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Acceptability and feasibility of a community based participatory research project comparing cytology and urine HPV DNA testing for cervical cancer screening in Yap, Federated States of Micronesia

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Abstract

Non-invasive, self-collected sampling methods for HPV DNA detection in women, which are reliable, efficient, and acceptable have the potential to address barriers to cervical cancer screening in underserved communities, including low-middle income countries (LMIC) such as the island nation of the Federated States of Micronesia (FSM). Urine-based HPV testing has not been rigorously evaluated in clinical trials. A pilot community-based participatory randomized control research project evaluated use of urine HPV testing as a more culturally- and human resource appropriate method of cervical cancer screening in Yap State, FSM. Women participated in a cervical screening intervention using pap vs. urine test (N = 217). This manuscript described attitudes about screening feasibility and preferences. Stakeholders and women participants were interviewed (N = 23), and a survey also evaluated women's screening preferences (N = 217). Qualitative content thematic analysis with multiple coders identified themes from interviews on acceptability and feasibility of screening tests. Women research participants were comfortable with the urine test (95%), despite limitations in some to provide samples. While 82.0% indicated that they felt comfortable with Pap smear, they also preferred a clinician (42%) to do the Pap

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Conflict of interest

The authors declare they have no conflict of interest.

Author contributions

A.U. Sy contributed to the qualitative research instrument development, collected qualitative data, led analysis and interpretation of the data, drafted and revised manuscript content, and approved the final version.

B.Y. Hernandez led the study design, analyzed quantitative data, and revised manuscript content.

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smear, explaining that they preferred having a trained worker instead of themselves to do tests. Women want to be screened but accessibility remains a challenge. Education and training of professionals and community members alike will improve clinical skills, research capacity, knowledge of screening tests and behaviors including prioritizing HPV screening and testing.

Keywords

Human papillomavirus; Cancer screening; Early detection of cancer; Female; Pacific Islands; Papillomavirus infections; Prevention and control; Community based participatory research; Translational research

1. Introduction

1.1. Cervical cancer research in Federated States of Micronesia

Globally, cervical cancer is the third most common cancer in females and the second most frequent cause of cancer death, with the majority of cases, including a large proportion of late stage cancers, occurring in low-resource settings [1]. Cultural, social and geographic barriers impact access to cervical cancer screening in resource limited countries [2]. Human papillomavirus infection (HPV), primarily oncogenic types HPV 16 and 18, is the principal cause of nearly all cervical cancers [1]. Along with prophylactic vaccinations for HPV, screening remains an important component of cervical cancer prevention strategies. HPV DNA testing has proven to be an important adjunct to cervical cytology (Pap) screening for the early detection of precancerous lesions [3]. Recent studies have demonstrated that HPV DNA testing has higher sensitivity than Pap smear testing [4,5]. In March 2014, the U.S. Food and Drug Administration advisory panel recommended that HPV DNA testing could serve as the primary tool for cervical cancer screening.

The Federated States of Micronesia (FSM) is comprised of 607 volcanic islands and atolls scattered over 1 million square miles of the Northwestern Pacific Ocean. The land area totals 704.6 square kilometers, with 7192 square kilometers of lagoon area. The FSM consists of four geographically separate states: Chuuk, Kosrae, Pohnpei, and Yap [6]. FSM is one of the most resource-limited US Affiliated Pacific Island (USAPI) jurisdictions, suffers large cancer health disparities, but also has some of the strongest community-public health partnerships in the USAPI [7].

Micronesian women disproportionately suffer from cancer disparities having among the highest rates of cervical cancer in the world including women in Yap State. Yap has an age-adjusted cervical cancer incidence rate of 20.4 per 100,000 (2007–2012) which is twice the incidence rate in the US. Only 28% were diagnosed at Stage 1. Seventy percent of the women diagnosed in 2007 or later have died [8]. Funding limitations presently allow 4–10% of women to receive cervical cancer screening per year by traditional cytology or using visual inspection with acetic acid (VIA) in accordance with the 2010 FSM National Standards on Breast and Cervical Cancer Screening [9].

Yap State has demonstrated ability to mobilize women from the main and outer islands to tailor cervical cancer education materials, build local capacity for and provide screening, and

has been expanding their local capacity for rigorous evaluation of public health programs and policies as part of their partnership with Center for Disease Control and Prevention (CDC) sponsored program with the University of Hawai‘i (UH). Although resource limited, Yap has capacity for appropriate follow-up and treatment of abnormal Pap or VIA and can treat Stage 1 cervical cancers on island. Yap State has a well-organized Wa'ab Community Health Center network that provides most primary care services on the main island and has outer island health assistants trained to provide cervical cancer screening. Annually since 2008, the Yap Cancer Program has been able to recruitin just one week over 200 women from the outer islands and main island for Women's Health Week cervical cancer screening.

