research team member has checked the transcripts for accuracy. Only the research team and the transcription company will have access to the audio files and transcripts.

Aim 2 procedures include a one-time baseline survey followed by saliva testing. After enrollment and completion of online questionnaires, saliva test kits are ordered and mailed to the participant by Vault Health, Inc., a fee for service vendor that is not engaged in research, with a prepaid envelope to return the sample. Vault Health remotely supervises participants while they collect their saliva sample (via Zoom video call if needed) and reports results to participants. Participant's role in the study ends in phase 1 at the completion of the virtual community conversation/focus group/key informant interview and for phase 2 after receipt of their test result.

B. Data Points

N/A—No long term follow-up is planned.

C. Study Duration

The proposed project will be conducted over a 2-year period (See Section 1.10 for timeline). Aim 1 will be completed by Month 6. Aim 2 will be completed by Month 18. Final data analyses, preparation of manuscripts, and final dissemination materials will be completed by Month 24.

D. Endpoints

N/A

1.4 Preliminary Data

Community and stakeholder engaged research

The NJ HEROES TOO team builds on existing New Jersey Alliance for Clinical and Translational Science (NJACTS, our CTSA Hub) infrastructure and brings proven capacity in community and stakeholder engaged research. Rutgers has a rich history of scientific achievement through community and stakeholder engaged research. NJACTS Community Engagement Core in partnership with The Rutgers Office of University-Community Partnerships (OUCP) provide the established infrastructure and community partnerships that are necessary for the proposed work and sustainability for future pandemic mitigation efforts. Founded and led by **Hill,** OUCP is a unique institutionalized office at Rutgers dedicated to advancing university-community partnerships. OUCP has long-term and extensive ties to organizations serving a variety of consumers. Renowned for her

expertise in building community relations, **Hill's** community engagement portfolio and work with vulnerable populations spans the life course from early childhood through aging adults. The NJACTS Community Engagement Core extends this expertise. The Core Leadership and Advisory Council consists of citizen scientists and established investigators with expertise in community engagement. The Core is co led by **Hudson** and **Tallia** with **Hill, Jimenez** and **Crabtree** on various workgroups. We have a strong history of collaborative community engaged research with vulnerable populations using innovative methods to conduct this work including Hudson's work with recruitment of minority participants in clinical trials,[10-12] engaging Houses of Worship in health promotion,[13] disparities in tobacco use (R01CA231139, **MPI: Hudson**) and engaging community members in design of community education and screening programs.[11,14,15] **Jimenez and Tallia's** community engaged needs assessment among homeless individuals culminated in a New Brunswick based medical student run health clinic that has operated in partnership with a local social service agency for 15 years. [16] Collaborative work between **Jimenez, Hudson, and Crabtree** uses qualitative research methods to engage community leaders and low-income Latinx families in intervention development and then conducting a hybrid effectiveness implementation randomized trial overseen by a stakeholder advisory board to test the intervention. This has led to an ongoing community engaged research program that tests structural interventions designed to reduce inequities in developmental and behavioral health for young Latinx children including families with limited English proficiency (1R01HD099125, **PI: Jimenez, co-Is Hudson, Crabtree**) as well as a cross sector partnership between RWJMS and a local charter school to improve school readiness among dual language learners.

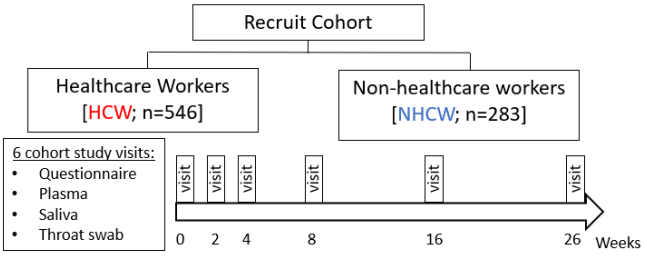
Healthcare organization interventions and mixed methods research

Members of our collaborative team have exceptional experience conducting organizational change interventions, project evaluation, and mixed-methods research. Over the past 20 years, **Crabtree, Hudson, Tallia, and Ferrante** have collaborated on multiple NIH and foundation funded healthcare intervention and practice-based research studies (R01HL070800, R01CA112387, R01CA176838, R01CA176545). **Crabtree, Hudson, Tallia, and Ferrante** are all adept using the data collection/analyses planned in this mixed methods project. We have cultivated expertise in user centered design and rapid ethnography methods including focus groups and key informant interviews.[17-20] [12-14,21-28] Our studies use a mixed methodology that include qualitative analyses [29,30] that inform quantitative interpretations of intervention evaluations. [26,27,30-35]

Ongoing studies of SARS-CoV-2 among HCW cohorts

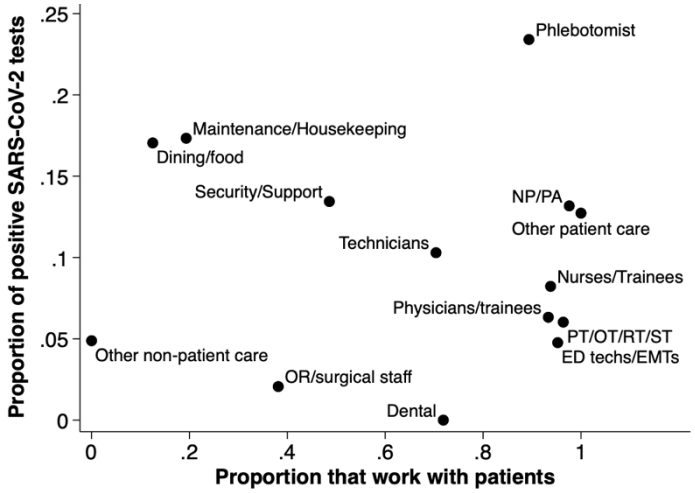
As described above, our team **(Panettieri, Blaser, Carson, Barrett, Horton, Roy)** built the RCC and RWJSS, large-scale studies of SARS-CoV-2 to ensure the safety of our vulnerable frontline HCWs and their families (**A.4**). Participants in these studies are among the index participants in our intervention strategy (**Aim 2**). As detailed below, our success in the RCC and RWJSS demonstrates our team's ability to engage and test HCW. This success, combined with our team's experience in community engaged research, health equity research and dissemination and implementation science, will provide the critical relationships underlying our innovative HCW-centered outreach approach.

