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Integration of Cervical Cancer & Family Planning Services in Mozambique: The MULHER Study

TogetHER Webinar Series November 2, 2023

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TogetHER

MULHER Study in Mozambique

Mila Pontremoli Salcedo, MD, PhD The University of Texas MD Anderson Cancer Center, Houston, USA



No conflict of interest

THE UNIVERSITY OF TEXAS MDAnderson Cancer Center

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Cervical Cancer in Mozambique

- Mozambique has one of the highest burdens of cervical cancer in the world
- Due in part to a lack of access to cervical cancer screening and few medical providers skilled in the treatment of women with pre-invasive cervical disease



Brandao M et al. Eur J Cancer Prev 2019; WHO Globocan 2020

MD ANDERSON CANCER CENTER

Challenges of cervical cancer prevention in Mozambique

- Lack of infrastructure
- Lack of equipment and resources required for screening
- Lack of pathologists and pathology supplies
- Lack of human resources there are few providers skilled in delivering diagnostic and therapeutic services for cervical cancer screening and treatment of women with abnormal screening tests

For patients:

Lack of access to screening and treatment facilities





Collaborative Research

THE UNIVERSITY OF TEXAS MDAnderson Cancer Center

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Capacity building in research The Capulana Study

- First collaborative research project between MD Anderson,
 Brazil and Mozambique, completed 2020
- Primary HPV testing for cervical cancer screening
- 898 women
- HPV+ rate of 23.7%
- HIV+ rate of 20.2% (39.2% of WLWH were HPV+)
- >90% of HPV+ women completed all steps of their diagnostic work-up and treatment (cryotherapy, LEEP, or referral to Gyn/Gyn Onc)

Supported by Anadarko Petroleum Corporation



Salcedo MP et al. *IJGC* 2020 MD ANDERSON CANCER CENTER

The Capulana Study - training

 Research training for nurses, laboratory technicians and research personnel







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MULHER Study: a prospective trial of <u>Mozambican women undergoing cervical</u> cancer screening with <u>H</u>PV testing in conjunction with family planning services



Mozambique, Africa





Expanding Cervical Cancer Screening and Preventive Therapy (CCS&PT) through Introducing New Technologies and Integrating with Voluntary Family Planning

This PEER sub-program sponsored by the <u>United States Agency for International Development</u> (USA(D) and implemented by the U.S. National Academies of Sciences, Engineering, and Medicine. It seeks to facilitate the introduction and scale-up of innovative CCS&PT approaches in Malawi and Mozambigue that can be implemented in conjunction with voluntary family planning activities, with a focus on generating evidence that will inform sustainable scale-up of cervical cancer control programs in LMICs. A primary focus of this partnership is be to leverage longstanding investments in voluntary family planning programs, as well as other efforts to address cervical cancer, and to build capacity in partner countries to sustainably address the burden of cervical cancer.



New Awards Announced

On January 31, capping Cervical Health Awareness Month 2019, PEER was proud to announce and recognize the two projects selected for support by USAID following the completion of a peer-review process convened by the National Academies. The projects are expected to begin in March 2019 and run through September 2021. Separate project pages will be created and linked through the titles below once the activities begin.

Collaborative Research

MULHER Study: a prospective trial of <u>Mozambican</u> women <u>undergoing cervical</u> cancer screening with <u>HPV</u> testing in conjunction with family planning s<u>er</u>vices

Evaluating innovative technologies and approaches to addressing cervical cancer

- Women screened with HPV (self collected) in Maputo and Gaza
- Ablation using thermal ablation
- New technologies developed by Rice University bioengineering department:
 - POC HPV tests,
 - Optical imaging to diagnose precancerous lesions





MULHER Study

- To expand reach to services by integrating cervical cancer screening with voluntary family planning programs
- From January 2020 to January 2023, 9,014 women underwent cervical screening
- 97.5% of women chose self-collection
- The HPV positivity rate was 31.1% overall and 39.5% among WLWH
- Of the 2,805 HPV-positive women, 2,588 (92.3%) returned for follow-up and treatment, including ablation (n=2,383, 92.1%), LEEP (n=169, 6.5%) and CKC (n=5, 0.2%)
- 31 women (1.2%) were diagnosed with invasive cancer and referred to gynecologic oncology



