

Study Title: Impact of COVID-19 on Marshallese Communities in the U.S.

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Background and Rationale

While there is much we do not know about the differential effects of COVID-19, early data shows that minority communities are disproportionately effected by the virus.¹⁻⁴ There are many factors that may increase the likelihood of contracting COVID-19 including: 1) community spread because of lack of access to testing in low-income communities, 2) work environments that may increase exposure, 3) more densely populated housing that reduces the ability to social distance, 4) limited understanding of preventive measures due to literacy and language barriers, 5) constrained financial resources to stay home and not work, and/or 6) lack of trust in the health care system. The Marshallese are a Pacific Islander population experiencing significant health disparities with some of the highest documented rates of type 2 diabetes mellitus (T2DM) of any population in the world.⁵⁻⁷ Estimated type 2 diabetes rates among Marshallese in the United States range from 25%-50%, 400% higher than the general US population.^{5,8} People with diabetes are more likely to experience severe symptoms and complications when infected with COVID-19; however, those that manage their diabetes well are less likely to become extremely ill from the virus.⁹ In order to reduce the disparities caused by COVID-19 and ultimately compare the effectiveness of prevention interventions among the low-income minority communities most effected by COVID-19, it is critical to understand minority populations': 1) risk exposure, 2) knowledge of preventive recommendations, 3) barriers and facilitators to implementing preventative recommendations, 4) barriers and facilitators to COVID-19 testing when appropriate, and self-care behaviors during COVID-19.

Specific Aims

Aim 1: Document COVID-19 risk exposure for Marshallese community members.

Aim 2: Document Marshallese community members' knowledge of preventive recommendations.

Aim 3: Document barriers and facilitators to implementing preventative recommendations.

Aim 4: Document Marshallese community members' barriers and facilitators to COVID-19 testing when appropriate.

Aim 5: Document self-care behaviors during COVID-19.

Aim 6: Explore COVID-19 pandemic related barriers and facilitators to diabetes self-management among Marshallese adults with T2DM.

Aim 7: Assess the effect of the COVID-19 pandemic on diabetes self-management activities among Marshallese adults with T2DM.

Study Design and Procedures

Up to 2000 Marshallese will complete an online or telephone survey. Up to 100 participants will be invited to complete an in-depth qualitative interview.

The study will be advertised by posting an informational flyer on social media. The flyer will contain a link to the study information sheet and survey documents. Study team members will also reach out to study participants via phone or electronic mediums (e.g. email, text, or messenger). Study staff will send potential participants a link to an electronic survey using REDcap.¹⁰ The REDcap system will include electronic documentation of consent prior to completing the survey. Participants electing to access the survey through a telephone interview rather than the online process will be read the study information sheet before the survey instrument is completed. For those randomly selected to complete an in-depth qualitative interview, study team members will recruit them via phone or electronic mediums (e.g. email, text, or messenger) and schedule the interview by phone or secure web connection such as

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ZOOM, Skype, or Facebook.

Study Population

We will recruit up to 2000 Marshallese participants for the study. As part of UAMS IRB study #207034, the study team has recruited 386 Marshallese participants.¹¹ 378 of these participants have consented to be contacted for future studies. Additional Marshallese participants will be recruited through our engagement network if needed to rapidly reach recruitment goals.

Community based recruitment will be achieved by posting the survey information on websites and Facebook.

Participant inclusion criteria:

- 1) Self-reported Marshallese
- 2) 18 years of age or older
- 3) Live in the Continental U.S. or Hawaii

Measures/outcomes

Using a mixed-methods concurrent triangulation design,¹²⁻¹⁸ the study team will utilize a survey and interview guide. Our survey and interview will be based on CDC risk assessments^{19,20} and utilize the NIH funded COVID-19 items that are part of the PhenX Toolkit.²¹ See survey attached. Those participants with T2DM will be asked to complete questions pertaining to diabetes management during COVID-19.

Potential risks to study participants are minimal and no greater than usual care or standard health screenings. There is a potential risk for loss of confidentiality. Measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section. The alternative to participating in the interventions is to not participate in the interventions. Further, any participant can choose to leave the study at any time.

Remuneration: Each participant who completes the survey will receive a \$20 Walmart gift card for remuneration and each person who completes the qualitative interview will receive an additional \$40 Walmart gift card in remuneration. Participants will only receive gift cards for the part of the study they complete.