Figure 6. The established Rutgers Corona Cohort Study Schematic



The RCC is an intensive longitudinal study of 829 participants recruited at the start of the local COVID-19 epidemic and tested over 6 months (**Figure 6**). The funded aims of the RCC (**NIAID 3U01AI122285-05S1**) include assessment of prevalence, incidence, and clinical and occupational risk factors of SARS-CoV-2 infection and COVID-19. Additional translational studies based on this cohort are ongoing (**NCATS 3UL1TR003017-02S1**). 191 participants (23.0%), including 136 HCW (24.8%) are underrepresented minorities. [36] RCC retention has been exceptional, with >98% of the cohort completing the 4th study visit; the 5th study visit is ongoing.

Figure 7. Prevalence of SARS-CoV-2 infection based on role in the hospital and direct patient care responsibilities



Notes: ED, emergency department; EMT, emergency medical technician; NP, nurse practitioner; OR, operating room; PA, physician's assistant; PT, physical therapist; OT, occupational therapist; RT, respiratory therapist; ST, speech therapist

The RWJSS involves 3904 hospital employees and affiliated clinicians who received SARS-CoV-2 virus and antibody testing at a single time-point and are being followed for self-reported COVID-19 prospectively. 1202 (30.8%) tested participants are URM. A total of 9.8% of participants tested positive for SARS-CoV-2 virus or antibodies, with higher rates observed among Black (14.8%) and Latinx (15.5%) HCW. Notably, compared to non-Hispanic White participants, the odds of a positive test were twofold higher among Black (OR: 2.15, 95% CI: 1.55, 2.97) and Latinx participants (OR: 1.94, 95% CI: 1.42, 2.66). Importantly, infection rates were especially high among lower status medical roles (e.g., technicians, phlebotomists) as well as hospital support roles (dining/food, maintenance /housekeeping, security/support) (**Figure 7**).

1.5 Sample Size Justification

For Phase 1,Virtual Community Conversations we will convene 8-10 community focus group conversations of 10-12 ethnically homogenous participants each representing Black and Latinx stakeholders (i.e., healthcare workers, family members and community organizers). The literature suggests that for our purposes, 2-3 focus groups are sufficient to capture 80% of themes, including the most prevalent themes, and three to six groups for 90% of themes in a homogeneous study population using a semistructured discussion guide. [37] To reach the desired number of 15-20 healthcare workers we will supplement community conversations with individual key informant interviews with healthcare workers given they have not been able to participate in group meetings. Hennick et al suggest code saturation can be established with as few as 6 interviews with full saturation reached at nine interviews.[38] They determined the first interview conducted contributes more than half (53%) of new codes and three quarters (75%) of high-prevalence codes, with subsequent interviews adding a few new codes each until saturation. [38]

Rate (expected #/month) in NJ HEROES TOO arm			
RR	**80**	**100**	**120**
1.15	0.78	0.82	0.81
1.2	0.94	0.96	0.95
1.3	0.99	0.99	0.99

For Phase 2, to test our Aim 2A hypothesis which compares testing uptake between the two arms power calculations are based on the primary outcome measure, testing uptake rate. We report power for rate ratios (RR; ratio of rate in comparison arm relative to intervention arm) of 1.15, 1.2, and 1.3, when expected tests per month in the intervention arm range from 80 to 120 (Table). We will have about 80% power or greater for RR of 1.15 or greater. To test hypothesis 2B, we will compare participants in the two arms on key

characteristics that may be barriers to testing (participant trust, health literacy, English proficiency and patient activation). We will do so through linear regression models, adjusting for covariates including participant age, race/ethnicity, sex, and highest level of educational attainment.

1.6 Study Variables

In Aim 1, we will co-design, develop and implement an innovative, HCW-centric outreach intervention strategy to engage Black and Latinx minority communities. We will explore community perceptions about COVID-19 testing, treatment, and vaccination to design COVID-19 testing materials and messages that are culturally tailored to address concerns of Black and Latinx minority communities. In Aim 2, we will conduct a mixed methods study to evaluate the effectiveness and cost of: (1) the HCW-focused outreach intervention strategy versus (2) standard community engaged outreach, working with community based organizations (CBOs). We will explore contextual factors (individual, family, and community) affecting COVID-19 testing implementation outcomes and scalability. The primary outcome will be uptake of COVID-19 testing in the targeted populations.

A. Independent Variables, Interventions, or Predictor Variables

RADxUP has provided a list of common data elements that include PhenX Toolkit items with Spanish translations that will be collected across funded consortia projects. Data elements include demographics, medical history, health status, vaccine acceptance, COVID-19 testing experience and trusted information sources. We will also assess trust in healthcare using the Revised Healthcare System Distrust Scale; 9 items.

B. Dependent Variables or Outcome Measures

Our primary outcome, testing, will be measured through Vault's receipt of a saliva kit from the participant with virus test results provided directly to participants as well as to the study team.

1.7 Drugs/Devices/Biologics

A. Drug/Device Accountability and Storage Methods

N/A

1.8 Specimen Collection

A. <u>Primary</u> Specimen Collection

Saliva is collected at home by participants (under remote supervision via Zoom as needed) using GCP compliant test kits prepared by Infinity BiologiX and mailed to participants by Vault Health. The kits are then mailed via prepaid return labels to the Infinity BiologiX where they will test for SARS-CoV-2 using our novel FDA-authorized saliva test. Testing results will be reported to participants by Vault Health clinical providers and will be received by the study team as well.

B. <u>Secondary</u> Specimen Collection

N/A

1.9 Data Collection

A. Primary Data Collection

<u>Aim 1:</u>

The main data source will be audio/video recordings of the virtual focus groups and community conversations. Supplemental key informant interviews that use the approved focus group guide questions and script will be conducted with HCW. Digital recordings of conversations will be transcribed verbatim and imported into ATLAS.ti™to facilitate coding and analysis.