Supported by USAID-PEER (Partnerships for Enhanced Engagement in Research)/NASEM

MULHER Study

- WLWH were more likely to test positive for HPV (39.5%) compared with HIV-negative women (24.2%)
- WLWH were more likely to have cervical lesions ineligible for ablation (13.0%) compared with HIV-negative women (8.2%)
- Loss to follow-up → if lesions ineligible for ablation and patients referred to gynecology: WLWH (36.9%) vs. HIVnegative patients (15.4%) → Of the 89 patients lost to follow-up at this step, 75 (84.3%) were living with HIV
- Pathologic results by HIV status for the 217 participants who had a histopathologic diagnosis available from LEEP, cold knife conization, or cervical biopsy:
 - 83 patients diagnosed with CIN 2/3 \rightarrow 58 (69.9%) were WLWH
 - 31 patients diagnosed with invasive cancer \rightarrow 19 (61.3%) were WLWH



Collaborative Research Next Steps - New study will start in January 2024

- A randomized clinical trial to assess the effectiveness of thermal ablation vs Loop Electrosurgical Excision Procedure for cervical cancer risk reduction in women living with immunodeficiency virus in Mozambique
- A randomized controlled trial of thermal ablation vs. LEEP for WLWH who test positive for HR-HPV and have a diagnosis of CIN2/3
- All women will have a pathologic diagnosis and will be followed at 6 and 12-months post-treatment
- This will provide more data on the effectiveness of thermal ablation among WLWH
- In partnership with CISPOC, HCM Starts in 2024



Supported by NCI (U01)

Collaborative Research

Next Steps - New study will start in 2024

The AVANÇO Research Consortium: A Mozambique/Brazil/Texas Alliance to advance novel and affordable technologies for the prevention and diagnosis of cervical cancer in women living with HIV

- A prospective study to evaluate the barriers and facilitators to follow-up and care for women who are ineligible for ablation and are referred for LEEP, CKC or biopsy
- Development of new technologies:
 - In-vivo diagnosis of cervical dysplasia
 - A digital platform to provide histologic-quality images of cervical biopsies and LEEP specimens to enable high-quality, rapid diagnostic pathology services in resource-constrained settings
- In partnership with UEM, HCM and Brazil

Many collaborators and partners



NIH NATIONAL CANCER INSTITUTE

Final Considerations HPV testing and treatment of pre-invasive disease:

- Cervical cancer screening with selfsampling HPV testing is feasible
- Good rates of treatment (>92%) for women with positive screening tests is achievable
- Development of new strategies and new technologies for low-cost Point of Care diagnostics and treatment will improve access for screening and treatment and reduce the burden of disease towards the global elimination of cervical cancer

Education, training and capacity building are key!

Thank you! Muito Obrigada!

Thank you for Capulana and MULHER Study Teams!

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INTEGRATING FAMILY PLANNING AND CERVICAL CANCER SERVICES TO OPTIMIZE UPTAKE IN MOZAMBIQUE

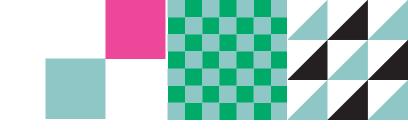
MARCOS CHISSANO DIRECTOR OF EVIDENCE, PSI MOZAMBIQUE

NOVEMBER 02, 2023





BACKGROUND

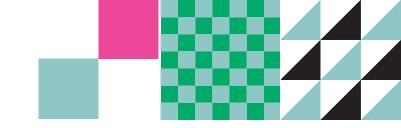




Why integration and why Cervical Cancer Screening and Preventive Therapy with Family Planning?

- Integration is a high impact practice and has been examined through HIV/FP, immunizations/FP, ANC/PNC and FP
- There is a nascent body of literature showing the feasibility and costeffectiveness of integrating cervical cancer screening and preventive treatment (CCS&PT) with other services (including HIV and/or FP).
 - Little known about the effects of integrating FP with Cervical Cancer Screening and Preventive Therapy

STUDY GOAL

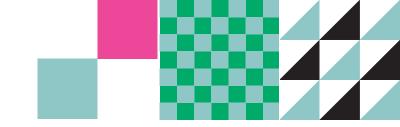


The goal of our overall MULHER study was to develop, implement and test integrated CCS&PT and voluntary Family Planning service delivery models as part of the (PEER) project, to evaluate whether integrated service delivery can optimize uptake and impact of both services.

