PROTOCOL TITLE:
Impact of Community Health Worker Home Deployment on COVID-19 Vaccine Confidence and Uptake (Project PEACH Community Study)

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
V6	03-12-2023	Add Post-Intervention Interview
V5	04-18-2022	Modified inclusion criteria and participant safety plan Revised study timeline Add COVID-19 testing plan
V4	03-23-2022	Revised participant safety plan
V3	03-04-2022	COVID-19 Home Testing Protocol Update recruitment methods section to include EHR report fields that will be used to identify patients
V2	02-03-2022	Add Project PEACH participant to exclusion criteria Modify incentive amount for interview participants Remove waist circumference from the clinical measures Add oxygen saturation to clinical measurements Add COVID-19 rapid testing requirement by CHW, participant, and family members prior to starting home visits Add ICD-10 codes that will be used to identify eligible AAPHC patients Clarify the role of the CHW for patient contact, screening, and consent

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1. Study Summary

Study Title	***Impact of Community Health Worker Home Deployment on COVID-19 Vaccine Confidence and Uptake.***
Study Design	Mixed Methods Study
Primary Objective	To maximize effective outreach, education, and communication through CHWs to facilitate improved COVID-19 vaccine confidence and uptake in underserved and vulnerable communities.
Secondary Objective(s)	To evaluate feasibility of CHWs to improve diabetes outcomes (e.g., blood glucose) and self-management behaviors among adults with uncontrolled diabetes in rural Georgia.
Research Intervention(s)/Interactions	Community Health Worker (CHW) deployment to the homes of adults with increased risk of morbidity and mortality (i.e., African Americans or Latinos with uncontrolled diabetes or prediabetes, age <50 years, and non-COVID-19 vaccinated) to educate them about diabetes, COVID-19, and related vaccines.
Study Population	Persons aged 18+ years, self-identify as African American/Black or Latino, and have received care for a diabetes or prediabetes diagnosis within one of the AAPHC 27 community sites. Our priority population will be those less than 50 years with uncontrolled diabetes and who have not yet received a COVID-19 vaccination.
Sample Size	3-5 participants for interviews 100 participants for CHW Intervention
Study Duration for individual participants	30–60-minute visits will occur twice weekly for 6-weeks. (6-12 hours total over 6 weeks).
Study Specific Abbreviations/ Definitions	AAPHC- Albany Area Primary Health Care
Funding Source (if any)	NIH/NIDDK

2. Background

SARS-CoV-2 (COVID-19) impact on people with diabetes disproportionately. Nationally, rates of COVID-19 infection are increasing for those under 50 years, with those 18-24 years having the highest weekly infection rate. Those between 25-34 years of age have the 3rd highest after teens 14-17 years.[1] Additionally, those under 50 years now account for the most hospitalized COVID-19 patients in the country — about 35% of all hospital admissions.[2]Diabetes doubles the risk of death in COVID-19. Between 14-41% of COVID-19 deaths are among people with diabetes with increased medical costs, hospital rates, and ICU admissions among diabetic patients with COVID-19.[3-12] Diabetes-pathophysiology, comorbidities, and underlying socio-economic and healthcare disparities contribute to these excess risks.[13-16] Moreover, socioeconomically disadvantaged people and racial/ethnic minorities (African Americans, Hispanic/Latinos) have higher diabetes rates as well as higher risk of severe COVID-19 outcomes compared with Whites.[17-21] Given the elevated risk of severe disease in our priority populations, it is imperative that those with diabetes and prediabetes receive COVID-19 testing, vaccines, and follow recommended guidelines for disease management and/or risk reduction. Our RADx-UP Diabetes Community Partners Program is working collaboratively with local community and clinical stakeholders to ensure the work that is proposed is guided by community insight, experience, and expertise.

Diabetes and COVID-19 Risk within Households. A variety of studies have found evidence of the social transmission of lifestyle behaviors, including eating patterns, consumption of fat and fiber, exercise, alcohol consumption and smoking.[22-32] This shared risk applies to COVID-19 exposure and risk behaviors, as well as the social determinants of health. Diabetes risk within households is of increasing concern and interventions targeting other family members in the household ("bubble") are an important leverage point.

Community Health Workers. MSM has trained and deployed CHWs in a broad array of research projects, health initiatives, and other policy, systems, and environmental change approach strategies. Areas of focus have included, but are not limited to, diabetes, cardiovascular health, cancer, primary care prevention strategies, and linkages to patient-centered medical homes.[33-40] MSM scaled its CHW efforts toward addressing the crosscutting priorities of fostering future learners and leaders in health disparity communities and building community-engaged initiatives that foster neighborhood leadership through establishment of the first high school community health worker training program in the nation, with the support of the Atlanta Regional Collaborative for Healthcare Improvement.[41] MSM continues to be a thought leader and collaborate in statewide coalitions positioning, visibility and outreach strategies central to CHW leadership in public health at large, and in pandemic response.[33]

RADx-UP Early Learnings: Key informant interviews with rural FQHC employees indicate that a major barrier to accessing care, including COVID-19 testing and vaccinations, is lack of transportation. Linking CHWs with high need patients and their bubble through bringing health education to their home would overcome this barrier. This approach will also provide the critical opportunity for the CHW to build trust through assisting the patient with an existing health need (diabetes management). Ongoing social media and media monitoring as well as in-depth interviews with individuals with or caring for a person with diabetes in the parent RADx-UP Diabetes project and locally tailored health communications products developed through Georgia CEAL will inform tailored messages around diabetes management and preventive behaviors during COVID-19 including testing, vaccination, social distancing, and masking.