<u>Aim 2:</u> There are four main sources of materials:

1. **COVID-19 testing data derived from saliva samples provided at home by participants** (See section 1.8). Saliva will be collected from participants ages 4 and above.
2. **Questionnaire data provided by participants through REDCap**: Questionnaire data will be completed by participants aged 18 and older. Parents or legal guardians will be responsible for completing questionnaires for children ages 4 to 17. Questionnaires will include items regarding demographics, possible COVID-19 exposures and testing history, overall health and lifestyle. Additional REDCap questionnaires related to acceptance of testing will query health literacy, English language proficiency, patient activation, attentional style, and patient trust. Survey data will be automatically downloaded from REDCap for direct import into a statistical analysis software program, e.g., SAS.
3. **Focus group data from virtual community conversations and community engagement virtual salons:** Focus groups of virtual community conversations and community engagement virtual salons as well as key informant interviews will be conducted via Zoom.
4. **Key informant data provided by select HCW ambassadors, community and healthcare organization stakeholders regarding implementation of the outreach strategies.** Field notes, meeting minutes and an activity tracker from administrative meetings with members of the participating organizations will be collected.

Data storage: All study data will be stored on a Rutgers secure server (located at Liberty Plaza, 335 George St., 2nd floor, New Brunswick, NJ 08901). Qualitative audiofiles will be downloaded from Zoom and stored on the server as well as their transcripts. Quantitative data will be entered into the study REDCap database. REDCap is a secure, password-protected web-based application designed to support data capture for research studies. A unique study participant ID will be assigned in REDCap at the time of screening. All data used for analysis will be fully de-identified upon data export from REDCap and stored on an encrypted, password-protected computer network to which only study investigators and staff have access. De-identification of data will consist of removal of all personal identifiers from analytic files as well as random shifting of dates to preserve participants' anonymity. Audits of REDCap data access will be completed regularly to ensure there is no unauthorized access of REDCap data.

B. Secondary Data Collection
N/A

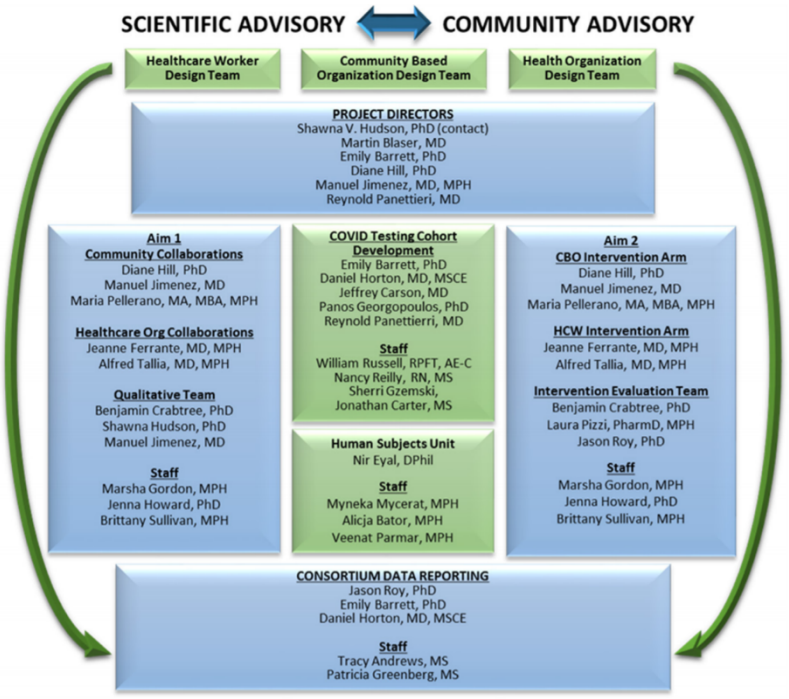
1.10 Timetable/Schedule of Events

The project will be conducted over a 2-year period (See Table below). Start-up activities took ~ 1 month. Aim 1 data collection is complete. Dissemination is ongoing with an abstract accepted for presentation at Acadamy Health in June 2021, a manuscript under review *at JAMA Open Network* and 3 other manuscripts in development. Aim 2 will be completed by Month 18. Final data analyses, preparation of manuscripts, and final dissemination materials will be completed by Month 24.

	2020				2021												2022							
MILESTONES AND ACTIVITIES	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**
IRB approvals and revisions	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Convene Scientific and Community Advisory Groups	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Convene Design Teams	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Participate in monthly CDCC cross site meetings/workgroups	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Aim 1:																								
Convene Virtual Community Conversations	X	X	X																					
Convene Community Engagement Virtual Salons			X	X	X																			
Conduct rolling qualitative analyses	X	X	X	X	X	X																		
Summarize results and prioritization of messages and strategies	X	X	X	X	X	X																		
Co-design of intervention messaging and materials			X	X	X	X																		
Finalize intervention materials with SmithGifford						X	X																	
Progress reports to CDCC (i.e., barriers and facilitators of COVID-19 testing)	X	X	X	X	X	X																		
Aim 2:																								
HCW and CBO intervention arms							X	X	X	X	X	X	X	X	X	X	X	X						
-Intervention activities							X	X	X	X	X	X	X	X	X	X	X	X						
-COVID-19 testing and participant data collection							X	X	X	X	X	X	X	X	X	X	X	X						
Cost analyses							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Process evaluation							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
-Key informant interviews									X	X	X	X	X	X	X	X	X	X	X	X				
Progress reports to CDCC (i.e., testing results, barriers and facilitators of COVID-19 testing)							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Analysis and Dissemination																								
Manuscript preparation and dissemination							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