Protections against risk. All data collectors involved in the interventions will have received training on: participant consent procedures, the study protocol, human subjects protection, HIPAA regulations, survey administration, maintaining confidentiality of study participants, mandatory reporting, and appropriate treatment of participant data. Access to study data will be limited to only those personnel who need it to complete relevant job duties. All data, regardless of whether it is identifiable or not, will be stored in a locked file cabinet in a locked room, or on a secure UAMS server that requires two-factor authentication.

Potential Benefits of the Proposed Research to Human Subjects and Others

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

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Data Capture

The survey will be captured through REDcap¹⁰ or telephone interview and will take approximately 30 minutes to complete. Qualitative interviews will be conducted by phone or secure web connection such as ZOOM, Skype, or Facebook. A semi-structured interview guide will be used to ensure consistency across the interviews. The interview guide will also allow participants to discuss in their own words their lived experiences related to COVID-19. Each interview will have an anticipated duration of one hour. Qualitative data from interviews will be audio recorded, transcribed, and translated verbatim.

Data Handling and Recordkeeping

The Principal Investigator and study team will carefully monitor study procedures to protect the safety of research subjects, the quality of the data, and the integrity of the study. Access to study data will be limited to only those personnel who need it to complete relevant job duties and who have completed all required trainings for study activities and in maintaining confidentiality. Participant identification numbers will be used to track study forms. All records will be retained consistent with the UAMS Administrative Guide (seven years after final reporting or publication of a project).

Data Analysis

In a mixed-method concurrent triangulation design, study data is analyzed separately and then combined during the interpretation phase.¹²⁻¹⁸ This method will allow us to cross-validate and confirm study findings to provide a more complete illumination of the research question. The mixed-method concurrent triangulation design will allow us to overcome the inherent weaknesses of using qualitative or quantitative methods separately. Quantitative data analysis of the survey results will include descriptive as well as inferential statistical techniques, including correlation, *t*-tests, and non-parametric tests. Given the descriptive nature of the study aims, the analytic strategy will focus on presenting results of item-level descriptive analyses, with an emphasis on frequencies and proportions. Inferential analyses will focus on comparing groups of respondents who may be expected to have differences in risk exposure, knowledge, barriers and facilitators from one another (e.g., comparisons between respondents with different education and/or income levels, English proficiency, job sectors). For inferential analyses, alpha will be set at .05 two-tailed, and effect size indicators will be included.

For each descriptive and inferential analysis, each respondent's data will be included if she or he responded to the relevant items, regardless of the amount of missing data for that respondent on other items. However, there will be no attempt to impute missing responses for any items. For each analysis, the number of included responses will be reported.

Researchers with qualitative research experience will code the text of the open-ended questions for emergent themes. In order to rapidly assess the large number of open-ended responses, a coding template is the most appropriate and effective strategy to analyze the text.^{22,23} The initial coding template will categorize responses based on the *a priori* themes. As the data is coded, emergent themes will be identified and incorporated into the template. The data will then be extracted from the open-ended responses and incorporated into the codebook in order to provide illustrative excerpts from the responses for each theme or domain they best represent.

Confirmation coders will then review the data. Finally, the study team will confirm that the data and illustrative excerpts are applied to the correct domain by critically reviewing each analytic

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product to ensure rigor and reliability. Any discrepancies in interpretation will be discussed and resolved via consensus of the three coders.

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).

Study team members will share the recruitment flyer on social media and also reach out to potential participants via phone or electronic mediums. Those potential participants who express interest in taking part in the study will be sent a link to an electronic survey using REDcap.¹⁰ The REDcap system will include written information about the study prior to completing the survey. Participants electing to access the survey through a telephone interview rather than the online process will be read the study information sheet before the survey instrument is completed. For those randomly selected to complete an in-depth interview, study team members will recruit them via phone or electronic mediums (e.g. email, text, or messenger). Prior to collecting qualitative data, the study information sheet will be provided again prior to data collection.

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 presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant. The study will be listed on clinicaltrials.gov in accordance with (funder and/or journal) requirements. Aggregated results may be returned to participants in an infographic that is provided by e-mail to the participants if we have their email address. We will also work with stakeholders to disseminated aggregated information in town hall meetings.

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