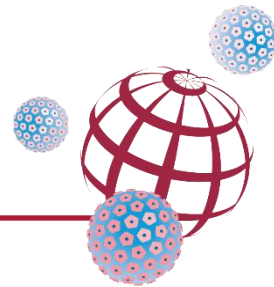


HPV Prevention and Control Board Focused Topic Technical Meeting

Gina Ogilvie MD MSc FCFP DrPH
Carol Nakisige MB BS PhD (cand)

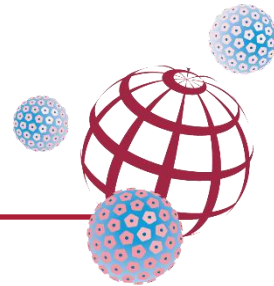
June 2023
Antwerp, Belgium



Community-integrated self-collection HPV-based cervix screening programs to increase screening and treatment coverage: Results from a pragmatic, cluster randomized trial



Anna Gottschlich, Beth A. Payne, Jessica Trawin, Arianne Albert, Jose Jeronimo, Sheona Mitchell-Foster, Nadia Mithani, Ruth Namogusa, Priscilla Naguti, Heather Pedersen, Angeli Rawat, Princess Nothemba Simelela, Joel Singer, Laurie W. Smith, Dirk van Niekerk, Jackson Orem, Carolyn Nakisige, and **Gina Ogilvie**

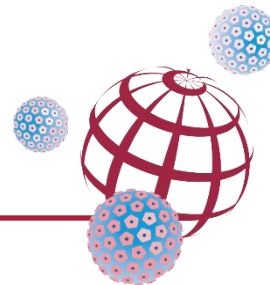


Background

- Uganda has one of the highest cervical cancer incidence rates in the world (56.2 per 100,000 in 2020) (GLOBOCAN, 2020)
- 2020: 6959 women diagnosed with cervical cancer and 4607 died (GLOBOCAN, 2020)
- Very low current screening coverage (~2.0-5.0%) (Ndejjo et al., 2016)



<https://gco.iarc.fr/today/data/factsheets/populations/800-uganda-fact-sheets.pdf>
<https://doi.org/10.1371/journal.pone.0149696>