2.0 Project Management

2.1 Research Staff and Qualifications



This project brings together a team of investigators at Rutgers partnered with citizen scientists representative of community based organizations (CBOs), healthcare organizations, and HCWs (Figure X). This MPI team led by Hudson, Barrett, Blaser, Hill, Jimenez, and Panettieri is truly a team science initiative that leverages exceptional combined expertise in community engagement and health equity (Hill, Hudson, Jimenez, Pellerano), infectious disease (Blaser), biospecimen-based cohort studies (Barrett, Carson, Horton, Panettieri), bioethics (Eyal, Budolfson), enviro-informatics (Georgopoulous), mixed methods research and implementation science (Crabtree, Hudson, Jimenez), healthcare organizational change (Crabtree, Ferrante, Tallia), cost analyses (Pizzi) and biostatistics (Roy). The MPI team has divided scientific leadership for various components of the study aims. Hudson has scientific oversight and responsibilities that involve coordinating the mixed method evaluation activities across the development and implementation of Aims 1 and 2. Hill and Jimenez co-lead our community engagement efforts. Barrett, Blaser and Panettieri lead the RCC and RWJSS cohorts and will oversee the COVID-19 testing and laboratory aspects of the science.

2.2 Research Staff Training

Staff are CITI trained and receive continuous training and professional development in the conduct of human subjects research. Weekly project administration meetings focused on data collection, quality and management are employed.

2.3 Resources Available

A. Facilities

This research is supported by a multi-disciplinary collaboration of faculty from the NJ Alliance for Clinical and Translational Science (NJ ACTS) inclusive of Robert Wood Johnson Medical School, Rutgers School of Public Health, Center for Advanced Biotechnology and Medicine and the Rutgers Office of University-Community Partnerships. NJ ACTS is funded by the National Center for Advancing Translational Sciences (NCATS), an institute of the National Institutes of Health (NIH). The NJ ACTS CTSA is designed to provide infrastructure and resources to promote and foster an institution's capacity for conducting clinical and translational research. The overall goal of the CTSA program is transform the translational science process in an effort to speed the delivery of new drugs, diagnostics and medical devices to patients and to use those research discoveries to change public policy, impact healthcare delivery and improve population health. NJ ACTS provides infrastructure for our faculty and staff as well as quantitative data collection/management (e.g., automated survey data collection using Redcap) and qualitative data collection (e.g., depth interviews, field observations, participant observation, focus groups) and management using ATLAS.ti software.

2.4 Research Sites

Rutgers Biomedical and Health Sciences is the research site for this study. Rutgers staff will conduct all research activities.

While we are working with Vault Health, Inc. to collect study specimens and Parker Health, the Visiting Nurse Association, University Hospital and Robert Wood Johnson University Hospital and 18 community based organizations to inform potential participants about the availability of the research, their engagement in the project does not meet the definition of engaged in human subjects research under items #1 (Vault) and #4 of the section entitled: ***Institutions Not Engaged in Human Subjects Research***: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

Vault Health meets the criteria of non-engagement under stipulation #1: It is an organization whose employees perform commercial services for investigators (i.e., COVID testing) and their services for this project: (1) do not merit professional recognition or publication privileges; (2) their COVID testing services are typically performed for non-research purposes for the NJ Department of Health and direct to consumers; and, (3) the outreach materials and strategies in this protocol are the intervention not the COVID test; therefore, Vault's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

Similarly, the healthcare and community based organizations meet the criteria of non-engagement under stipulation #4: These organizations employees or agents will only be engaged in: (1) informing prospective subjects about the availability of the research; (2) providing prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators; (3) providing prospective subjects with information about contacting investigators for information or enrollment; and/or (4) seeking or obtaining prospective subjects' permission for investigators to contact them.

3.0 Multi-Center Research

This project is funded by the NIH RADxUP program and is coordinating data collection with the RADxUP Coordination and Data Collection Center at Duke University. A draft of the data use agreement which is in final signature process and awaiting approval of the Aim 2 consent form by the Rutgers IRB has been included as an attachment.

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

We will work with 18 community based organizations, Parker Health, the Visiting Nurse Association, University Hospital Newark and Robert Wood Johnson University Hospital to develop strategies to identify and engage potential research participants. To ensure that the NJ HEROES TOO intervention is relevant to healthcare worker families and their communities, we will engage them and their advocates in a co-design process. Based on the results of this process in Aim 1, we will widely implement recruitment strategies engaging low income HCWs as ambassadors to recruit their families/contacts into the NJ HEROES TOO arm as well as general community members through the traditional arm of the study.

B. Recruitment Details

Recruitment of Aim 1 participants. The purpose of Aim 1 is to Co-design and develop innovative, user centered outreach intervention strategies that will then be used in Aim 2. To recruit participants for the virtual community conversations and key informant interviews that will inform Aim 1, we will use snowball sampling methods, as we have done in previous studies, drawing on confirmed participants to identify additional potential participants who will serve confirming and disconfirming roles. As needed, we will work with our collaborating healthcare institutions and community-based organizations to identify potential participants. They will advertise the virtual community conversation opportunity through their preferred standard community outreach channels (e.g. posted flyers (see recruitment flyers), mailings with flyers enclosed and announcements at community events using language from the flyers) as well as through additional multimedia approaches such as attaching the flyers to emails sent to list serves. Interested individuals will initiate contact with the Rutgers study team via email or phone using information included in the flyer. A Rutgers research staff member will screen participants for eligibility. Aim 1 participants will be Black and Latinx individuals who are knowledgeable and able to speak about their experiences and the factors that are important and impact COVID testing from diverse perspectives. We will convene 8-10 community focus group conversations, consisting of 10-12 ethnically homogenous participants each, representing Black and Latinx stakeholders. We will also recruit 15-20 HCW for key informant interviews. The literature suggests that for our purposes, 2-3 groups per strata and 6-10 interviews are sufficient to reach full saturation. We will offer a $30 gift card incentive to all participants.