Non-invasive, self-collected sampling methods for HPV DNA detection in women, which are reliable, efficient, and acceptable have the potential to address current barriers to cervical cancer screening in underserved communities, including low middle income countries (LMIC) such as the FSM. Hernandez et al. demonstrated that – self-collection for detection of penile HPV was preferable to clinician-collection among U.S. males [10]. CDC-funded projects in the USAPI have shown high preference for alternatives to traditional cytology based screening [11]. Nonetheless, urine based HPV testing has not been rigorously evaluated in clinical trials. The primary objective of this pilot study was to determine the acceptability and feasibility of culturally- and health workforce-appropriate cervical cancer screening methods, recently published American College of Obstetricians and Gynecologists Committee Opinion 624 [12].

1.2. Community based participatory research

A secondary objective of this pilot study was to examine the community based participatory research (CBPR) used in the study, how this approach contributed to study completion and fidelity, and the extent HPV screening tests are feasible and preferred. CBPR is an approach in health promotion research that especially addresses health disparities through the engagement and partnership of researchers and community members in all phases of the research [13]. This collaboration has the potential to be transformative for all those involved wherein partners (e.g. researchers, community residents and service providers) participate in multiple aspects of research, from determining goals to developing methods and procedures to disseminating results [14].

Pinto et al., developed and described the International Participatory Research Framework (IPRF) to advance CBPR. The IPRF presents steps and actions to improve the abilities of researchers and practitioners worldwide to systematize the development of research partnerships and which can facilitate participatory research in myriad international settings. The CBPR literature lacks specificity regarding how to initiate, employ and sustain participation when working with partners internationally in developing countries [14]. The IPRF serves as a relevant CBPR project framework because the IPRF describes the international participatory processes that the collaborative team demonstrated, contextualized to the host country, Yap State, FSM.

2. Materials and methods

2.1. Study design

Women undergoing Pap smear screening in Yap State in the FSM were randomly assigned to one of two arms: (1) urine collection followed by clinician cervical sampling; or (2) clinician cervical sampling followed by urine collection. Measures included patient- and provider acceptability of the sample collection procedures and qualitative data collection to gauge readiness for scale-up of HPV DNA testing as the primary screening method as well as participation in formal cancer research.

CBPR was included in this study to tailor the randomized control trial methodology to be more feasible and meaningful to the communities and researchers. Pinto et al's IPRF comprises four recursive steps: (i) contextualizing the host country; (ii) identifying collaborators in the host country; (iii) seeking advice and endorsement from gatekeepers, and (iv) matching partners' expertise, needs and interests [14]. Using this CBPR framework, these steps were operationalized in the current HPV CBPR trial. This manuscript reports on the CBPR methods and results to ultimately address the acceptability and feasibility of cervical vs. urine sample for study participants and project stakeholders (Results of the urine versus pap detection of HPV are reported elsewhere.)

Collaborations between the academic researchers and Yap spanning a decade has provided best practices on successful collaborations involving community feedback and shared decision making used in this project. CBPR was operationalized through a project steering committee (SC) in Yap [15] that included members integrally involved in improving cervical cancer screening and who have a 10-year history of engagement with the academic collaborators. Members of the Yap SC developed the pilot project proposal with the project investigators. Monthly calls and frequent reporting were conducted to evaluate the project's process, progress, intended and unintended impact on the health system in Yap, and any needed changes were discussed and addressed. The Yap SC contributed to all project activities including dissemination. Research protocols and materials were approved by the Western Institutional Review Board.

2.2. Recruitment and randomization

The SC and outreach staff recruited 217 Yapese women and as many outer island women as feasible. Eligible subjects were women aged 21–65, who had not had a hysterectomy and were not currently pregnant, and who had not had cervical cancer screening within the past three years or who had had abnormal screening results within the past three years. –This population was targeted in order to yield higher numbers of HPV DNA+ women than would be derived from a previously screened population. Additionally, targeting these women provided tremendous benefit to Yap and appropriately directed resources toward the population at highest risk for cervical cancer.

Trained staff met with potential study participants, obtained written informed consent and ensured completion of the exit survey after specimen collection was completed. Study subjects were randomized into cervical cell or urine collection groups. Upon conclusion of

the study visit, subjects were provided with an incentive worth approximately $15 (i.e., project logo-printed multi-purpose bag).