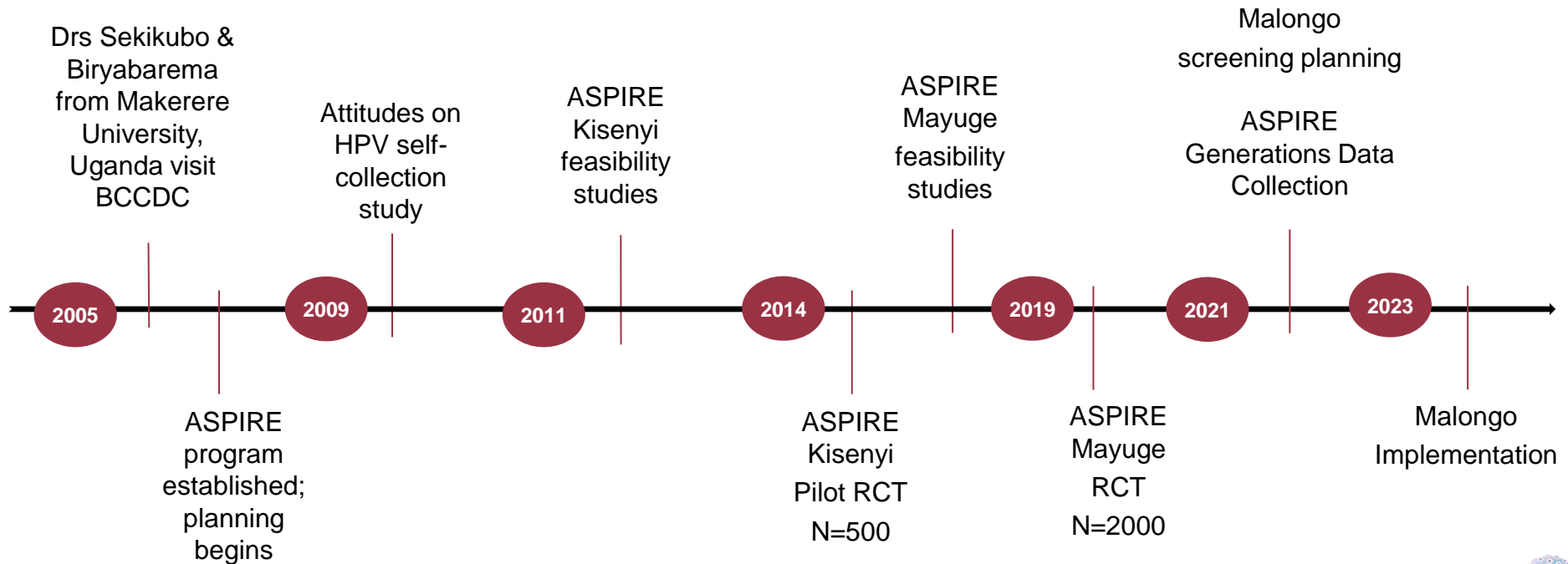


The ASPIRE Program of Research

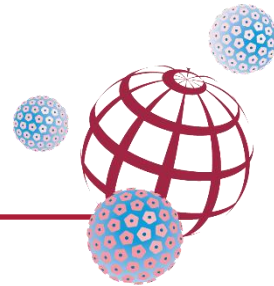
- Partnership between UBC, Makerere University and Uganda Cancer Institute
- Consultation with MoH and health care leaders developing National strategy for cervical cancer elimination
- Phased pragmatic research approach to designing cervical cancer screening program



ASPIRE Timeline (2005-2021)



19 Publications to date



How to best implement HPV-based cervical cancer screening?



THE UNIVERSITY
OF BRITISH COLUMBIA

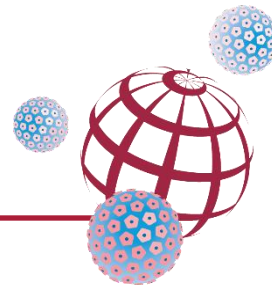


Mayuge District, Uganda



<5% ever screened
for cervical cancer

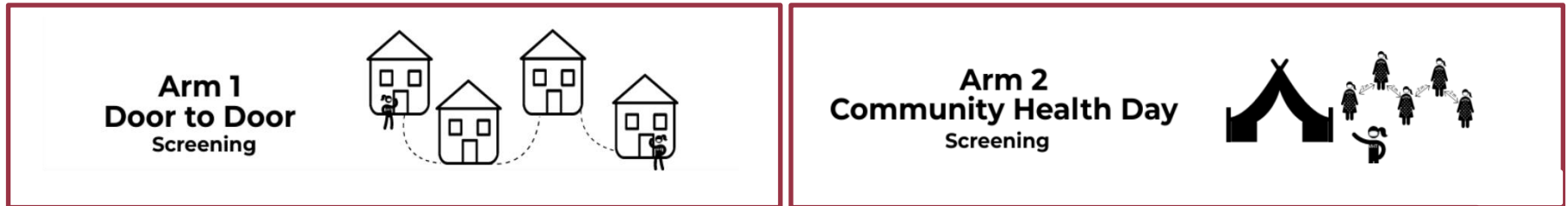
(Ndejjo et al. 2016)



ASPIRE Mayuge Trial Design

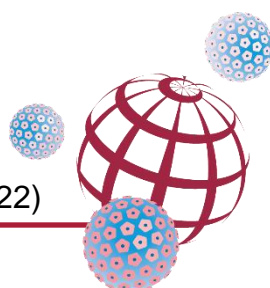
Goal: to see which strategy would produce the greatest number of women attending follow-up to receive HPV results and treatment.

2 HPV screening delivery strategies:



Community Health Workers deliver screening and results.

