

Study Title: Community Based COVID-19 Testing Evaluation

Background and Rationale

Racial and ethnic disparities have been observed in the rates of COVID-19 infections and deaths in the US.¹⁻⁸ Black and Hispanic community members are less likely to receive testing than Whites, but more likely to test positive for COVID-19 when they are able to receive a COVID-19 test compared to Whites.⁹⁻¹² Black Americans diagnosed with COVID-19 were 3.57 times more likely to die than their White counterparts, and Hispanics were 1.88 times more likely to die than Whites.¹³

Racial and ethnic disparities have been observed at the state level in Arkansas, where minority communities were disproportionately affected by COVID-19. For example, Black Arkansans accounted for 22% of the total COVID-19 deaths in the state¹⁴, however, only 15.5% of the Arkansas population is Black.¹⁵ Hispanic Arkansans have not had a disproportionate death rate, representing 7% of the total COVID-19 deaths in Arkansas¹⁴ and 8% of the state's population.¹⁵ The Hispanic mortality rate, however, should be interpreted with a degree of caution, as how and when data on race and ethnicity are collected varies by setting and leads to potential misclassification.¹²

One contributing factor to racial and ethnic disparities during the COVID-19 pandemic maybe the accessibility and acceptability of COVID-19 testing. Previous studies found that access to testing has not been equitable across several sociodemographic indicators. Rural areas, lower income areas, and areas with more minority residents have been shown to have lower testing rates.^{11, 16} States such as Texas, North Carolina, and West Virginia have improved accessibility to testing by establishing testing sites in underserved communities, as well as holding testing events in non-traditional locations such as churches, schools, and community centers.¹⁷⁻²² There is limited peer-reviewed research on which COVID-19 testing locations are preferred. A better understanding of testing site preferences could improve testing and reduce delays in receiving a diagnosis. The purpose of this study is to document the preferred testing locations of Arkansans and to examine differences across sociodemographic factors.

Aims

Evaluate access and uptake strategies of several community-driven COVID-19 testing approaches to understand effectiveness and impact for vulnerable populations.

Aim a. Evaluate which testing sites are most effective in reaching specific vulnerable populations based on age, race/ethnicity, and sex.

Aim b. Examine how social determinants of health influence testing behaviors and preferred testing location.

Study Design and Procedures

Title: Community Based COVID-19 Testing Evaluation

This study will implement and evaluate COVID-19 testing approaches across the state. Including UAMS, federal qualified health center, and community based locations.

COVID-19 testing may be promoted through local traditional and nontraditional media channels including: church e-mail lists, community-based organization's websites, local newspapers, radio, and social media. A survey will be administered during testing to examine the effectiveness of these approaches.

Persons with COVID-19 symptoms will be referred to local medical resources based on the medical acuity and severity of symptoms using a protocol developed by the Arkansas Department of Health's Director of Infectious Disease and following CDC recommendations. All participants with negative results will be notified by text, e-mail, phone call, mailed letter, or through their medical records portal based. All written and oral notification will be in participant's language of choice (English, Spanish, Marshallese). All participants with positive results will be notified by phone by a UAMS nurse practitioner or physician with bilingual support if needed. All positive tests will be reported to the Arkansas Department of Health for contact tracing. The Arkansas Department of Health has a dedicated contact-tracing unit with Spanish and Marshallese staff. UAMS also has an enhanced case management protocol that will help connect positive cases with additional social needs to successfully self-quarantine.

The number of people tested at each site will be documented. After a short registration for COVID-19 testing, participants will be asked to participate in the study. Potential participants will be approached by a bilingual worker before or after testing (while they are waiting in line) and will be provided with the opportunity to participate in a short survey that will take less than 10 minutes to complete. The consent will be presented to participants both on paper and electronically in Research Electronic Data Capture suite (REDCap).²³ By completing the survey participants are consenting to participate in the study and allow collection and use of information for the study. This is a minimal risk study and a waiver of consent documentation is being requested. They will have time to read the consent and ask any questions. If the participant prefers, a bilingual research associate will read the consent. All participants will receive a paper version of the consent in their preferred language to take with them. Consent materials will be in English, Spanish, and Marshallese. The consent will include re-contacting the participant for follow-up studies related to COVID-19, allowing data from this study to be linked to other studies about COVID-19 conducted by UAMS, and allowing the study team access to participant medical records for the purpose of this study.