Research Overview and Scope: We will leverage community partnerships and existing networks and will also apply evidence-based approaches to evaluate the feasibility of rural area FQHC CHWs to improve diabetes outcomes, COVID-19 vaccine confidence and uptake among adults diagnosed with diabetes and their "bubble." As with the RADx-UP Diabetes parent project, this supplemental project will also be guided by the EPIS framework, which considers the multilevel nature of healthcare, organizations within systems, and patient needs.[42,43] The proposed 1-year supplemental project will implement and evaluate a brief CHW intervention through the AAPHC, a rural FQHC. The primary aim of this study is to maximize effective outreach, education, and communication through CHWs to facilitate improved COVID-19 vaccine confidence and uptake in underserved and vulnerable communities. CHWs will be deployed to the homes of adults with increased risk of morbidity and mortality (i.e., African Americans or Latinos with uncontrolled diabetes or prediabetes, age <50 years, and non-COVID-19 vaccinated) to educate them about diabetes and COVID-19. Health assessments, including blood glucose assessments, will be conducted on the index patient and offered to all other adult family members in their "bubble." A secondary aim is to evaluate feasibility of CHWs to improve diabetes outcomes (e.g., blood glucose) and self-management behaviors among adults with uncontrolled diabetes in rural Georgia.

3. Study Endpoints

The primary outcomes of interest for this study are vaccine confidence and uptake among individuals with uncontrolled diabetes in rural Georgia. Our secondary outcomes of interest are participant blood glucose levels and self-management behaviors among our study population.

4. Study Intervention / Design

CHWs will conduct phone and home visits to provide health education based on the participant's needs and interests and clinical health assessment results. All adults in the household will be invited to participate in the health education discussions. The discussion of COVID-19 beliefs, perceptions, and related behaviors will be raised during a later visit, i.e., after rapport and trust has been established and if it has not been raised by the participants during the earlier visits. At each visit, the CHW will use diabetes management and COVID-19 educational materials to facilitate and inform discussions. CHWs will also make available at-home COVID-19 testing kits with instructions for the patient and their household family members. In addition, CHWs will help schedule vaccination and healthcare appointments upon participant's interest.

5. Procedures Involved

Unstructured Interviews: To inform final details of the CHW visits, we will conduct 3-5 unstructured interviews. During these interviews we will discuss meeting logistics (when, where, how, and how often). We will also inquire about their experiences managing their diabetes and their thoughts surrounding the pandemic including testing, vaccination, and social distancing measures. These unstructured interviews will help refine the questions and discussion topics during the CHW intervention. Interviews will occur either over the telephone or via zoom and will last about 30-60 minutes.

CHW Training and Messaging: CHWs will be trained by the MSM Prevention Research Center personnel through CHW program experts in chronic diseases, diabetes self-care, and COVID-19. Training on COVID-19 will occur through the COVID-19 Digital Classroom Initiative (COVID-19 DCI). [44] COVID-19 DCI courses are primarily designed for CHWs who practice in low- and middle-income countries. It covers a range of topics on COVID-19, including basic information on the virus and how to mitigate its public health effects. CHWs will also utilize Georgia CEAL COVID-19 communication messages developed through its CCB and their health communications working group to drive vaccine confidence and uptake in communities that may be distrustful and disinclined to participate in COVID-19 vaccination. Messages will be enhanced using our RADx-UP Diabetes study tools for monitoring media reports and social media and dynamically index these communities' themes against the barriers and issues previously identified through our RADx-UP Diabetes activities. We will focus on local news and social media traffic to calibrate for local communication barriers (e.g., trust, misinformation, disinformation, and message framing) among target communities. Additionally, culturally appropriate educational materials targeted for the individual from Diabetes Community Action Coalition and American Diabetes Association (ADA) will be utilized for diabetes education.