(Gottschlich et al., 2022)



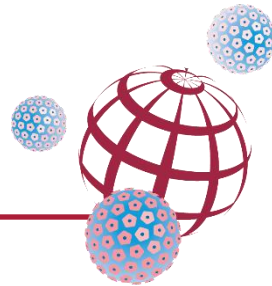
ASPIRE Mayuge Trial Design

Primary Endpoint (*Total Pop'n*)

Attendance at a scheduled treatment follow-up appointment after receiving a positive HR-HPV result

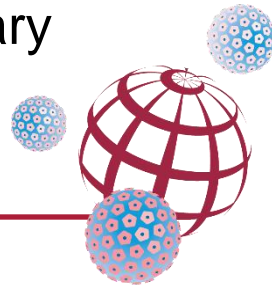
Secondary Endpoints (*Pop'n Subset*)

- Cervical cancer knowledge six months after recruitment into the trial
- Patient-reported experience measures for self-collected cervix screening



Methods

- Villages were randomized (unblinded) to strategy and participants 25-49 with no prior cervix treatment were eligible.
- Participants completed a survey and participated in SCS
- Primary outcome: Follow-up attendance after a positive screen
- Screening uptake and HPV positivity rates are also reported.
- Mixed-effects log-binomial regression models were run to compare follow-up adherence between arms and investigated secondary outcomes (knowledge retention and trial experience).



Integration into existing infrastructure



Community health workers



GeneXpert
(used to HIV/TB testing)



Lab staff and nurses

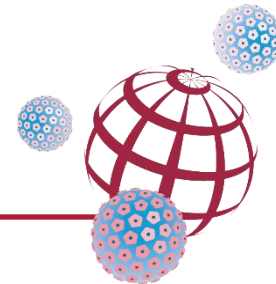


Local health centers



THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

Collaboration
with MOH



Randomization by village

ARM 1

ARM 2



Door to door recruitment with individual VHT

Health education for women and family

Self-collection in home



Results and counseling by VHT at home

Community mobilization by VHT for health day recruitment

Community health education

Self-collection in private tent

Follow-up group health education event

Results and counseling by VHT in private tent

Sample tested at Kigandalo HCIV with GeneXpert

HPV+ women referred for follow-up VIA and treatment at HCIII



WOMEN'S HEALTH RESEARCH INSTITUTE AT BC WOMEN'S



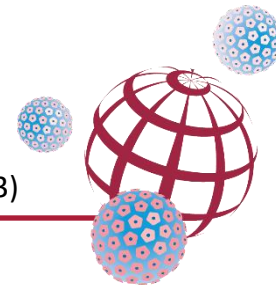
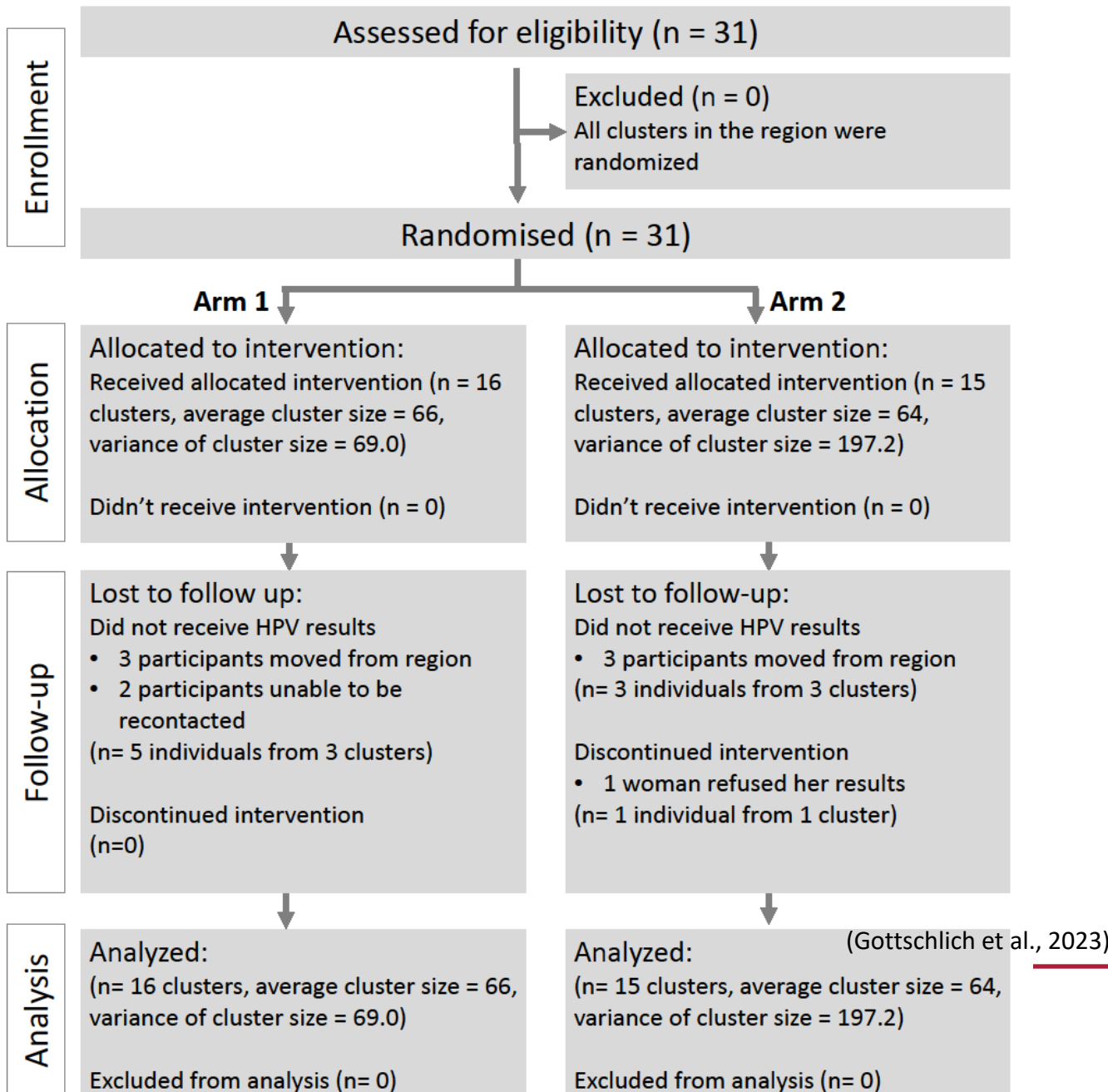
BC Centre for Disease Control
An agency of the Provincial Health Services Authority