The study was conducted in 4 public health facilities in 2 provinces in Mozambique from January 2020 to July 2022.

Women aged 30-49 presenting for CCS&PT services or FP services were eligible to participate, in line with WHO CCS age guidance.

METHODS



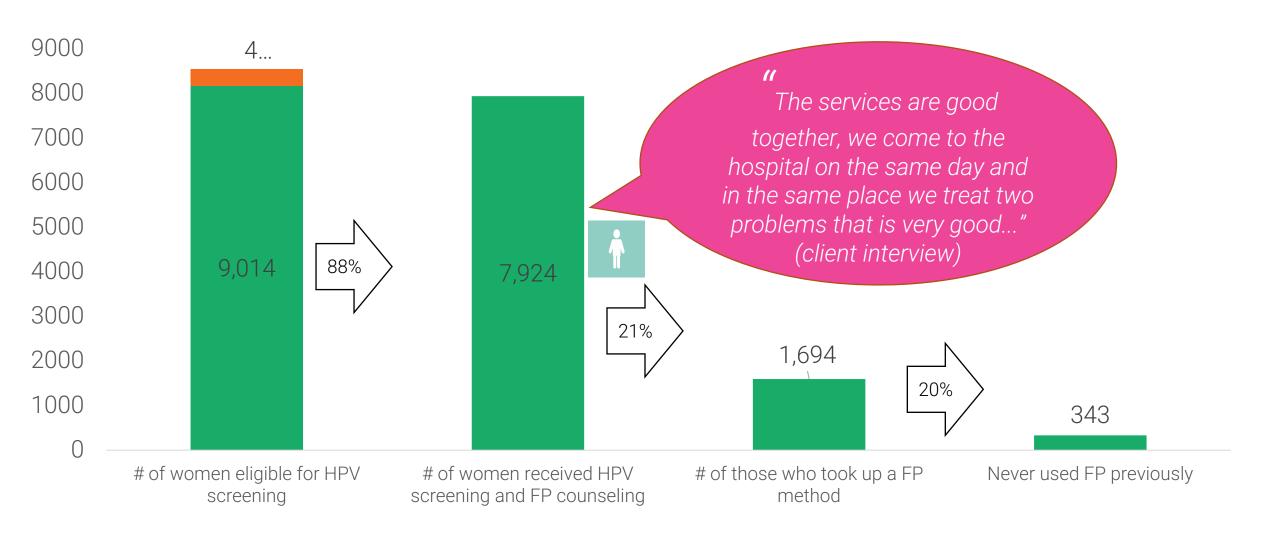
This mixed method study under the whole of MULHER used a combination of research and monitoring data.

- Routine monitoring data with 9,014 clients to determine estimates of visits pre-study and monthly trends in volume during study period.
- Quantitative client exit surveys with 504 clients to measure acceptability on integrated FP/CCS&PT services and overall client satisfaction with integrated services.

 Qualitative data through in-depth interviews with 64 clients and 10 providers to better understand their experience accessing integrated services
 For the purpose of this study, we defined Integration as clients accessing both quality voluntary FP information and services and CCS&PT services, provided by one provider or multiple providers working as a team on the same visit.

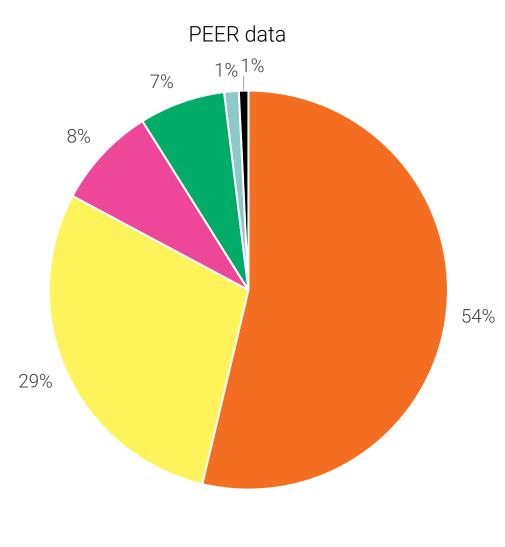


AMONG THOSE WHO WERE ELIGIBLE FOR HPV SCREENING 7924 (97%) RECEIVED HPV SCREENING AND FP COUNSELLING AND 1694 (21%) OF THOSE TOOK UP A METHOD (INITIATED, SWITCHED, CONTINUED)