Implementation Strategy: To test program effectiveness, we will measure outcomes in people with uncontrolled diabetes, (and/or prediabetes), and their "bubble." Trained CHWs will initially be deployed for telephone and home visits to targeted patients based on AAPHC EMR. CHWs will use the home visits as an opportunity to build trust, educate the patient and their "bubble" about diabetes and COVID-19. Our education strategy will be guided by feedback from the RADx-UP Diabetes Community and Scientific Advisory Board, and the latest evidence-based guidelines. The CHW visits are expected to last 30-60 minutes each and will occur twice weekly for 6-weeks. Each visit will involve targeted education based on the participant's needs and interests. It is anticipated that two CHWs can complete approximately 25-30 home visits each week. All adults in the household will be invited to participate in the health education discussions. Discussions will be initiated based on results of the in-home clinical health assessment where the CHW will explain all results. Prior to leaving the first home visit, the next visit (by phone or in person) will be scheduled for 3-5 days later. A brief clinical health assessment will be conducted at the start each home visit and is expected to initiate the ensuing discussion. The discussion of COVID-19 beliefs, perceptions, and related behaviors will be raised at the 3rd or 4th home visit, if it has not been raised by participants during a previous visit. At each visit, the CHW will use ADA and COVID-19 educational materials to inform the discussions. CHWs will also make available at-home COVID-19 testing kits with instructions for the patient and their bubble at each visit. Additionally, CHWs will bring tablets to each home visit for the ability to show diabetes education videos as well as data collection. Furthermore, CHWs will coordinate with the AAPHC Mobile unit visits to communities in order to provide community-based access to COVID-19 vaccinations. The mobile units will travel to a central location in each community on designated days and times biweekly throughout the program. Patients and their family members will be advised of the dates and times that the mobile unit will arrive in their community. CHWs will have the ability to schedule patients and their "bubble" for COVID-19 vaccination appointments, if interested. CHWs will also provide

patients and their family members of locations for where they can go to receive free COVID-19 PCR testing and home rapid tests.

***Data Collection Methods*:** Once study implementation is initiated, data will be collected on all consented participants, allowing us to track adoption and implementation of health promoting behaviors throughout the study period. Consent for participants to share their survey data with NIH and/or CDCC will be discussed upon enrollment. Survey and clinical data collection timeline for our priority population is listed in Table 1. Surveys will be completed at the initial home visit (T1) and the last home visit (T12). Clinical health assessment data will be collected at each visit. COVID-19 at-home testing kits will be made available and related results shared with participants. For AAPHC patients, all results will be reported in their electronic medical records and the Project PEACH study database. For those that test positive, the CHW will send a telephone encounter to patients PCP making them aware. For family members that are NOT AAPHC patients, positive results will reported via SENDSS database and the CHW will instruct them to contact their PCP.

When necessary, CHWs will have the ability to make follow-up clinic appointments for participants. Participants' 3-month follow-up data will be abstracted from the AAPHC EMRs 3-months after the last home visit. RADx CDCC Tier 1 common data element survey questions will be collected on all enrolled participants. We will also seek to understand how social determinants of health affect COVID-19 testing, vaccine confidence and uptake, diabetes outcomes, and the role of psychosocial factors such as social support, anxiety, depression, and diabetes distress in COVID-19 testing, vaccine uptake, and diabetes-COVID-19 management. For the clinical health assessments, minimally invasive methods (i.e., finger stick) will be used to measure HbA1c, oxygen saturation using a pulse oximeter, measuring, height, and body weight at T1 and T12. Blood glucose, blood pressure, and body temperature will be assessed at each visit (T1-T12). The CHW will measure the participant's arm to determine the correct size cuff to take their blood pressure. Additionally, participant's experiences, understanding of results, assessment of educational needs, education regarding behaviors to lower risk of COVID-19 transmission (e.g., isolation, distancing, hygiene, mask use, homecare) and communication of their results to key family members or others will be assessed at each visit.

All project personnel will be trained in procedures to minimize the potential for breaches of confidentiality, including but not limited to ensuring that all files are closed, and that no conversations about individual project participants occur in public settings. Names and other easily recognizable identifiers will be removed from all data files and will not be included in any electronic databases. All data files will be maintained under password protection at all times, at each participating site and at the coordinating center.

Table 1

Measures	Frequency			
	T1 Baseline	T12 Post	EMR 3m	Each Visit
RADx-UP CDCCC Tier 1 Survey	x	x		x
COVID-19 Vaccine Measures				
• COVID-19 Testing Status	x		x	x
• COVID-19 Vaccine Status	x		x	x
• COVID-19 Vaccine Confidence & Behaviors	x	x		
Diabetes Measures				
• Diabetes Distress	x	x		
• Diabetes Self-Management	x	x		
• Diabetes Medication Adherence	x	x		
Psychosocial Factors				
• Anxiety	x	x		
• Depression	x	x		
Clinical Health Assessment Measures				
• Height, Weight, Oxygen Saturation	x		x	
• HbA1c	x		x	
• Blood Glucose, Blood Pressure, and Body Temperature				x

6. Data Storage

Overall: All program data will be stored in accordance with NIH and IRB guidelines following conclusion of the study. All qualitative data (de-identified verbatim transcripts of interviews), quantitative data, data collection tools, consent documents, study and committee reports, PHI/data from medical records and protocols will be housed on an Morehouse School of Medicine Drive server (HIPPA compliant, cloud-based file sharing and storage platform), in a secure HIPAA compliant folder maintained by the Information Technology staff, in Qualtrics, and/or in REDCap and available to the entire investigative team. Data from EMR will be abstracted and stored only after the participant has consented to participation in the study. Medical and treatment history such as lab test results, diagnoses, medications, and allergies will be collected.