Provincial Health Services Authority



Canadian Institutes of Health Research
Instituts de recherche en santé du Canada



Trial results

Arm 1 Door to Door Screening

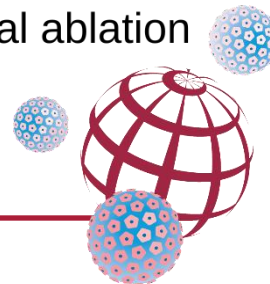


Arm 2 Community Health Day Screening



- ✓ August - December 2019
- ✓ 16 Villages
- ✓ At home survey & self-collection with Community Health Worker (CHW)
- ✓ Results delivered to the home by CHW
- ✓ HPV+ referred to VIA & thermal ablation

- ✓ November - July 2021
- ✓ 15 Villages
- ✓ Survey & self-collection at community health day with CHW
- ✓ Results delivered to the home by CHW
- ✓ HPV+ referred to VIA & thermal ablation



Study Population

2,019
Participants

Average Age
of 34

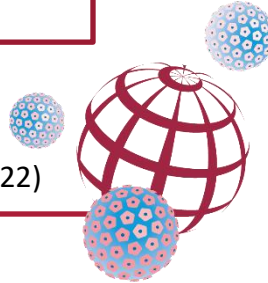
Average of 5
pregnancies
in a lifetime

26.5% HPV+

85.5%
Married

Most have a
P1 to P7
Education

(Gottschlich et al., 2022)