Cervical cell specimens were collected by a trained clinician using liquid based cytology (ThinPrep). Up to 30 mL of first catch urine specimens were collected by the participant in the restroom using a labeled sterile collection cup. Specimens were stored in the clinic refrigerators then transported daily to the hospital lab where they were refrigerated until shipment. Samples were batched and shipped to the UH.

2.3. Data sources and collection

Data on the acceptability of cervical cancer screening methods were derived from a self-administered or staff administered survey, focus groups and key informant interviews. The survey was distributed to the participants to complete after specimen collection, where staff verbally translated where needed. Questions included basic demographic and social characteristics, prior cervical cancer screening and HPV vaccine history, and acceptability issues-including preference of urine versus clinician collection.

A qualitative researcher who has also worked with Yap SC members on cancer and chronic disease projects conducted on site key in person informant interviews (KII) and focus groups discussion (FGD) at the end of the study. These data sources would provide descriptive data about the method of cervical cancer screening, feedback on the project itself, and issues affecting sustainability. The SC recruited women research participants, providers and public health staff. Three sessions were conducted: One FGD with eight cervical cancer screeners, individual one-on-one KIIs with nine steering committee members and other stakeholders, and one FGD with six women from the community who were research participants.

The FGDs and KIIs were guided by semi-structured questions developed and pilot tested by the project team. The questions for the cervical cancer screeners and SC members contained ten items and other stakeholder interview questions contained nine items. Questions were similar and covered the extent participants were trained and prepared for their roles, lessons learned about the process and research, suggestions to make cervical cancer screening available in Yap, and research participation interests.

The project coordinator and research assistant served as translators when needed for KIIs and FGDs during the women research participant focus group. The qualitative researcher facilitated all sessions using the FGD and KII guides, asking probing questions when needed. All sessions were audio recorded. The qualitative researcher and project coordinator served as note takers for both of the FGDs thus producing two sets of notes for these sessions. One set of nine notes, corresponding to each KII was produced. The notes comprised the datasets for the qualitative content thematic analysis. Each focus group lasted approximately one hour and stakeholder interviews ranged from 15 to 30 min.

2.4. Data analysis

Descriptive statistics were used to analyze the survey and demographic data.

Notes form the audio recordings of the FGDs and KII were transcribed using key phrases and not verbatim because responses were straightforward and used to inform the program. However informative quotes were transcribed verbatim in the notes.

A thematic content analysis was conducted with transcripts for each dataset, i.e., cervical cancer screener FGD, SC member KIIs, and women research participant FGD, and thematic codes were developed inductively by each question response. For example, for the steering committing KII question: *Although there are still a few more women needed to get to the required 200, are there any lessons that you've learned so far*? Responses covered themes related to "organization and paperwork," "infrastructure," and "new techniques," as examples. Themes were identified inductively because the qualitative researcher was not a clinician or clinical researcher. Codebooks that contained thematic codes for each question, description of the code, and examples were developed for each of the data sets.

Once the set of thematic codes were developed into the codebook, two Hawaii based coders with varying backgrounds on HPV topics and community culture were trained on coding the transcripts, using coding forms. Because both FGDs, i.e., cervical cancer screeners and women research participants, had two sets of notes, each set was also coded by each coder. The qualitative researcher reviewed the coding results from the two coders by examining agreement in codes. Where there was disagreement, the qualitative researcher reviewed the transcript passage, and decided on the thematic code.

3. Results

3.1. Women research participant survey

Surveys were completed by all 217 – research participants. The age distribution of participants were as follows: – 20–29: 17.1%, 30–39: 30.4%, 40–49: 29.9%, 50+: 23.5%. Over seventy eight percent were residing on the main island of Yap during the time of screening. A history of Pap smear screening was reported by 39.6% of participants and 59.5% reported prior screening by either Pap smear and/or visual inspection with acetic acid (VIA).

Ninety five percent and 82.0% of women indicated that they felt comfortable with urine and pap smear collection, respectively. The most common reason for discomfort with the pap smear was that participants were scared though only 8.8% indicated this reason for feeling uncomfortable. The most popular screening test was having a doctor or nurse do the pap smear (44.2%), and the second popular test was providing their own urine sample (38.3%).

3.2. Cervical cancer screeners and steering committee members

Key themes discussed by the SC members and cervical cancer screeners are presented in Tables 1 and 2. Overall the themes discussed by the SC members and cervical cancer screeners corroborated.