Recruitment of NJ HEROES TOO arm (Aim 2). In this arm of study aim 2, we will recruit low income health care workers (HCW) employed at several NJ healthcare centers in affected counties to be “ambassadors” to help extend recruitment to their family members and community contacts. We will do so through our two current HCW cohorts, the Rutgers Corona Cohort (RCC) and the Robert Wood Johnson Screening Study (RWJSS) (total Black and Latinx n~1300) which have recruited participants at University Hospital and Robert Wood Johnson University Hospital. Additionally, to increase the reach of our HCW intervention beyond academic medical and healthcare system settings, we have partnered with Parker Health (representing nursing home and assisted living facility HCWs) based in Middlesex county and the Visiting Nurse Association Health Group (VNA), which is a statewide home healthcare organization with significant activities in Essex, Union and Passaic counties. Specifically, the organizations will: (1) inform prospective subjects about the availability of the research (e.g.,

announce the study at meetings with their staff, post links to the study website on their website, on their list serves, in their newsletters and social media); (2) provide prospective subjects with information about the research (i.e., share recruitment materials with their staff); (3) provide prospective subjects from their staff with information about contacting investigators for information or enrollment; and/or (4) ask their staff permission for investigators to contact them.

These approaches leverage trusted relationships (with the HCW), use culturally and linguistically responsive materials, and reduce the burden of testing by using mailed saliva kits to address common barriers encountered by the targeted populations. Campaign materials will also include lists of community resources that can provide support in the event of positive test result, since the potential effects of a positive result and quarantine on employment and a person's ability to meet basic needs are themselves significant barriers. Where applicable (such as in our ongoing cohorts), we will send e-mail blasts/flyers, and place posters and informational kiosks in key hospital and clinical locations. Recruitment materials in English have been developed are part of this protocol amendment. Once they have been approved we will submit Spanish translations for IRB for approval prior to their use.
Electronic survey data collection: Interested individuals can click active hyperlinks, scan QR codes or type in URLs from recruitment materials to obtain more information on the study and assess their eligibility. Informed consent will be collected electronically after which consented individuals will complete demographic questionnaires about themselves and their households. They will then be asked to extend the invitation to their "spheres of influence" (household and other family members/community contacts) to reach populations who would not otherwise have access to testing. The ambassadors will receive an e-mail and/or text message with an URL link to forward to their contacts. By clicking that link, the household and other family member/community contact will be taken to a webpage with information on NJ HEROES TOO testing, including contact information for study staff.
Telephone data collection: For individuals who are not able to enter their own information electronically, a phone number will be provided for the study. They can use it to reach a research staff member who will consent them, administer the survey by phone and set them up with Vault Health for testing.

Recruitment of the community-based comparison group arm (Aim 2). For the traditional, community based arm of study aim 2, recruitment will be channeled through extant community-based organizations focused on underserved communities in the counties of interest. These partner organizations will advertise the testing opportunity through their preferred standard community outreach channels (e.g. mailings, flyers, community events) as well as through additional multimedia approaches identified and developed during Aim 1. As in the NJ HEROES TOO arm, interested individuals can either opt for electronic or telephone data collection.

C. Subject Screening

- **Eligibility Criteria**

  Aim 1: (1) self-identification as Black or Latinx; (2) age 18 or older; and, (3) have access to phone, internet and/or email/text messages; and, (4) ability to speak, understand, and/or read English or Spanish.

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  Aim 2 Healthcare Workers: (1) self-identification as Black or Latinx; (2) employment at one of the participating health care settings (Parker Health, Robert Wood Johnson University Hospital, University Hospital, Visiting Nurse Association); (3) resident of Union, Passaic, Middlesex, or Essex County, NJ; and, (4) age 18 or older..

  Aim 2 Healthcare Worker household members/contacts: (1) self-identification as Black or Latinx; (2) resident of Union, Passaic, Middlesex, or Essex County, NJ; (3) age 4 or above; (4) able to provide informed consent/assent; and (5) ability to speak, understand, and/or read English or Spanish.

Aim 2 Community members: (1) residence in the counties of interest (Union, Passaic, Middlesex, or Essex County, NJ); (2) self-identification as Black or Latinx; (3) age 18 or older; (4) ability to speak, understand, and read English or Spanish; (and, (5) ability to provide informed consent.

Aim 2 Community household members/contacts: 1) self-identification as Black or Latinx; (2) resident of Union, Passaic, Middlesex, or Essex County, NJ; (3) age 4 or above; and (4) able to provide informed consent/assent; and (5) ability to speak, understand, and/or read English or Spanish.

Aim 2 Children: (1) Age 4 or above; (2) Parent/ legal guardian able to provide permission to participate

4.2 Secondary Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

We anticipate a total of 3000 participants will be enrolled across the two study aims.

Aim 1: We recruited 13 groups and 8 individual interviews with stakeholders who identified as Black and/or Latinx (n=111 individuals).

Aim 2: The goal is to enroll approximately 1000 participants in each of the two study arms (N=2000) over a 12 month period.

We are experiencing a high loss to follow-up rate in Aim 2. Though interest, consent rates and survey completion are high there is also a high rate of loss to follow-up. COVID-19 testing is the study outcome and uptake among participants is low. Therefore, we may need to enroll more than 1000 per arm.

B. Total Number of Subjects If Multicenter Study

N/A

C. Feasibility

For Aim 1 and Aim 2 community based organization arm, drawing from long-established relationships and community partners of MPIs Hill, Hudson, and Jimenez we have engaged 18 community organizations in the design and development of this project. Organizations serve the cities of Newark, Elizabeth, Irvington, Hillside, Caldwell, Paterson, New Brunswick, Perth Amboy, and their surrounding areas. They range in size, scope and focus from faith-based organizations to large social service groups.

For the Aim 2 HCW arm, our current COVID-19 surveillance cohorts include nearly 4000 HCWs, of whom we estimate 32% (n~1300) meet criteria to serve as ambassadors. We anticipate that approximately 1000 more HCWs from Parker Health and the Visiting Nurse Association will be eligible.