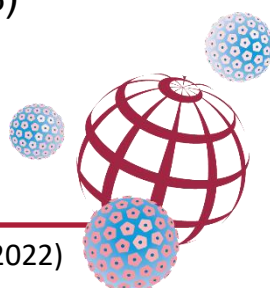


Results

100% of participants chose to self-collect

| Screening and Follow Up Results | Arm 1 (n=1055) | Arm 2 (n=964) |
|--|--------------------|--------------------|
| Previously Screened for Cancer | 21 (1.99%) | 23 (2.39%) |
| HPV+ Result | 296 (28.1%) | 240 (24.9%) |
| Received HPV Results | 1050 (99.5%) | 960 (99.6%) |
| Attended Follow-Up (entire pop'n) | 233 (22.1%) | 162 (16.8%) |
| Attended Follow-Up (HPV+ pop'n) | 223 (75.3%) | 160 (67.2%) |
| Received VIA (HPV+ pop'n) = n=534 | 206 (92.4%) | 158 (99.4%) |
| Positive VIA Result (HPV+ pop'n) | 29 (14.4%) | 38 (23.9%) |
| Negative VIA Result (HPV+ pop'n) | 29 (14.1%) | 38 (23.9%) |
| Indeterminate | 8 (3.9%) | 8 (5.0%) |
| Suspect Cervical Cancer | 4 (1.9%) | 5 (3.1%) |

(Gottschlich et al., 2022)



Trial Findings

Table 4. Results from mixed-effects logistic regression models estimating the odds ratio of VIA attendance between study arms

| Predictors | M1 N=2019 | | | M2 N=2012 | | | M3 N=2019 | | | M4 N=536 | | |
|---------------------|-------------|-----------|--------------|-------------|-----------|--------------|-----------|-----------|--------|----------|------------|--------------|
| | OR | CI | P | OR | CI | P | OR | CI | P | OR | CI | P |
| Intercept | 0.4 | 0.28-0.57 | <0.001 | 0.39 | 0.17-0.90 | 0.028 | 0.12 | 0.05-0.25 | <0.001 | 4.83 | 1.88-12.44 | 0.001 |
| Study arm* | 0.71 | 0.56-0.90 | 0.005 | 0.74 | 0.57-0.95 | 0.018 | 0.81 | 0.64-1.02 | 0.072 | 0.69 | 0.38-1.26 | 0.17 |
| Woman's age | | | | 0.99 | 0.98-1.01 | 0.477 | | | | | | |
| Woman's education | | | | | | | | | | | | |
| Primary | | | | 0.97 | 0.68-1.38 | 0.860 | | | | | | |
| O-level | | | | 1.10 | 0.74-1.62 | 0.646 | | | | | | |
| A-level | | | | 1.87 | 0.75-4.66 | 0.177 | | | | | | |
| Tertiary/University | | | | 1.35 | 0.73-2.50 | 0.340 | | | | | | |
| Health visit (Yes) | | | | 1.07 | 0.80-1.45 | 0.642 | | | | | | |
| Marital status | | | | | | | | | | | | |
| Separated/Divorced | | | | 1.37 | 0.78-2.41 | 0.266 | | | | | | |
| Single | | | | 1.54 | 1.08-2.20 | 0.018 | | | | | | |
| Widowed | | | | 1.91 | 0.89-4.11 | 0.096 | | | | | | |
| Clus HPV pos rate | | | | | | | 1.04 | 1.02-1.06 | <0.001 | | | |

*Arm 2 compared to Arm 1

Model 1: Unadjusted with cluster as random intercept

Model 2: Adjusted for age, education, health visit in last year, and marital status with cluster as random intercept

Model 3: Adjusted for cluster HPV positivity rate with cluster as random intercept

Model 4: Subset to HPV positive participants

Gottschlich, et al. Community-integrated self-collection HPV-based cervix screening programs to increase screening and treatment coverage: Results from a pragmatic, cluster-randomized trial. Under review.

Results from Mixed Effects Logistic Regression Models

Significant difference in attendance at follow-up between arms

Model 2: Adjusted for age, education, health visit in last year, and marital status with cluster as random intercept

| | M2 | N=2012 | |
|-------------------------|-------------|------------------|--------------|
| Predictors | OR | CI | P |
| Intercept | 0.39 | 0.17-0.90 | 0.028 |
| Study arm* | 0.74 | 0.57-0.95 | 0.018 |
| Woman's age | 0.99 | 0.98-1.01 | 0.477 |
| Woman's education | | | |
| Primary | 0.97 | 0.68-1.38 | 0.860 |
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| Single | 1.54 | 1.08-2.20 | 0.018 |
| Widowed | 1.91 | 0.89-4.11 | 0.096 |
| Clus HPV pos rate | | | |
| ICC | 0.005 | | |