■ Eligible ■ Ineligeble ■ Injectable ■ Ocs ■ Condoms ■ ImpaInte ■ IUD ■ Other

RESULTS: METHOD MIX AMONG WOMEN SCREENED FOR HPV WHO TAKE UP FP LOOKS SIMILAR TO THE GENERAL POPULATION

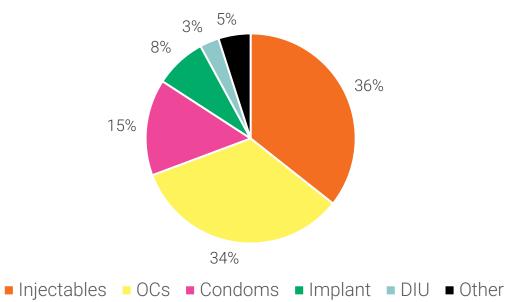


Short acting methods are the most reported uptake method among those screening for HPV 91% short acting, 8% LARC, 1% "other"

Higher levels of injectable, and lower levels of OCP and condoms seen when compared with the 2015 AIS data for this age/location

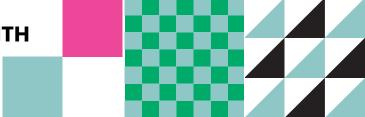
AIS data

Data from 2015 AIS survey (Gaza & Maputo, age 30-49)



Injectables OCs Condoms Implant DIU Other

IN-DEPTH-INTERVIEW DATA SUGGESTS OVERWHELMINGLY POSITIVE EXPERIENCES WITH INTEGRATED CARE, AMONG CLIENTS AND PROVIDERS.



Client experience with Integrated FP and CCS&PT

What do you think about receiving both services (CCS&PT and FP/Cervical Cancer Screening and Family Planning) on the same day?

"I think it's very good, because I wouldn't have to go to another health unit to do either family planning or cervical cancer screening, since both services could be done on the same day and in the same place. In the past you would go for screening and then you would go to another health unit...for family planning.

But nowadays I come here and I do screening and FP in the same place and the nurse doesn't change I feel more comfortable, because they are intimate matters that few people know better... [Laughs] So doing it with the same person in the same place and day is an added value." **Client**

Providers experience with integrated FP and CCS&PT

"It has made it easier because the two have a connection, it is easier because the patients here have two services, in one office, so they come and they can do the FP and the screening consecutively because it is also a constraint that she is in the [family] planning queue and after the planning queue is over, she comes to do the screening, so it has become easier because the women have two services at the same time" **Nurse** 140 120 100 80 COVID ThinPrep Before PEER COVID Lockdown stockout 60 Implementation Lockdown 25 on Average during PEER 40 20 9 on Average before PEER 0 February March February March February March January April May June August October January June July July August October July April May June August October January April May December November December July December November September September November September Baseline 2019 PEER PEER PEER 2020 2021 2022

---Maputo Clients receiving Integrated services before and after

LIMITATIONS

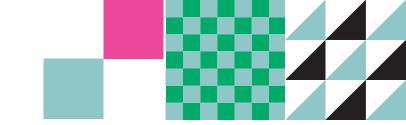
Limitations

- Stop/restart due to pandemic, stockouts, ...
- Baseline data were very patchy
- Anecdotal evidence of FP method stockouts in public sector, but no hard data
- Patients were recruited for a cervical cancer project

Outstanding research questions

- What does integration look like outside of a pandemic?
- What does integration look like outside of the constraints of a clinical trial?
 - What does it look like when CCS&PT is added to a FP clinical setting with no recruitment targets for CCS&PT
- What is the impact of self-sampling on method mix?