The short survey will collect information about race, ethnicity, household size, COVID-19 testing attitudes test results, COVID-19 vaccine attitudes, food insecurity, English proficiency, health literacy, education, number of children in the household tested at the event under the age of 18, and COVID-19 test advertisements. Surveys will be conducted on iPads using REDCap or participants can access a link to take the survey on their own electronic device. Paper and pen or phone alternatives will also be available. Participants will be handed sterilized iPads with the survey, will be given the link to the survey to take on their own electronic device, can have the survey administered to them by a bilingual research staff, can request a paper survey to complete, or to take it over the phone. Participants that choose to take the survey on paper, a personal device, or over the phone will be asked for their full name and date of birth, so the medical data including demographic information and COVID-19 test results can be linked to

their survey. Participants will be provided a gift bag with an approximate value of \$20 if they participate the survey.

The consent has a HIPAA release and medical record data collected for registration at the testing event will be abstracted for those who participate in the survey. COVID-19 testing results will also be abstracted from the survey participants medical record.

Those who agree to participate in the survey may be randomly selected to take part in an audio recorded interview that will last about one hour. The interviews will be done remotely using tools such as phone and video conferencing. The semi-structured interview guide will ask participants to describe their experience at the COVID-19 testing event, vaccine attitudes and beliefs, impact of COVID-19, and food insecurity. All participants who participate in an interview will be issued a \$40 Wal-Mart gift card.

Community members, stakeholders, and COVID-19 testing staff will also be invited to participate in a semi-structured qualitative interview for process improvement of COVID-19 testing events. All community members, stakeholders, and COVID-19 testing staff who participate in an interview will be issued a \$40 Wal-Mart gift card.

People will not be denied a COVID-19 test even if they choose not to participate in the study.

Study Population

All persons who come to the testing location for a COVID-19 test will be offered the opportunity to participate in the survey, but they will be offered a COVID-19 test even if they choose not to participate in the survey. We anticipate recruiting 3,000 to participate in the survey.

Inclusion Criteria

- 18 years or older
- Participation in COVID-19 testing
- Speak English, Spanish, or Marshallese

Exclusion Criteria

- Under 18 years of age
- Unable to participate in English, Marshallese, or Spanish

Risks and Benefits

A risk to study participants is the potential for loss of confidentiality of study data. Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

There will be no direct benefits to the study participants; however, knowledge gained from the study could potentially benefit patients in the future.

Data Handling and Recordkeeping

The principal investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material will be assigned a unique identifying code or number. The key to the code will be kept in a locked file cabinet in a locked file room in the Office of Community Health and Research. Only the principal investigator and the study coordinator will have access to the code and information that identifies the subject in this study. All study related electronic records, including audio recorded qualitative interviews, will be stored on a secure UAMS server. At the conclusion of the study, the data will be permanently de-identified and the key code will be destroyed.

The study will comply with UAMS Admin Guide Policy 3.2.01 – research data, reports and analyses be retained for seven years after final reporting or publication of a project, or longer if required by a sponsor or regulation.

Data Analysis

In preliminary analyses, we will examine descriptive statistics and distributional forms for each variable and identify issues with missing or out-of-range values. Missing data should be minimized through research design (e.g., use of REDcap to collect data), but if there are issues with missing data we will use a multiple imputation approach with sensitivity analyses comparing results from complete case analysis to those from the multiply imputed data sets.

Aim a. To examine whether one type of testing site is better for reaching participants in vulnerable populations, we will compare participants' age, race/ethnicity, and sex across the two types of testing sites. Initially we will use χ^2 tests to examine the bivariate association between these three factors and type of testing site. We will then conduct logistic regression analyses with type of testing sites as the binary response variable and age, race/ethnicity, and sex as predictors.