4.4 Consent Procedures

A. Consent Process

Informed consent/assent will be obtained prior to participation. Electronic Consent: Potential participants will be sent a web link where they are presented a document that lists all elements of

informed consent, including: (a) that activities involve research; (b) that participation is voluntary; (c) the purpose, procedures, and duration of the research; (d) any reasonably foreseeable risks, discomforts, and benefits of the research; (e) how confidentiality/privacy will be maintained; (f) circumstances when the investigator may withdraw their participation; (g) how many people will be in the study; (h) incentive for participating; (i) ability to withdraw at any time; (j) that the de-identified data may be shared with other researchers; and (k) name and contact information for Principal Investigator. Consent will be obtained from adults 18 and over and parents/guardians will provide consent for their children if they wish to have them tested. Children age 7 and older will be asked to provide assent in addition to the parental consent. Verbal Consent: Research staff will read the consent document and initial the document. A copy of the consent document will be sent to the participant via email or regular US mail.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  N/A
- **Destruction of Identifiers**
  Aim 1 and 2 identifiers will be destroyed at the close of the study. Aim 1 data will be de-identified prior to analysis once transcripts have been generated. Aim 1 de-identification of data will consist of removal of all personal identifiers from analytic files and substitution of pseudonyms for participant names. Aim 2 data used for analysis will be fully de-identified upon data export from REDCap and stored on an encrypted, password-protected computer network to which only study investigators and staff have access. De-identification of Aim 2 data will consist of removal of all personal identifiers from analytic files as well as random shifting of dates to preserve participants' anonymity. Audits of REDCap data access will be completed regularly to ensure there is no unauthorized access of REDCap data.
- **Use of Deception/Concealment**
  N/A

C. Documentation of Consent

- **Documenting Consent**
  For Aim 2 we will provide both electronic and verbal consent options. Electronic Consent: Individuals will receive an electronic survey with a check a box on an electronic consent form agreeing to participate before starting the survey (Aim 2). At the end of the survey, participants must check a box confirming agreement to submit a saliva sample and enter their address where the saliva testing kit will be sent.
- **Waiver of Documentation Of Consent (i.e., will not obtain subject's signature)**
  For Aim 1 and Aim 2 verbal consent procedure we are requesting a waiver of documentation of consent. For Aim 1, we will read an information sheet with the elements of consent at the beginning of each virtual zoom focus group (see script uploaded). Those participants who choose to stay in the meeting will be recorded by study staff as providing consent. For Aim 2, we will read the electronic consent at the beginning of the phone call and input the participant's information in the system. For those participants with email, they will receive copies of their consent electronically. For participants without email, a paper of copy of the electronic consent will be mailed.

4.5 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults

Our study population includes healthcare workers, age 18 and over, as well as their household and community members. Children age 4 and older will be included. Children age 7 or greater will provide assent in addition to parental consent. There will be no upper age limit. The parent/legal guardian permission and assent process will follow a similar procedure as outlined above.

Parents/legal guardians with children between age 4 and 18 years will receive an electronic parent permission form before starting the survey with a checkbox providing permission for the child to participate. For children age 7 and older, there will be an electronic assent form with a simplified description of the study procedures and language that offers an option to not participate. Given that this is a minimal risk study and parental/legal guardian permission will be electronically documented, waiver of documentation of assent is requested.

B. Wards of the State
Wards of the state will not be enrolled.

C. Non-English-Speaking Subjects
Spanish

- **Process for Non-English-Speaking Subjects**
  - Participants who identify Spanish as their preferred language will be recruited. The research team includes individuals who speak Spanish fluently and we will use translated informed consent documents.
- **Short Form Consent for Non-English Speakers**
  N/A

D. Adults Unable to Consent / Decisionally Impaired Adults
N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
N/A

B. Compensation/Incentives
Aim 1: We will offer a $30 gift card incentive to all focus group and key informant interview participants.

Aim 2: We will offer a $35 Target gift card incentive to all survey/COVID-19 testing participants. Target gift cards were chosen because they can be used for a variety of items for adults and children including the purchase of age appropriate games, toys or books inclusive of shipping costs. A 2004 NAM report on the ethical conduct of clinical research with children describes gift certificates and cash payments ranging from $10-100 as median incentive amounts for pediatric studies.[39]

The incentive for Aim 2 is slightly higher than the aim 1 incentive given the additional saliva data collection proposed.

C. Compensation Documentation
For Aim 1 our staff documented the name and address of the participant receiving the card, the cash value of the card, serial number on the card and date of mailing and initialed each entry. For Aim 2, our research staff has identified a gift card management system Rybbon for that interfaces with REDCap and maintains a log that documents distribution of gift cards.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects
This is a minimal risk study, which means that risks from study procedures are similar to those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. There are no test articles (investigational new drugs, devices, or biologics)

to be used in this study. No risks are anticipated from completion of the virtual focus groups, community conversations, surveys, or self collection of saliva samples. Breach of confidentiality of participants is the main potential risk. However, safeguards are in place at Rutgers University to ensure that confidentiality is maintained through the use of unique study IDs, password protected encrypted computers, and software, as well as other techniques described above. Information is provided to participants regarding the handling and the identification process involved with the data. Information that identifies subjects and subject number will be kept in secure servers. Antivirus software and firewalls are updated regularly to prevent any potential virus infection or hacking attempts. Only study staff that has contact with participants will have access to this information. None of the information being asked would pose any physical, psychological, financial, legal or other risk to participants.

Another potential risk is receipt of a positive COVID-19 test, with potential psychological (e.g., distress) and financial effects (e.g., due to mandatory quarantine on employment). These risks are described in the consent and explained by study personnel prior to enrollment. The protocol poses no other physical, psychological, financial, legal or other risk to participants. The protocol incorporates several steps to minimize all of these risks.

Finally, an additional potential risk may be receipt of an inaccurate test result. Our saliva test was the first saliva-based test to detect SARS-CoV-2 that was granted emergency use authorization by the FDA, and it is the only one authorized for at-home self-collection in the U.S. To date, 200,000 tests have been performed. The test is very sensitive for the presence of SARS-CoV-2, with 98% of tests providing either a positive or a negative result, and only 2% of tests providing an inconclusive result. The test can detect fewer than 10 copies of viral genes per milliliter of saliva, and it can detect the presence of virus in the saliva within 2 days of infection and up to 28 days after infection. Across all known gene sequences of SARS-CoV-2, the test detects the ones in the genes of interest ~100% of the time, making it highly sensitive and specific for those genes. While false positive and false negative rates for this test cannot be calculated currently (the lab does not receive data on what happens to patients after they receive the test), emerging data about false negative rates of saliva-based COVID tests are showing that the false negative rate may be closer to 10%, which is significantly lower than those of nasopharyngeal swab-based tests, which are in the 25-35% range.