3.2.1. Project preparation—Cervical cancer screeners and steering committee members indicated that they felt prepared for the project, though in different ways. SC members described that the discussions and meetings on the project were helpful and that the set

schedule made the implementation easy and convenient. Screeners commented that they had equipment and supplies readily available

> "The system was prepared for the project." [cervical cancer screener}

> "Management went well. Communicative team, good team. UH is very clear with what it wants. Then set the tone. What needs to be done, who needs to be involved, constant communication. We never got together internally. Conference call was main way to communicate. Then had subgroups through emails. Everyone copied on emails." [SC member]

3.2.2. Challenges—Challenges to the project for both groups were regarding urine collection. For screeners, challenges also included the resources and procedures and required to conduct, store, and transportation involved with the pap test.

> "We have lights, gooseneck lamps here [on Main], but in Outer Islands, we had a hard time because room was hot during the drought, there was no power, the plastic specula were difficult to use. Let's bring metallic ones from main-island next time."

For steering committee members, challenges were that there was additional work, and that it was time consuming given time provided to complete it. "The time was too short for the project. We have own jobs duties."

3.2.3. Training—For all project participants, training in general research and on specific aspects of conducting research was requested. Both groups also wanted training on conducting specific cervical cancer screening procedures.

> "More training so that they are well versed to discuss about the research" [cervical cancer screener]

> "More training on pelvic exams. Right now only doctors do it" [cervical cancer screener]

The screeners and SC members' most common response as to how UH could have better prepared members through the research project was having more time to perform, prepare for and conduct the project. At the same time, many of the SC members in their interviews individually indicated that UH staff prepared them well. "It went very well, had supplies, conference calls."

3.2.4. Future research—The screeners and SC members were willing to participate in future research projects with UH and other universities though some stated that the research needs to truly benefit and impact their community. One benefit that both groups identified is that research can identify ways to address the resource limitations and also bring in resources such as supplies and equipment, and funding. The screeners also indicated that while they would welcome research collaborations, it may require a commitment given all their present responsibilities. This comment was consistent with the SC members' feedback about challenges of time constraints in carrying this project. Research topics that both groups identified to address were d vitamin A deficiency, STIs, and youth health promotion.

"Research would bring more exposure that Yap is doing different things. Others will want to work with us because of our research experience." [SC member]

"Yes if there is likelihood that we'll take it further than just researching us for UH and for others." [SC member]

"Hard to do screening if there are no supplies. Good to study is it necessary or the same" [cervical cancer screener]

3.2.5. Screening availability—Project participants recommended health worker trainings to conduct screenings as a way to make them more widely available to women throughout Yap. The cervical cancer screeners and steering committee members also suggested having more accessible screenings with the screeners recommending having dedicated screening days so that women will expect it and attend. SC members' suggestions were consistent with learning that women are interested in getting screened, and they recommended providing more accessibility to address having screenings more widely available in Yap.

"In Outer Islands—techniques are difficult—Need to have other ways of testing to be easier. We needed equipment—ice pack, no electricity. Accessibility." [SC member]

"Smallness gives good us coverage. Health workers can integrate education on screening as part of their work to talk about screening. Offer a focused time frame. Everyone can participate in a yearly screening event." [cervical cancer screener]

3.3. Women research participant focus group

Results from the women research participant FGD helped to contextualize and explain the quantitative results. Also, comments from women research participants corroborated with the comments from screeners and SC members. Common themes discussed are listed in Table 3. Themes of early detection and prevention, desire to stay health and have quality of life, and wanting to know about their cancer status were brought up for several questions.

"Early detection is better than late for cervical cancer. This cancer has been a problem in Yap because a lot of women have died from it. Late detection won't help"

"I have it yearly. They [other women] don't all take advantage. They're not comfortable with the procedure. It's available. Women need to take charge of own health. They're not aware of what prevention they could have, not educated but if so, they will know risks and motivated to get tested." [research participant]

These comments corroborated with SC members indicating that women in Yap want to get screened but that future screenings need to be more accessible.

Research participants discussed their preferences on having skilled and knowledgeable screeners, corroborating with comments on training needs to be able to conduct screenings. This preference also explains why almost half of the research participants chose having a clinician doing the pap as the preferred method of screening. The most important factor on what type of screening method that the women preferred appeared to be that health

professionals, or in this case screeners, are well trained, even over participants' privacy concerns.

> "I'd rather have the expert do the sampling than me"
>
> "I'd prefer to have someone well-trained, especially to make me feel at ease with such an uncomfortable procedure"

Additionally, since about a third of women research participants preferred the urine test, challenges, e.g., places to provide the sample, participants being able to provide samples, expressed by the cervical cancer screeners regarding collection should be addressed.