[nature](#) > [nature medicine](#) > [articles](#) > [article](#)

Article | [Published: 10 April 2023](#)

Community-integrated self-collected HPV-based cervix screening in a low-resource rural setting: a pragmatic, cluster-randomized trial

[Anna Gottschlich](#) , [Beth A. Payne](#), [Jessica Trawin](#), [Arianne Albert](#), [Jose Jeronimo](#), [Sheona Mitchell-Foster](#), [Nadia Mithani](#), [Ruth Namugosa](#), [Priscilla Naguti](#), [Heather Pedersen](#), [Angeli Rawat](#), [Princess Nothemba Simelela](#), [Joel Singer](#), [Laurie W. Smith](#), [Dirk van Niekerk](#), [Jackson Orem](#), [Carolyn Nakisige](#) & [Gina Ogilvie](#)

Results: Thermal Ablation

Study Question:

Are the side effects of Thermal Ablation treatment for cervical precancer acceptable to those who are screen-positive and receive the treatment?

POPULATION



Screen-positive participants of the ASPIRE Mayuge trial in rural Uganda

LOCATION

Mayuge District, Uganda

PRIMARY OUTCOME

Side effects experienced during procedure and recovery

INTERVENTION

N=2019 in ASPIRE Trial

↓
349 received thermal ablation

↓
135 completed experience survey

FINDINGS

Side effects

Pain: 90%
Pain Rating: 2.4/5
Cramps: 51%
Light-headed: 23%

Recovery

Pain: 15%
Discharge: 62%
Bleeding: 23%

90% of women who received thermal ablation and completed the experience survey reported that they would recommend the treatment to others

Trial Findings

Arm 1 Door-to-door:



- Participation in self-collection: 100%
- HPV positivity: 28%
- **Follow-up attendance: 75%**

Arm 2 Village Health Day:



- Participation in self-collection: 100%
- HPV positivity: 25%
- **Follow-up attendance 67%**

Gottschlich, et al. Community-integrated self-collection HPV-based cervix screening programs to increase screening and treatment coverage: Results from a pragmatic, cluster-randomized trial. *Nature Medicine*

- 17% received thermal ablation
- **98% would recommend the treatment to others**

Gottschlich, et al. Experiences with thermal ablation for cervical pre-cancer treatment after self-collection HPV-based screening in the ASPIRE Mayuge randomized trial..

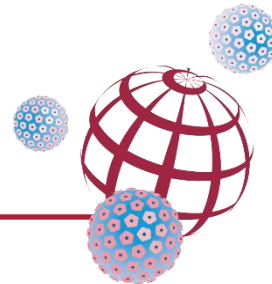
Implications

HPV-based self-collection for cervix screening led to higher screening coverage

Both door to door & community health day screening strategies could be integrated into existing health systems, leading to high rates of screening and follow up

Both arms demonstrated high reach, fidelity, acceptability, and adoption amongst participating communities

This trial informs implementation roadmaps to help districts prioritize screening within the limits of their health system

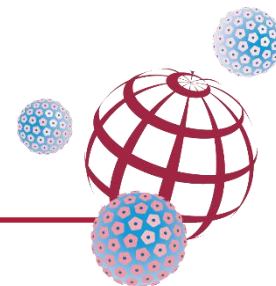


Next Steps

Ongoing evaluation of costing and economic implementation of different approaches

Understanding social and economic impacts of cervical cancer

Evaluation of program implementation



Acknowledgments



Anna Gottschlich
Beth A. Payne
Sheona Mitchell-Foster
Joel Singer
Dirk van Niekerk
Gina Ogilvie

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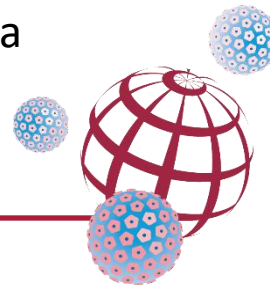


Uganda Cancer Institute
Research is Our Resource

Carolyn Nakisige
Ruth Namogusa
Priscilla Naguti
Jackson Orem



Princess Nothemba
Simelela



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