Investigators at all collaborative institutions (Morehouse School of Medicine and Emory University) will participate in program evaluations, with aim-specific evaluations being led by different cross-institutional teams. In addition, community investigators, key contacts at participating community sites (i.e., AAPHC), and other individuals offering topical expertise or community-focused interpretation of the data will be invited to participate in deidentified data reporting and manuscript preparation.

All study tools, results, best practices, challenges, sharable data (e.g., newly collected data and publicly available datasets), and any other information that can improve nationwide COVID-19 testing and cross-site collaborations will be shared with or made available to the Coordination and Data Collection Center (CDCC), the network of Testing Research Projects (announcements NOT-OD-20-120 and NOT-OD-20-121), and the Social, Ethical, and Behavioral Implementation

(SEBI) program participants (hereafter, the RADx Consortium). The CDCC is being managed by the Duke Clinical Research Institute (DCRI). The DCRI will build two RADx-UP databases (systems that hold electronic information). These data will be kept at the DCRI. The DCRI will not share these data with the NIH. Participant information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and their electronic health record, among others. Only if the participant agrees, will the DCRI keep information that can identify them in order to contact them for future research studies. If they do not agree, this information will stay with the study team, as applicable. These data at DCRI will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of this data at the DCRI will be able to see this information. The second database will not hold information that can identify participants. Participants will be assigned a study code and will only be identified in this database by this study code. The DCRI plans to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated. When using the data from this second database, researchers will only have access to non-identifiable data and cannot link the data back to participants. Because the data cannot be linked back to participants, DCRI will not contact participants to inform or ask permission before sharing the data with researchers.

We will transfer sharable data to the DCRI, which helps maintain data for the RADx Consortium. We will uphold all data protection policies stipulated by the NIH's statements and guides for sharing research data (in order to protect the privacy and rights of all participating human subjects). We will undertake to share ONLY de-identified study data files, with one exception. Specific identifiable data and protected health information will be shared with DCRI, as outlined in the Data Transfer Agreement. Sharing data with researchers outside of the RADx Consortium will ONLY be permitted under strict data-sharing agreements and/or user registration. As part of the registration/data-sharing agreement process, users must agree to the following conditions governing use of the data, including: 1) restrictions against attempting to identify study participants, 2) a commitment to securing the data using appropriate computer technology, 3) destruction of the data after analyses are completed, 4) reporting responsibilities, 5) restrictions on redistribution of data to third parties or for commercial purposes, and 6) proper acknowledgement of the data source.

7. Sharing of Results with Participants

Results of the study will be shared directly with AAPHC. Data will be both aggregate and site-specific, unless providing site-specific data compromises the deidentification of participants. In addition, results will be disseminated widely through national peer-reviewed journals, the nationwide RADx-UP coordinating Center, the Georgia Center for Diabetes Translation Research (GCDTR) and study partner websites (e.g., gcdtr.org), international and national conferences, and the media.

Aggregate study results will be shared with participants once the study has been completed. Links to results published on GCDTR and study partner websites will be shared via email, along with a description of what the results mean. If results are not published on study websites, we will still send a summary of the results and what they mean to participants via email or postal

mail. Because some participants will not have access to email, we will disseminate hard copies of the email content to community partners and FQHCs, involved in recruitment, to distribute to their constituents.

8. Study Timeline

- The duration of an individual participant's participation in the study: Between 6 and 12 hours (30-60 minutes per visit, twice a week, for six weeks)
- The duration anticipated to enroll all study participants: 4 months
- The estimated date for the investigators to complete this study (complete primary analyses) is one year.

Table 2: Study Timeline

Activity																			
	Jan 2022	Feb 2022	March 2022	Apr 2022	May 2022	Jun 2022	Jul 2022	Aug 2022	Sept 2022	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	March 2023	April 2023	May 2023	June 2023	July 2023
IRB Submission	X																		
IRB Approval		X																	
IRB Modification			X	X															
CHW Hire	X		X																
CHW Training	X	X		X															
Participant Recruitment				X	X	X	X	X	X	X	X	X	X						
Unstructured Interviews				X	X														
Home Visits				X	X	X	X	X	X	X	X	X	X	X					
EMR 3m Follow-up Data Extraction							X	X	X	X	X	X	X	X	X	X	X		
Data Analysis																X	X	X	X
Dissemination																	X	X	X

9. Study Population

Inclusion Criteria: Participants must be 18+ years, self-identify as African American/Black or Latino, English speaking, and have received care for a Type II diabetes or prediabetes diagnosis within one of the AAPHC 27 community sites. Pregnant women with gestational diabetes will also be eligible for participation. We will identify eligible adults through electronic medical records (EMR) of patients within the AAPHC system. Although our priority population will be those less than 50 years old with uncontrolled diabetes (HbA1c > 9%, on their last health care visit) who have not yet received a COVID-19 vaccination, all AAPHC patients diagnosed with diabetes or prediabetes will be eligible. It may be difficult to identify patients who are unvaccinated since this may not be on their health record, so we will include both vaccinated and unvaccinated individuals.

