

Research Study Protocol

Protocol Title: Alive Church Network: Increasing COVID-19 Testing in Chicago's African American Testing Deserts

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OBJECTIVE

This study takes a population-based approach which aims to increase uptake of COVID-19 testing within a highly segregated and underserved African American (AA) community in Chicago. The proposed project utilizes the Alive Church Network (ACN) infrastructure to create a network of church-based testing sites in our target area that will provide COVID-19 testing and education as well as linkage to healthcare and social resources. Pastors who serve predominantly AA congregations on the South Side of Chicago will form a coalition to promote community-wide COVID-19 testing in local churches. Residents of all ages will receive COVID-19 education and free SARS-CoV-2 PCR testing with rapid turn-around of results from an on-site clinical team, as well as connection to local resources to address social needs, including food, housing, and medical care. Our church network will also provide infrastructure for scientists to conduct future studies related to COVID-19 and other diseases that disproportionately impact AAs.

Our team plans to perform 10,000 SARS-CoV-2 PCR tests within 31 weeks at churches located in testing deserts in South Side neighborhoods. A clinical team comprising registered nurses and community health workers will be deployed to the sites and will perform tests in designated areas of the churches that meet CDPH community-based testing standards. Testing will be available up to five days per week. To maximize efficiency of testing, residents will be encouraged to call ahead and schedule a test, however we will also provide testing to walk-ins. In addition to scheduled testing in churches, testing will be also be performed at church-based events where residents are congregating, such as Sunday church services, food pantries, and other gatherings. In order to increase testing in children, testing will be performed at youth activities such as camps and sports league practices and games. Covid-19 home tests will also be distributed at churches, church-based events and youth activities to provide a convenient at home testing option for residents. Residents will be provided with at home tests for their own use and to distribute to others in their social network. During the testing process, study staff will educate participants about COVID-19, including providing advice about infection control and guidelines for what to do in the event of a positive test result.

BACKGROUND/RATIONALE

The epidemic of novel coronavirus disease 2019 (COVID-19) has caused an unprecedented public health crisis in the United States. African Americans (AA) have been disproportionately impacted, as systemic inequities have contributed to increased exposure and vulnerability to COVID-19. Evidence suggests that AAs are delaying testing and care for COVID-19, which increases risk of transmission and poor outcomes. In Chicago, segregated AA neighborhoods have experienced some of the highest COVID-19 mortality rates in the city, yet large portions of these neighborhoods remain testing deserts. Providing trusted, accessible, community-based testing in underserved AA communities is critical to ensuring that AAs receive an early diagnosis, thereby reducing the risk of further transmission and improving clinical outcomes. This study leverages the Alive Church Network (ACN), a long-standing, community-driven coalition of African American pastors and public health researchers that was developed as a sustainable infrastructure to address health inequities in chronic disease in segregated AA neighborhoods in Chicago. The ACN COVID-19 testing intervention is to place COVID-19 testing sites in AA churches on the South Side of Chicago.

TESTING INTERVENTION

Study Subjects/Method

Recruitment

Recruitment efforts will be guided by a Pastor Advisory Board (PAB), which will recommend strategies for recruiting and engaging members of their churches and the surrounding communities.

The Pastors will distribute flyers to their church members and potentially use a multi-pronged approach to publicize their Coalition. The communication strategy may include: news releases in community newspapers, local media outlets (radio, TV and editorial) and social media on the church's platforms.

Study Inclusion Criteria

All individuals who request a COVID-19 test will be included in the study, including pregnant women and children of all ages. However, only adults will complete the survey portion of the study. Children will only be eligible to participate in the COVID-19 testing. Individuals who have tested positive for COVID-19 in the prior 3 months will not be eligible for the study.

Registration and Consent Process

For scheduled church testing and church-based event testing, participants will register by phone or in person at the testing site. In both cases, we will perform the informed consent process verbally rather than using written consent forms. For youth testing, written registration and consent forms will be completed by parents prior to testing.

For scheduled church testing and church-based event testing, we will be conducting the consent process in multiple stages. When people register for a test (either in person or on the phone) we tell them basic details about the study and request consent to put their information into Epic. Participants have the option of doing the Covid-19 test and the Resource survey, doing the Covid-19 test only, doing the resource survey only (if they are not eligible for the Covid-19 test), or doing nothing at all and not registering. (see Registration Information sheet in portal section 5.5).

If a parent wants a child to be tested we will read the section of the Registration Information Sheet about children and ask for consent for the child. Children between age 7 and 17 will be read a separate information sheet for their assent when they are onsite, before testing. Children will not complete the survey but will only receive a COVID-19 test. Research staff will document participants' consent and children's assent on a separate document that will be maintained separately from the survey responses. If the participant chooses not to consent they will be provided other locations where they can be tested.

Participants who complete the Resource survey will be given a longer information sheet describing the test and the survey. They are asked to consent at this point for the test and survey. (see Survey information sheet in portal section 5.5.)

Participants who complete the test only and not the resource survey will be given a separate information sheet describing only the test. (see Test only Information sheet in portal section 5.5.)

If the participant chooses not to consent they will be provided other locations where they can be tested.

For youth testing, a written registration form and a written consent form will be given to parents or legal guardians to provide general consent to regular COVID-19 testing for the duration of the camp or sports season for their children. Children will be read a separate information sheet for their assent during the camp or sports activity, before testing.

Survey

Adults will complete a short survey prior to receiving their COVID-19 test. The survey will take approximately 15 minutes. If participants enroll over the phone, they will be sent an email with a link

to the questionnaire in SNAP (HIPPA compliant software). If the participant enrolls on site, they will complete a paper survey or complete the survey on a tablet.