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
N/A

E. Minimizing Risks of Harm
The investigative team will abide by the protocols laid out by our ongoing IRB-approved cohort surveillance studies. All data used for analysis will not contain any PHI. Data will be transferred according to safe data transfer policies utilized by both studies and stored on password protected, encrypted computers. All co-investigators will also sign a confidentiality agreement to prevent both a breach of confidentiality and deductive identification of the de-identified data. All study personnel have been trained in methods of maintaining confidentiality and have passed the Rutgers educational program requirement on the protection of human subjects (CITI training), Good Clinical Practice, and HIPAA regulations at regular intervals. In addition, audit trails, reports for monitoring and other checks will be made to ensure data integrity. These checks will be overseen by the study PIs and research team.

Finally, saliva specimens sent to the lab for analysis will be coded by study ID; no PHI will be provided to these laboratories. The laboratory data will then be merged with other study research data by study ID. These merged files will be securely e-mailed using the study's safe data transfer protocol by the study staff to the study PIs and statisticians for analysis. Again, at no time will PHI be e-mailed or provided to investigators conducting data analysis. Antivirus software and firewalls are updated regularly to prevent any potential virus infection or hacking attempts.

Vault Health, Inc provides administrative and physician services to RUCDR Infinite Biologics for ordering the saliva test, remotely supervising people while they collect their sample (via Zoom video call if needed), and reporting results. When ordering the test, people are asked whether they wish to receive results over email or not. Results are provided within 24-48 hours after the sample is received at the lab. For those who agree to email notification, they receive an email with the test result (positive, negative or inconclusive). Otherwise, they receive an email notification with a link to the results in their Vault account when the results are ready to view. Positive results are communicated via phone by a clinician from Vault, and people are given general CDC recommendations and advised that they need to contact their healthcare provider for follow up care. In the event that participants do not have a primary care provider, they will be referred to an RWJ Barnabas Health Partners provider or a Federally Qualified Health Center (in the case of no insurance) near their residence for follow-up care for COVID symptoms and any psychological distress. Vault reports test results as required by the applicable healthcare government authorities.

F. Potential Benefits to Subjects

The immediate benefit to study participants in Aim 2 is that they will learn if they are SARS-CoV-2 positive or negative. Larger scale benefits to society include potential reduction of transmission through identification of virus-positive individuals. Additional benefits to society are anticipated through the identification of strategies to better engage underserved communities in testing efforts and subsequent COVID-19 vaccination efforts, which can be implemented in NJ and beyond.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

The study informed consent provides direct authorization for Vault Health to share COVID testing results and PHI information in the participant's Vault health record with the research team in accordance with this research protocol.

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. Special Populations

Health care employees will be recruited as health care "ambassadors" for this study, however it is solely the individual's choice as to whether or not to participate. No study results will be reported to the employers.

Children will be enrolled in Aim 2 of the study after approval of the appropriate consent/assent forms and data collection instruments. Given that children are susceptible to SARS-CoV-2 infection, this study includes children and their parents as subjects. No greater than minimal risk to participating children is presented in this study. Children will only participate with the permission of their parent or guardian as outlined above. Children age 7 and older will provide assent. Assent would not be developmentally appropriate for younger children.

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

Aim 1

Qualitative data analysis of Zoom transcripts: Data collected will be analyzed to understand and process perspectives of participants' and to adapt and tailor materials and messaging that is meaningful to HCWs, their families, and community participants. Transcripts and fieldnotes will be managed using ATLAS.ti software. Independent data coding will be conducted by 2 team members with discrepancies reviewed at team meetings and resolved through consensus. We will compare and contrast data in the transcripts and fieldnotes within and across stakeholder groups as part of an iterative cycling process of reading, summarizing, and re-reading the data using qualitative interpretive analysis.

Aim 2

Quantitative: To compare participation rates in the two arms, our primary outcome, we will use data on the number of tests performed per month (over the up to 12 month study period). For each intervention, the start time is the date of first attempted contact with potential participants and the end date is either the end of the study period, or the date at which the 1000th individual was tested (whichever comes first). We assume that the number tested follows a Poisson distribution within the time period. We will test the null hypothesis that there is no difference between the two interventions, and also report a 95% confidence interval for the rate ratio. Secondarily, we will examine the proportion of tested participants from vulnerable and underserved populations of interest (e.g. Black and Latinx, immigrants, children, and low-income households) in each arm through logistic regression models. We will additionally examine proportion of positive tests in the two study arms to examine whether recruitment through index HCWs taps into more highly exposed participant groups, as hypothesized. To do so we will fit logistic regression models, where the outcome is positive test results (yes/no) and the primary predictor is study arm, adjusting for covariates including participant age, race/ethnicity, sex, occupation, and highest level of educational attainment. Power calculations for this aim are based on the primary outcome measure, testing uptake rate. We report power for rate ratios (RR; ratio of rate in comparison arm relative to intervention arm) of 1.15, 1.2, and 1.3, when expected tests per month in the intervention arm range from 80 to 120 (Table X). We will have about 80% power or greater for RR of 1.15 or greater. To test hypothesis 2B, we will compare participants in the two arms on key characteristics that may be barriers to testing (participant trust, health literacy, English proficiency, and patient activation). We will do so through linear regression models, adjusting for covariates including participant age, race/ethnicity, sex, and highest level of educational attainment.