Exclusion Criteria: Participants not meeting the Inclusion Criteria or who are enrolled in the parent RADx-UP Project PEACH study, who are unable or unwilling to provide informed consent to participate in the study will be excluded. Incarcerated individuals, and children will not be eligible for participation in the study. Additionally, those who have received a terminal cancer diagnosis, have chronic kidney disease (stage 4-5), pregnant women, and people with severe psychological disorders (i.e., dementia, suicide ideation) will be excluded from participation in the study.

10. Recruitment Goal

We plan to enroll 3-5 participants for the cognitive interviews and 100 participants for the CHW intervention.

11. Recruitment Methods

Eligible adults will be identified through electronic medical records (EMR) within the AAPHC system using ICD-10 codes. The AAPHC EMR staff will use the following ICD-10 codes and report fields to generate a report of patients.

- **ICD-10 Codes**
  - E11.65- Type 2 diabetes mellitus with hyperglycemia
  - R7303-Prediabetes
- **Report Fields**
  - Patient ID
  - Facility Name
  - Patient Name
  - Phone Number
  - Email
  - Race
  - Ethnicity
  - Age

- COVID Vaccine Visit Types
- HbA1c Level

The CHW employed by AAPHC will use the report to contact patients to invite them to participate in the study. Study invitation messages will be disseminated to patients by AAPHC through the patient portal, by email, or text if responses to the calls made by the CHW are low yield. Patients will also be reached by mailing documents (e.g., consents) and mailing flyers. All recruitment efforts will be initiated by the CHW employed through AAPHC. Participants that take part in the interviews will receive a $75 incentive and those who participate in the CHW intervention will receive $125 over the course of 6-weeks.

Screening and Consent

Patients interested in the study will be screened by the CHW to determine if they are eligible to participate in the study. If a patient is eligible, the CHW will obtain oral consent. Once oral consent is obtained, the patient will officially be enrolled in the study. If time does not permit after the screening, the CHW will schedule an appointment to complete the oral consent at a time convenient for the patient.

12. Withdrawal of Participants

A participant may withdraw at any time by contacting the study staff at the number or email provided on the consent form. The data collected to the point of withdrawal will be retained but no further participation or contact will occur after withdrawal, unless the participant agrees to be contacted about future research opportunities. The PI will also have the discretion to withdraw a participant from the study.

13. Risks to Participants

Risks to participants include the possibility someone could gain access to the personal health data. All personally identifiable data will be carefully controlled and maintained on a secure HIPAA compliant server and only authorized study team members involved in data collection and analysis will have access to the data. The study team will be responsible for de-identifying the dataset prior to sharing outside of the study team. Additionally, all data will be reviewed to ensure that it was appropriately de-identified prior to sharing data with non-authorized team members and/or submission of reports and dissemination of study findings. Identifying information will be maintained in a separate, password protected folder. Participants may also feel slight discomfort when blood is collected by finger stick to measure their HbA1c and fasting glucose levels. There may also be some psychological discomfort when discussing diabetes and COVID-19 effects on their health and the possible outcomes of those conditions.

14. Potential Benefits to Participants

Individuals participating in the interviews may not benefit from the study directly. We will learn new things that will help improve the CHW intervention. The interviews are intended to provide a direct benefit to people who participate in the CHW intervention, although they will receive information about diabetes and COVID-19. Participation in the CHW intervention is intended to help participants and their families better understand the importance of diabetes self-care, COVID-19 vaccinations, and ultimately increase uptake of vaccines.

15. Data Analysis, Management and Confidentiality

Analysis Plan: As a preliminary step, descriptive statistics and frequency distributions will be examined to identify outliers and ensure data quality and integrity. Preliminary analyses will examine baseline differences within and between participants to determine any predisposing factors (demographics, health history, relationship and health status at baseline, vaccine status). Where significant associations with baseline measures are detected, these potential confounders will be controlled for in subsequent analyses using covariate model adjustments. Multi-level mixed effects models (MLM) will be employed to test for changes over time in Table 1 Measures. Additional follow-up analyses will be performed to test if any possible treatment modifications occurred due to (a) family engagement (number of family/household members who attend home visits) and (b) dose (number of sessions that occurred. STATA v.17 (STATA Corp LLC) and R 4.x (R Code Team 2021) will be used for all analyses with 5% level of significance. All codes will be thoroughly documented and retained following reproducibility workflow principals for future data and code sharing. Outputs: Results from this study will inform the public, policy makers, and health actors in the local vaccine environment. We will evaluate heterogeneity in patient outcomes by baseline characteristics, such as age, sex, and race/ethnicity.