4. Discussion

The acceptability and feasibility of any cervical cancer screening initiative requires feedback from all stakeholders involved in implementing an initiative as well as the project participants. As a first ever randomized control trial in Yap on HPV screening, the CBPR approach allowed for timely project completion according to protocols, because, as expressed by SC members, they were involved in the planning of each step. Cervical cancer prevention and detection requires multi-level approaches: training of the health workforce, having services accessible and available for the community, and continuing research to improve the health promotion system. The accessibility and availability of well-trained screeners should be widely communicated and promoted through all channels, i.e., interpersonal such as through friends and family, professional such as through health workers, and community wide media.

Stakeholders' exposure to and participation in this pilot research trial fostered their desire to participate in future research and to consider research's direct benefit on their community. Research and collaborations with universities were welcomed especially because research could address how to overcome resource limitations in providing screenings. Two concerns to be addressed are to ensure that results will benefit and impact the community and that adequate time and personnel are available to conduct the research. Suggested priority research topics are vitamin A deficiency, STIs, and youth health promotion.

5. Conclusions

Wallerstein et al. identified pathways by which CBPR processes result in particular outcomes. Wallerstein et al.'s CBPR conceptual model suggests that if structural and relational partnership processes are effective within their dynamic contexts, then these partnership decisions will have an impact on and change intervention design, and the research [16]. Furthermore prior successful international collaboration steps including those operationalized in this current research project aligned with Pinto et al.'s IPRF [14].

Yap State has a small but strong public health and quality improvement infrastructure along with established collaborations abroad. This contributed to this research project operationalizing CBPR according to existing frameworks and ultimately the timely completion of the first ever research trial in FSM and objectives. At the same time project procedures were acceptable and feasible to professional and community stakeholders.

This research project is the first study using an experimental design comparing self-collected urine and clinician-collected samples for the detection of cervical HPV infection in females in the FSM. These results on acceptability and feasibility of HPV screenings provides valuable information for future research and/or demonstration projects which utilize alternatives to cytology based screening in resource-limited, geographically dispersed island settings like those throughout the Pacific and Caribbean. Because screening methods are acceptable and feasible, future projects have the potential to be sustainable and improve cervical cancer screening across throughout Yap State. Finally these findings and HPV screening acceptability and feasibility may serve as a model to also implement projects throughout the rest of the USAPI. Self-collected urine HPV DNA testing holds promise as a culturally acceptable, less resource-intensive method of detecting risk for cervical dysplasia for underserved populations in the US and internationally.

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Table 1

Cervical Cancer Screeners Themes Discussed.

Thematic Code	Description	Ave # times coded
Which test is better	Project purpose is comparing tests	5.8
Time	Needed More time to prepare and conduct project	4.9
Prepared-general	General feedback that they felt prepared	4.8
Collaborations	Would benefit from or enjoy research collaborations	4.3
Overall prevalence	Abnormal paps, high cervical cancer rates	4.0
Supplies-equipment	Had supplies & equipment	3.5
Dedicated screening	Dedicate a day, time, weekend to do screening, e.g., Women's Health Week	3.3
Specific cervical procedure	Need Trainings on cervical cancer screening procedures	2.5
Collecting urine	Challenges in collecting urine from participants, in Main & Outer Islands	2.0
Specific NCDs	Name NCDs (cardiac, hypertension, diabetes)	2.0
Positive results	How to handle positive results	1.3
Impact	Willing to do research if there is real contribution and purpose	1.3

Table 2

Steering Committee Member Themes Discussed.

Thematic Code	Description	Ave # times coded
General research	Want general training on research	5.5
Resources	In need of money, supplies	5.0
Time-prep	Needed more time to prepare and conduct project	4.0
Other research	Suggested research topics: Vitamin A, deficiency, Rota virus, STIs	3.5
Organization Paperwork	Planning, paperwork, scheduling, coordinating	3.0
Time-duties	Work was time consuming	2.5
New	Research is new in Yap	2.5
Collaborations	Would benefit from or enjoy research collaborations	2.0
Duties-time	Willing for future research but acknowledges time commitment given jot responsibilities	2.0

Table 3

Women Research Participants Themes Discussed.

Well trained	Participants like when they feel that screener is well trained	6.8
Professional screener	Prefer professionals to do screening because they are the experts	5.0
Detection-Prevention	Detection early and prevent cancer *is important*	3.5
Waiting	Being told to wait for results was challenging	3.0
Liked screener	Liked the nurse or screener	2.8
Good instructions	Liked clear instructions on how to provide sample	2.8
Free	Suggest Provide free screenings which is already being done, and other ways to offset costs	2.8
Convenient- free	Get screened Because it's available, convenient, free	2.0