CONCLUSION



- Integration seems to result in increased overall FP uptake and CCS&PT service uptake
- Our results suggests integration is appealing to both women and providers.
- Integration of CCS&PT with FP service provision does not seem to have an impact on the overall method mix in the population
- The implementation and potential scale-up in Mozambique represents an opportunity to enhance the impact that integration has on uptake of both CCS&PT and FP services among women.
 - This can result in increased efficiency in providing access to products and services that improve women's sexual and reproductive health on method mix?



Thank you

09

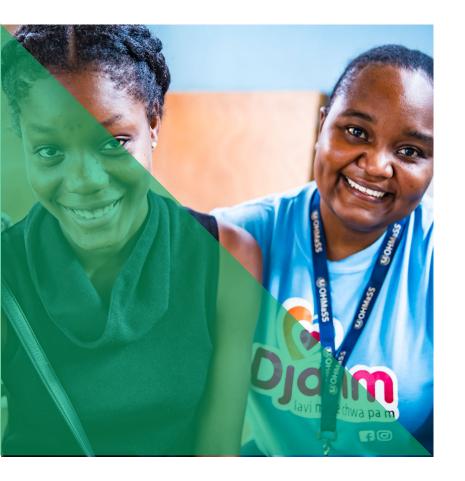


Facilitators and Barriers to Self-sampling HPV-DNA in Mozambique

Eva Lathrop Global Medical Director Population Services International November 2023







FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE

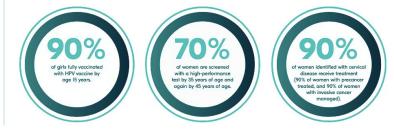
- Background:
- Cervical cancer is a leading cause of death among women worldwide
 - The vast majority of the over 300,000 deaths annually occurring in low and middle-income countries
 - The majority of cervical cancer deaths are preventable
- Mozambique
- Mozambique has one of the highest cervical cancer burdens in the world
 - A severe shortage of health care workers
 - Low clinical coverage for cervical cancer screening



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE

• Background:

Global Cervical Cancer Elimination Strategy :



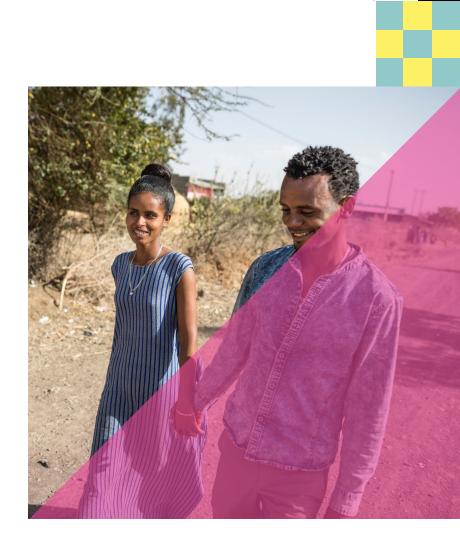
WHO recommendations for screening:
 HPV-DNA testing as the primary screening test
 General population and women living with HIV

Self-sampling is a highly accurate approach to HPV-DNA testing

WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, 2021

FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE

- Prospective cohort study of women 30-49 years of age [ClinicalTrials.gov NCT05359016]
- Maputo City, Maputo Province and Gaza Province, Mozambique





FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE

- Introduce and scale-up cervical cancer innovations:
- ↔ HPV DNA testing, HPV self-sampling, thermal ablation, integration into family planning services
- Assess acceptability of HPV self-sampling among providers and consumers
- Identify effective promotion strategies increase service uptake
- Determine cost of integrated services for cervical cancer-family planning



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE

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FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: METHODS

- Integrated cervical cancer screening and/or voluntary family planning services
- Offered self collection or provider collection of cervico-vaginal swabs
- Feasibility and acceptability of self sampling objective addressed through a mixed methods including:
 - Routine service delivery data
 - In depth interviews with women and providers



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: SERVICE DELIVERY RESULTS



✤Total study sample: 9,104

✤Median age at enrollment: 37 (30-49)

♦ Women living with HIV: 45.7% (4,122)

✤High Risk HPV positive: 31.1% (2,805)

✤Participants who chose self – sampling: 97.5% (8,792)



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: QUALITATIVE FINDINGS

♦Patient interviews: N=104

- ✤Identified barriers to self sampling:
 - Fears about technique
 - ✤Discomfort
 - Inadequate training to correctly perform sample collection





"I worry about self-sampling – if I am doing it correctly and also it could be a bit painful."