If the participant has already been tested with the ACN, they will not complete the survey if they have already completed it.

If a social need is identified on the study questionnaire, which includes screening for social determinants of health, study staff will phone participants and use NOWPOW database to connect them to resources to address their needs. If the participant has two or more social needs, or housing needs beyond rental assistance they will be referred to a social worker or senior community health worker. If someone needs help finding a PCP or health insurance they are referred to a navigator with that type of expertise.

No participant will be identified individually. Rather, all data will be reported in aggregate and confidentiality will be protected. All participant information will be maintained and kept confidential as required by law.

TESTING PROTOCOL

Once the participant is consented and completes the survey, study staff will register participants in Rush's Electronic Medical Record (EMR) System, Epic, if they are not already registered. Study staff will help participants enroll in the Rush patient portal, MyChart, if they are not already enrolled. Then participants will receive the COVID-19 test.

COVID-19 testing

For scheduled church testing and church-based event testing, security staff of churches, testing site staff and volunteers will assure that visitors to the testing site wear masks and follow social distancing guidelines. Testing staff include a Community Health RN, two Community Health Workers and a research assistant. The RN will oversee clinical operations at the sites. The Community Health Workers (CHWs) will assist the RNs at the sites, including registering participants, consenting, data collection, and distributing educational materials.

Prior to the testing event, labels for specimens for participants who preregistered will be printed at Rush by study personnel. If a person does not preregister, they will be enrolled on site by study. Samples taken from participants who were enrolled onsite will be given a handwritten label. All staff doing on-site SARS-CoV-2 testing will wear proper PPE, including a gown, disposable gloves, an N95 mask, a face shield and goggles.

Participants will be tested via the nasal swab by the CHW. For the nasal swab, the CHW will first brief the patient on what the testing procedure will be and instructions to follow during the exam. In addition, an estimated time period to expect the results will also be explained to participants. The swab will be broken off into a designated test tube. This tube will be placed into a specimen bag along with a label.

For youth testing, a rapid antigen or PCR test will be performed using a nasal swab. The nasal swab will be inserted shallowly into the participant's nose (less than one inch into the nostril). The swab will be broken off into a designated test tube. The tube will be placed into a specimen bag along with a label. Some children, depending on their age, will be allowed to self-collect their COVID-19 nasal swab depending on the manufacturer's instructions. The parent or legal guardian will be allowed to

authorize another guardian (≥ 18 years of age) to assist their child with collecting the self-collected nasal swab on the consent form. A Rush staff member may also assist the child with collection of the self-collected swab.

All specimens will be stored in a cooler until they are transported to the Rush University Medical Center Clinical Microbiology Laboratory, which is accredited by CLIA (CLIA Certificate Number 14D0696069) and by the College of American Pathologists (CAP) (CAP Accreditation Number 1872203). Specimens will be transported to the lab daily.

Communication of Results and Follow-up

Test results will be entered into Epic. If a participant is enrolled in MyChart they will receive an email informing them that their results are available. For participants with negative results, they will receive their results via MyChart and will receive an email or text informing them that their results are available. If the participant does not have access to MyChart they will be informed at the time of testing that if they have not received a phone call within 3 days indicating that their result is positive (see communication procedure for positive participants below) then their result is negative. They will be provided with the toll free phone number for Rush Access to call for their results.

In the case of a positive result, participants will receive a phone call from a nurse or community health worker within 24 hours. The nurse or CHW will provide instructions for how to quarantine and care for themselves during this period, screen the participant for social needs that may influence ability to quarantine safely or access care in the future, collect information about potentially exposed contacts to assure that they are contacted and receive testing, and connect the participant with resources to address identified needs using the NowPow referral platform. In the event the patient has more complicated issues, the CHW will refer the participant to a nurse or social worker for further assistance.

All positive participants will receive a follow-up call from the community health worker at 2 weeks and 4 weeks after the positive test to assist with any initial and emerging concerns they may have, assess COVID-19 symptoms, healthcare utilization due to COVID-19, and connection to referred resources.

At Home Testing Protocol

For at home testing, a distribution tracking form will be completed at the time of registration and will be used to record the name, cell phone number, and email address of the person who will be distributing the test(s). Both the at home test box and tracking sheet will contain an identical label showing the individual test ID numbers for each test distributed to the participant for tracking purposes. The individual distributing the tests will be provided with a test for personal use as well as tests to distribute to others in their social network. The registration and consent process for at home testing will be completed electronically using QR code technology. A QR code will be affixed to each at home test box and will provide access to the study information sheet using the participants smart phone. Participants will provide electronic consent before performing the test.

Participants using the at home tests will also complete a short survey electronically with their smart phone using the QR code. The brief survey will assess basic demographic information, history of Covid-19, and vaccination status and is to be completed before performing the test.

The individuals distributing the at home tests to their social network will receive a \$20 gift card electronically for completing the survey, performing a test, and distributing the tests. They will receive a follow-up text message or phone call after 7 days to assess whether or not they have used and/or

distributed their tests. Individuals who receive a test will be invited to become a test distributor and receive tests to distribute to their social network.

To perform at home testing, participants will download an app to their mobile phone and they will be instructed to watch an informational video. The test is designed for use without the aid of a healthcare professional. The test will be performed by inserting a nasal swab into the nostril until a cap containing the swab touches the nose; rubbing the swab tip around the nose cavity 3 times; removing the swab and repeating in the other nostril. The nasal swab, a dropper, processing fluid, and a blue tooth connected analyzer are provided with the testing kit to analyze the sample for Covid-19.

Covid-19 home test results are displayed on the participants smart phone after 15 minutes. Results are saved within the app and the time and date of the test and test result will be provided to Rush staff by secure download from the product manufacturer.