16. Provisions to Monitor the Data to Ensure the Safety of Participants

Given the increased risk of COVID-19 exposure, the CHW will take the following precautions below.

a. AAPHC CHW staff are required to have received the COVID-19 vaccination.
b. AAPHC CHW staff will be required to self-administer a COVID-19 rapid test on the days that they will visit the home of a participant.
c. Everyone present during a home visit will be given a COVID-19 rapid test prior to the CHW entering the home for the visit.
d. The CHW and all parties in the home will be required to wear an appropriate mask and maintain a safe distance, when possible. If participants in the home do not have a mask, the CHW will provide one.

A Data and Safety Monitoring Plan has been created that includes the plan to follow in the event of adverse events, elevated blood pressure, and elevated blood glucose levels (see appendix). The MSM PI will monitor data weekly.

17. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

- All research activities will be conducted in as private a setting as possible, and participants will have ample time to decide whether to participate in this study.
- The study participant's contact information will be securely stored in a password-protected file at the study sites. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the IRB, institutional policies, or other requirements.
- Access to data that are linkable to personal identifiers is available only to authorized research staff and used only to contact consenting participants.

18. Economic Burden to Participants

There is no cost to participants associated with participating in this study.

19. Consent Process

The study team will contact potential participants via email invitation, phone call, or in-person to invite them to participate in the study. Those interested in participating will be able to contact the research team by phone or email. Once a potential participant has expressed interest, the study team will read the verbal informed consent to them and answer any questions they may have. If they verbally agree to participate, the study team will schedule the first visit. The team will provide a hardcopy in-person or send a hardcopy of the informed consent via postal mail or encrypted email to participants who provide verbal consent for their records.

No minors, cognitively impaired adults, non-English speaking participants, or anyone requiring third party assent will be interviewed. Consent will be obtained orally. Before study enrollment, a trained staff member will review the oral consent document with the participant by phone, answer any questions the participant has, and obtain verbal consent for the interview and recording of the discussion.

For the cognitive interview, the staff member will document verbal consent for: study participation; recording of the interview; willingness to share data with the RADx-UP coordinating center; and willingness to be contacted about other studies. Participants will receive a copy of the oral and full consent form via mail, email, or in-person.

For the CHW intervention, the staff member will document verbal consent for: study participation; recording of the CHW session, when possible; willingness to share data with the RADx-UP coordinating center; and willingness to be contacted about other studies. Participants will receive a copy of the oral and full consent form via mail, email, or in-person.

20. Setting

We will build on long-standing community-based research infrastructures in Southwest Georgia. Specifically, this study will take place as a partnership between MSM, Emory, & AAPHC in Southwest Georgia. AAPHC coverage area includes six counties across Southwest Georgia. AAPHC is currently a community partner for the RADx-UP Diabetes parent grant and has a patient base of over 44,702 adults and children. Of relevance to the current proposal, AAPHC

has over 600 adult African American and Latino patients under 40yrs with uncontrolled diabetes. Additionally, over 13,000 patients that have yet to receive a COVID-19 vaccination as of February 2021.

21. Resources Available

The NIH has provided funding to cover the costs of this study. This includes the costs of effort for MSM Research Coordinators and MSM & AAPHC Community Health Workers working on this protocol. All study staff will be adequately trained on their duties prior to protocol implementation. There is an adequate number of patients to meet recruitment goals.

22. Multi-Site Research with MSM as the Lead Site

This is a collaborative project with research investigators at Morehouse School of Medicine and Emory University and one community partner, AAPHC. Total enrollment for the current research study includes up to 105 individuals. Recruitment methods will be the same across sites (see above sections) and will use referrals by AAPHC. Plans for data collection, sharing, and storage are described above. All study materials including protocol drafts, data collection tools, and consent forms will be shared across sites and stored on an MSM One Drive folder to improve access by all investigators and project team members. All changes to the IRB will be first routed through the MSM IRB (IRB of record) and uploaded to the Emory University IRB before any project activities are begun. Investigators across sites will follow all guidelines and protocol plans to ensure ethical treatment of participants and data, maintain data security, and guarantee team members are up to date on any required trainings. All local site investigators will conduct the study in accordance with applicable federal regulations and local laws. Any non-compliance will be reported to IRBs at Morehouse School of Medicine and Emory University. The full AAPHC Supplement study team will meet monthly while the Operations Committee will meet weekly to provide overall updates, discuss current progress (including, when applicable, study closure), and find solutions to any current challenges.

23. COVID-19 Testing Plan

Intended Use and Distribution

Community Health Workers (CHWs) will utilize the Quidel QuickVue Home Test Kit to distribute to study participants to self-test for COVID-19. The QuickVue At-Home COVID-19 Test is a self-collected anterior nares swab that allows for the rapid detection of SARS-CoV-2. The CHWs will test all present members of the household before entering the participants' residential space for each scheduled home visit. Serial testing will be required for asymptomatic participants who test negative at the time of the home visit. The CHWs will provide test kits at each home visit to ensure participants can participate in serial testing at least 48 hours after scheduled home visits. All test results will be captured in REDCap.