Table X: Rate (Expected #/month) in NJ HEROES TOO arm

RR	80	100	120
1.15	0.78	0.82	0.81
1.2	0.94	0.96	0.95
1.3	0.99	0.99	0.99

Cost Analysis: The cost of the intervention components will be calculated using wage rates for personnel at the healthcare organizations and CBOs involved in distribution of materials multiplied by time recorded in time logs. Fringe benefit costs (healthcare, disability, and life insurance) will be added to wages by applying the prevailing fringe benefit rate. The value of time will be calculated as the present value of earnings: (number of hours spent delivering NJ HEROES TOO components) x (interventionist's reported wage rates + fringe benefits). Staff training time will be captured and converted to costs based on application of hourly wage rates. Material costs will include the salivary test, educational print materials provided to study participants, and any other required supplies.

Qualitative/Process Analysis: We will conduct an ongoing mixed methods process evaluation to gather data on how the interventions are implemented while gaining critical insight into factors that influence implementation from multiple perspectives. We will collect quantitative and qualitative data on key intervention components to understand reach, engagement, and adoption of the interventions. Data on reach will assess number of family members/contacts per HCW enrolled. Data on engagement will include data on participation rates for HCWs and families participating across the four counties. Data on adoption will include distribution of educational materials and testing uptake across the four counties. Throughout the intervention, we will purposefully identify and select key informants, individuals with direct experience and knowledge about the intervention, including both those implementing the intervention and recipients of the intervention.

6.2 Data Security

Data will be accessed from the Family Medicine Research Division Offices located in the Rutgers Institute for Health, Healthcare Policy and Aging Research at 112 Paterson Street, New Brunswick NJ 08901. We will utilize standard Rutgers procedures and infrastructure for data and safety monitoring to ensure the security of our study participants' data (see section 6.3 for details). De-identified electronic data will be stored on the university's secure server for at least 6 years after completion of the study. Saliva specimens are completely used for the SARS-CoV-2 assay; there is no residual saliva, therefore, there will be no specimen banking.

Data stored for future use will only be accessible by the Principal Investigator and co-Investigators and the RADxUP Coordination and Data Collection Center at Duke University which serves as the national coordination site for all RADxUP grantees. Release of de-identified data or specimens, irrespective of whether the Principal Investigator has ownership of the research project(s) that require the banked data, will need to obtain separate IRB approvals. We will make the de-identified data available to other researchers only under a data-use sharing agreement (see Resource Sharing Plan for details). When the banked data are transferred or shared, they will not be associated with any identifiable data, personal information of the research participants, or the master code identifier for deciphering the codes.

6.3 Data and Safety Monitoring

For this study, we will employ the following data safety and monitory plan. On an ongoing basis, the data team will monitor study record, questionnaire completion, and laboratory results. They will conduct regular spot checks of the data, checking records of 10% of the data housed in the password-protected database for data quality and accuracy. If inaccuracies are found, then the data team will meet with the study's PIs and operations team to discuss data collection processes, identify reasons for inaccuracies, and improve data entry and management systems. In addition, a data check will be conducted approximately one month after the identification of any inaccuracies to ensure that any issues involving the data entry and management systems have been resolved.

All adverse events (including those related to receipt of a positive test) will be recorded by study staff and reviewed by the PIs upon report. As we are leveraging already-ongoing data collection in our COVID surveillance cohorts, the present study will be in keeping with existing ongoing data collection protocols, currently approved by the studies' individual IRBs. As such, any adverse events, such as psychological distress, will be reported to the Rutgers IRB within 72 hours as per our institution's monitoring plan. Outcomes of adverse events will be reported in annual progress reports to NIH. Adverse events reporting will include: (a) a description of the adverse event, (b) the severity of the adverse event, and (c) whether the adverse event was associated with the research study.

We will utilize standard Rutgers procedures and infrastructure for data and safety monitoring to ensure the security of our study participants' data.

Qualitative data will be entered into the firewall-protected Rutgers secure servers. Rutgers employs Virtual Local Area Networks (VLAN) and Virtual Private Networks (VPN), in conjunction with Intrusion Detection

Systems (IDS), encryption techniques and virus protection and detection controls. Access to the server is only allowed for authorized users with a password. The data kept on this server are in a folder with the project's name. Access to this folder is restricted to the PI and system administrator. Access by anyone else to this folder has to be specifically authorized by the PI and executed by the system administrator. All subsets of the original database that are created for analyses will be created on this server. Research personnel conducting data analysis may be granted permission to download the dataset to his/her workstation. These workstations are connected to the Rutgers server and are password protected. As soon as analyses are completed, the dataset will be moved to the project data folder on the server and removed from the workstation.

Survey data will be stored on a Rutgers secure server via data entry into the study REDCap database. REDCap is a secure, password-protected web-based application designed to support data capture for research studies.[40] A unique study participant ID will be assigned in REDCap at the time of screening. All data used for analysis will be fully de-identified upon data export from REDCap and stored on an encrypted, password-protected computer network to which only study investigators and staff have access. De-identification of data will consist of removal of all personal identifiers from analytic files as well as random shifting of dates to preserve participants' anonymity. Audits of REDCap data access will be completed approximately every 2 weeks to ensure there is no unauthorized access of REDCap data. Investigators will keep the data, including links to personal identifiers, for at least 6 years, and longer if we have scientific justification, funding, and regulatory approvals to continue working with these data.

All study personnel have been trained in methods of maintaining confidentiality and have passed the Rutgers educational program requirement on the protection of human subjects (CITI training) and HIPAA regulations at regular intervals.

6.4 Reporting Results

A. Individual Subjects' Results
N/A

B. Aggregate Results
We will make aggregate results available by sending electronic newsletters, posting research briefs, white papers, infographics and blog communications on the NJACTS website. We will also host virtual zoom forums where investigators will be available to answer community questions.

C. Professional Reporting
Data generated from the proposed study will be shared with the research community through presentations at scientific meetings and publications in peer-reviewed journals.

D. Clinical Trials Registration, Results Reporting and Consent Posting
This study has been registered as NCT04766333 at ClincalTrials.gov. Final and aggregate results including basic results will be reported in a publicly accessible manner within twelve (12) months of the trial's primary completion date

6.5 Secondary Use of the Data

N/A

7.0 Research Repositories – Specimens and/or Data

N/A

8.0 Approvals/Authorizations

N/A

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