"I cannot manage to do the self-sampling; it would be too difficult to see my genital organs. [I can only do it] if I have someone to help me collect."



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: QUALITATIVE FINDINGS

- ✤Patient interviews: N=104
- Identified enablers to self sampling:
 - Increased privacy
 - Prior peer referral



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: ILLUSTRATIVE PATIENT QUOTES

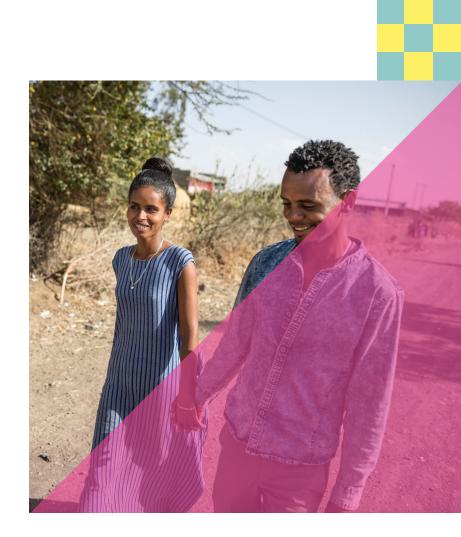
"I liked doing the self-sampling for the HPV. I did it alone and I had that [experience] of evaluating myself. I loved it and that's why, when I explain to the other mamas, I talk about how my experience was, I motivate them and say that it doesn't hurt, it is simple and easy, I say you will be proud and say that I went to the hospital and did an exam alone to save my life."

FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: *RESULTS*

✤Provider Interviews: N=15

✤Benefits of patient self-sampling:

- ✤ Faster screening process
- ✤Less need for equipment
- Potential for out of facility screening
- Concerns for patient self sampling:
 - Provider displacement
 - Incorrect sample collection



FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: ILLUSTRATIVE PROVIDER QUOTES

Women like to do self-sampling because from the moment that I explain to them how they should do their self-collection and she feels good, and from my experience I think that it is good for women to do the self-collections because they feel good about not being on a bed and saying position yourself here, because you have to spread your legs is something that women don't like."

"They really fear removing clothes in front of people, so that is why they are more comfortable with this"

FACILITATORS AND BARRIERS TO SELF-SAMPLING HPV-DNA IN MOZAMBIQUE: KEY MESSAGES

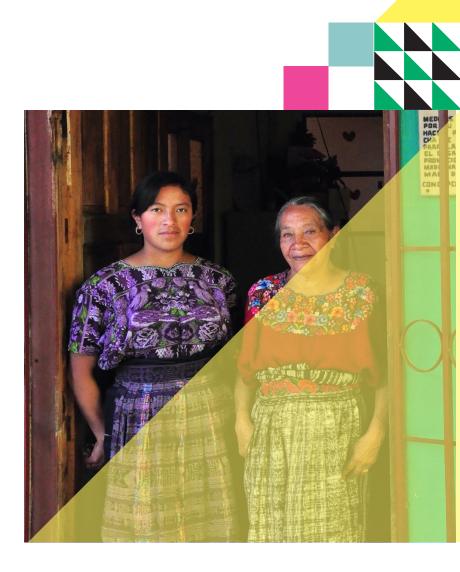


Contributes to a nascent literature that gives a picture of the prevailing fears and barriers and can advance a person-centered approach to delivering to cervical cancer screening

- Promotes equity by increasing control over where, when, and how women choose to be screened
- ✤HPV self-sampling holds great promise in improving access to screening
- Communicating the potential benefits of HPV self-sampling to providers, would improve acceptance of this approach
- Strengthening self-efficacy, bodily awareness, and the sense of agency to self-sample will enable the expansion of HPV self-sampling

THANK YOU TO ALL OF OUR TEAMMATES, PARTNERS AND PARTICIPANTS

- The University of Texas MD Anderson Cancer Center
- MISAU: Mozambique Ministry of Health
- Unites States Agency for International Development





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Question & Answer

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