Data Collection

Sample Collection

At each scheduled home visit, a CHW will meet participants at the front door, wearing proper PPE, and ask how many individuals over the age of 2 are in the home. The CHW will proceed by distributing the tests to all the individuals in the home. Individuals will then self-administer the test using the QuickVue instructions (see detailed instructions below). At each home visit, the CHW will remain at the front door while the participant and other household members swab and process the test. At the time of home visits, each individual will report their result to the CHW If a participant test negative, the CHW will provide additional tests for the participant to perform 2 in home tests at least 48 hours apart. The CHW will follow-up with the participants to obtain results.

Instructions for Collecting Sample during Home Visits

1. Participants will remove and identify kit components and instructions.
2. Participants will remove the cap from one pre-filled tube and place it back in the tube holder.
3. Participants will peel open the wrapper from the anterior nares swab. The participants will be instructed to not touch the swab head or remove the anterior nares swab until ready for sample collection
4. Participants will hold the swab approximately halfway up the handle and gently insert the swab ½ to ¾ of an inch into the nostril.
5. Participants will rub the swab in circles in the inside of one nostril at least 4 times.
6. Participants will rub the swab in circles in the inside of the other nostril at least 4 times using the same swab.
7. Participants will place the specimen swab in the tube and place the tube in the tube holder.

Performing the Test during Home Visits

1. Participants will stir the specimen swab in the tube 3 to 4 times.
2. After stirring, the swab will remain in the tube for at least one minute.
3. After one minute, participants will carefully remove the swab from the tube. While removing the swab, participants will rub the swab head against the wall of the tube to squeeze out as much liquid as possible. Participants will immediately discard the swab in the biospecimen bag provided by the CHW
4. Participants will carefully open the test strip and place it into the open pre-filled tube with the arrows pointing down. The CHW will set a timer for 10 minutes once the strip is placed into the tube.
5. After 10 minutes, the test strip will be removed from the pre-filled tube and placed on a flat surface.
6. To avoid inaccurate results, participants will read their results within 5 minutes after the swab is removed from the pre-filled tube.
7. Participants will disclose their test results with the CHW. If the participant is positive, the CHW will report the positive result in the AAPHC electronic health record system. The positive result will also be reported in the Georgia Department of Public Health COVID-19 Point of Care Test Reporting Portal (i.e., sendSS database). For household members

present during home visits, the CHW will enter the following data into REDCap: child/adult, gender, and test status.

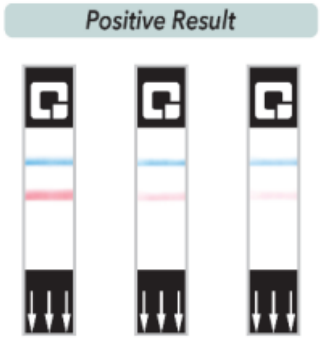
8. Participants will dispose of all home test kit contents.

Interpretation of Results

Results must be read between 10-15 minutes before results are invalid. Results can only be read for an additional five (5) minutes after being removed from the tube at the 10-minute read time. Do not read the Test Strip more than fifteen minutes after placing into pre-filled tube.

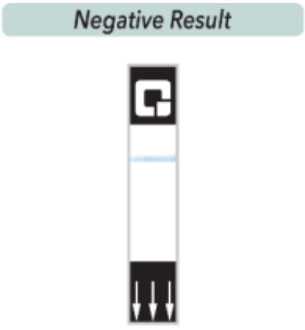
Positive Results

At 10 minutes, the appearance of **ANY** shade of pink-to-red test line **AND** the appearance of a blue procedural control line indicates a positive test result for the presence of SARS-CoV-2 antigen.



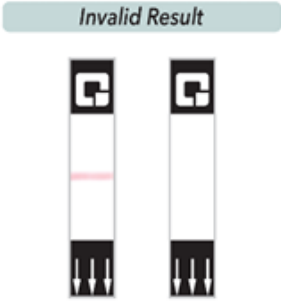
Negative Result

At 10 minutes, the appearance of ONLY the blue procedural control line indicates SARS antigen was note detected.



Invalid Result

If at 10 minutes, the blue control line does not appear, even if any shade of pink-to-red test line appears, the result is invalid. If at 10 minutes, the background color does not clear and it interferes with the reading of the test, the result is also invalid. If the test is invalid, a new swab should be collected, and the test should be performed again.



Expected Measure Outcomes

There are two main outcomes for the use of the QuickVue At-Home COVID-19 Test. The first is to ensure the safety of the CHWs and the participants that will take part in the study. The second outcome is to encourage and empower participants to test regularly.