Aim b. To examine whether participant social determinants of health are associated with type of testing site, we will first use χ^2 tests or independent samples t-test (based on distribution of response variable) to examine the bivariate association between these social determinants and type of testing site. We will then conduct logistic regression analyses with type of testing site as the binary response variable with the social determinants of health variables as predictors. Demographic variables of age, race/ethnicity, and sex will then be added as covariates.

Qualitative analysis will be completed using established processes for achieving reliability.²⁴ Interviews will be transcribed verbatim. Transcript summaries will be analyzed using thematic coding, with both a priori and emergent themes.^{25, 26} Coding will occur in an iterative fashion, expanding and refining the templates as needed. Data will be uploaded and analyzed in MAXQDA qualitative coding software.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

The survey instrument will include an introductory paragraph explaining the study and indicating that by completing the survey they are consenting to participate in the study and allow collection and use of information for the study. This is a minimal risk study and a waiver of documentation of consent is requested. The research involves no more than minimal risk to the subjects and the research involves no procedures for which written consent is normally required outside of the research context.

Dissemination of Data

Results of this study may be used for academic or community presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant. Aggregated results may be returned to participants in an infographic.

References

1. Price-Haywood EG, Burton J, Fort D, Seoane L. Hospitalization and Mortality among Black Patients and White Patients with COVID-19. *The New England Journal of Medicine*. 2020;382:2534-2543.
2. Kim SJ, Bostwick W. Social Vulnerability and Racial Inequality in COVID-19 Deaths in Chicago. *Health Education & Behavior*. 2020;47(4):509-513. doi:10.1177/1090198120929677
3. Wadhera RK, Wadhera P, Gaba P, et al. Variation in COVID-19 Hospitalizations and Deaths Across New York City Boroughs. *JAMA*. 2020;323(21):2192-2195. doi:10.1001/jama.2020.7197
4. Rentsch CT, Kidwai-Khan F, Tate JP, et al. Patterns of COVID-19 testing and mortality by race and ethnicity among United States veterans: A nationwide cohort study. *PLOS Medicine*. 2020;17(9):e1003379. doi:10.1371/journal.pmed.1003379
5. Selden TM, Berdahl TA. COVID-19 And Racial/Ethnic Disparities In Health Risk, Employment, And Household Composition: Study examines potential explanations for racial-ethnic disparities in COVID-19 hospitalizations and mortality. *Health Affairs*. 2020;39(9):1624-1632.
6. Rogers TN, Rogers CR, VanSant-Webb E, Gu LY, Yan B, Qeadan F. Racial Disparities in COVID-19 Mortality Among Essential Workers in the United States. *World medical & health policy*. 2020;12(3):311-327.
7. Garg S. Hospitalization rates and characteristics of patients hospitalized with laboratory-confirmed coronavirus disease 2019—COVID-NET, 14 States, March 1–30, 2020. *MMWR Morbidity and mortality weekly report*. 2020;69
8. Moore JT, Ricaldi JN, Rose CE, et al. Disparities in Incidence of COVID-19 Among Underrepresented Racial/Ethnic Groups in Counties Identified as Hotspots During June 5–18, 2020—22 States, February–June 2020. *Morbidity and Mortality Weekly Report*. 2020;69(33):1122.
9. Vahidy FS, Drews AL, Masud FN, et al. Characteristics and Outcomes of COVID-19 Patients During Initial Peak and Resurgence in the Houston Metropolitan Area. *JAMA*. 2020;324(10):998-1000. doi:10.1001/jama.2020.15301
10. Moore JT, Ricaldi JN, Rose CE, et al. Disparities in Incidence of COVID-19 Among Underrepresented Racial/Ethnic Groups in Counties Identified as Hotspots During June 5-18, 2020 - 22 States, February-June 2020. *MMWR Morbidity and mortality weekly report*. 2020;69(33):1122-1126. doi:10.15585/mmwr.mm6933e1
11. Lieberman-Cribbin W, Tuminello S, Flores RM, Taioli E. Disparities in COVID-19 Testing and Positivity in New York City. *American Journal of Preventive Medicine*. 2020;59(3):326-332. doi:10.1016/j.amepre.2020.06.005
12. Holtgrave DR, Barranco MA, Tesoriero JM, Blog DS, Rosenberg ES. Assessing racial and ethnic disparities using a COVID-19 outcomes continuum for New York State. *Annals of Epidemiology*. 2020/08/01/ 2020;48:9-14. doi:<https://doi.org/10.1016/j.annepidem.2020.06.010>
13. Gross CP, Essien UR, Pasha S, Gross JR, Wang S-y, Nunez-Smith M. Racial and Ethnic Disparities in Population Level Covid-19 Mortality. *medRxiv*. 2020:2020.05.07.20094250. doi:10.1101/2020.05.07.20094250
14. Arkansas Department of Health. *COVID-19 Update September 21, 2020*. 2020:1-6.
15. United States Census Bureau. American Community Service Demographic and Housing Estimates. <https://data.census.gov/cedsci/table?q=arkansas&tid=ACSDP1Y2019.DP05>
16. Souch JM, Cossman JS. A Commentary on Rural-Urban Disparities in COVID-19 Testing Rates per 100,000 and Risk Factors. *The Journal of Rural Health*. 2020;