24. Participant Safety Plan

- **Plan for mental health events**
    - If participant responds to the following questions during the screening and/or survey process, the CHW will provide the participant with the phone number to the Georgia Crisis Access Hotline and submit a behavioral health referral in the AAPHC electronic health system. If it is an urgent matter, the CHW will contact AAPHCs licensed clinical social worker to follow-up with the patient.
        - Based on reporting all 3's (nearly every day) on the Patient Health Questionnaire-4 (PHQ) items that states "Over the past 2 weeks have you been bothered by these problems? 1) Feeling nervous, anxious, or on edge, 2) Not being able to stop or control worrying, 3) Feeling down, depressed, or hopeless and 4) Little interest or pleasure in doing things
        - Based on responding "yes" to During the past month, did you ever seriously consider attempting suicide? or During the past month, did you make a plan about how you would attempt suicide?
        - Based on PHQ-9 item 9 that says, "Thoughts that you would be better off dead or of hurting yourself," participant responded several days
        - Based on PHQ-9 item 9 that says, "Thoughts that you would be better off dead or of hurting yourself," participant responded more than half of the days
        - Based on PHQ-9 item 9 that says, "Thoughts that you would be better off dead or of hurting yourself," participant responded nearly every day
- **Plan for elevated BP levels**
    - If participant has BP between140-180 systolic and/or greater than 90 diastolic blood pressure, the participant will be encouraged to allow the Community Health Worker (CHW) to make an appointment for treatment either with their own AAPHC primary care physician or another physician AAPHC if they do not have a primary care physician.

    - If participant has BP greater than 180 systolic and/or 110 diastolic blood pressure **with symptoms** (i.e. chest pain, shortness of breath, and heart palpitations), the participant will be strongly encouraged to get escorted by EMS officials (911) or a family member to the nearest urgent care or hospital for further examination. The participant will also be encouraged to allow the CHW to make an appointment for treatment either with their own AAPHC primary care physician

or another physician at AAPHC if they do not have a primary care physician. If participant refuses, then s/he will be required to sign a release form.

- If participant has BP greater than 180 systolic and/or 110 diastolic blood pressure **without symptoms**, the participant will be encouraged to allow the CHW to make an appointment for treatment either with their own AAPHC primary care physician or another physician at AAPHC if they do not have a primary care physician.

- **Plan for out of range glucose levels**
  - If participant has an HbA1c greater than 9% without symptoms of excessive thirst and/or urination, the participant will be encouraged to allow the CHW to make an appointment for treatment either with their own AAPHC primary care physician or another physician at AAPHC if they do not have a primary care physician.

  - If participant has a **random glucose** is between 200-400 mg/dL without symptoms of excessive thirst and/or urination, the participant will be encouraged to allow the CHW to make an appointment for treatment either with their own AAPHC primary care physician or another physician at AAPHC if they do not have a primary care physician.

  - If participant has a random glucose greater than 350 mg/dL with symptoms of excessive thirst and/or urination, the participant will be strongly encouraged to get escorted by EMS officials (911) or a family member to the nearest urgent care or hospital for further examination. If participant refuses, then s/he will be required to sign a release form.

  - If participant has **random glucose** less than 70 mg/dL, the participant will be strongly encouraged to drink juice or soda. The participants glucose test will be repeated after 20 minutes. If there is no improvement in the glucose level, participant will be strongly encouraged to get escorted by EMS officials (911) or a family member to the nearest urgent care or hospital for further examination. If participant refuses, then s/he will be required to sign a release form. *CHWs will also have glucose gels on hand for immediate assistance.*

  - If participant has a logbook showing **repeated random glucose** levels of 50-70 mg/dL, the participant will be encouraged to allow the CHW to make an appointment for treatment either with their own AAPHC primary care physician or another physician at AAPHC, if they do not have a primary care physician.

*****For anything out of the ordinary, reach out to AAPHC Primary Healthcare Clinic Lead Nurse, DON, ADON*****

25. Post-Intervention Interview

Unstructured Interviews: 8-10 study participants that have completed the intervention will be invited to participate in a post-intervention interview. Invitations to complete the post-intervention interviews will be sent out when the study reaches participant completion milestones of 25, 50, 75, 100. During these interviews we will ask about their experience during the weekly home visits, health education provided about diabetes management, referral to services, their thoughts on the incentives given during the program, and their thoughts on the community health workers implementing the intervention. Interviews will occur either over the telephone or via zoom and will last about 30-60 minutes.

26. Medical Release Form

Refusal of Emergency Treatment or Transport/ Referral

Project PEACH Community Program

Date: _____

This Certifies that I, _____ have refused to seek emergency medical treatment, as advised by the Albany Area Primary Health Care Project PEACH Community Study research team, at a local emergency medical facility or with my primary care physician. I also realize that such refusal may be harmful to my health and welfare.

I hereby release Albany Area Primary Health Care, Morehouse School of Medicine, Emory University, and its *Project PEACH Community* program team from any and all liability caused by my actions at this time.

Reason for referral _____

_____

_____

Participants Name (Printed)_____

Signature of Participant_____ **Date**_____

Responsible Party Signature_____ **Date**_____
(In the event Participant is not coherent)

Witness Name (Printed) _____ **Date**_____

Signature of Witness _____

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