17. McMinn S, Carlsen A, Jaspers B, Talbot R, Adeline S. In Large Texas Cities, Access to Coronavirus Testing May Depend on Where You Live. *Shots*. National Public Radio; 2020. <https://www.npr.org/sections/health-shots/2020/05/27/862215848/across-texas-black-and-hispanic-neighborhoods-have-fewer-coronavirus-testing-sit>
18. Price J. With Expanded COVID-19 Testing, NC Aims to Reach Minority Communities. *North Carolina Public Radio*. North Carolina Public Radio; 2020. <https://www.wunc.org/post/expanded-covid-19-testing-nc-aims-reach-minority-communities>
19. West Virginia Department of Health and Human Resources. Testing Opportunities for Minorities and Other Vulnerable Populations. 2020. <https://dhhr.wv.gov/News/2020/Pages/Testing-Opportunities-for-Minorities-and-Other-Vulnerable-Populations.aspx>
20. Tribune News Service. Undetected: Lack of access to testing among minorities keeps virus alive. *Health*. Tampa Bay Times; 2020. <https://www.tampabay.com/news/health/2020/05/10/undetected-lack-of-access-to-testing-among-minorities-keeps-virus-alive/>
21. New locations announced for mobile and walk-up COVID-19 testing. City of San Antonio; 2020. <https://www.sanantonio.gov/gpa/News/ArtMID/24373/ArticleID/18893/New-locations-announced-for-mobile-and-walk-up-COVID-19-testing>
22. Nikiforova B. Meet Communities Where They Are: COVID-19 Testing for Vulnerable Populations. Network for Regional Healthcare Improvement; 2020. <https://www.nrhi.org/covid-19-off-site-testing-project/testing-for-vulnerable-populations/>
23. Harris P, Taylor R, Thielke R, Payne J, Gonzalez N, Conde J. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-81. doi:10.1016/j.jbi.2008.08.010
24. Campbell J, Quicy C, Osserman J, Pederson O. Coding in-depth semistructured interviews: Problems of unitization and intercoder reliability and agreement. *Sociological Methods and Research*. 2013;42(3):294-320.
25. King N, Cassell C, Symon G. Using templates in the thematic analysis of text. In: Cassell C, Symon G, eds. *Essential guide to qualitative methods in organizational research*. Sage Publications; 2004.
26. Crabtree B, Miller W. A Template Approach to Text Analysis: Developing and Using Codebooks. In: Miller B, Miller W, eds. *Doing Qualitative Research*. SAGE; 1992.