

**Evaluating Determinants and Strategy Implementation of the Single-Visit Screen and Treat
Approach with Thermal Ablation in Kenya**

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Abstract

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Introduction: The availability of effective cervical cancer prevention interventions creates a clear pathway towards elimination. However, cervical cancer remains the leading cause of cancer-related deaths among women in low- and middle-income countries, primarily attributed to persistent implementation gaps. This dissertation explores the implementation of the single-visit, screen and treat approach with visual inspection with acetic acid (VIA) and thermal ablation (SV-SAT+TA) by identifying key determinants, characterizing provider-led strategy adaptations, and evaluating the alignment between implementation strategies and contextual barriers.

Methods: This dissertation is nested within a hybrid type III implementation trial aimed at developing and evaluating implementation strategies to support the national scale-up of the single-visit screen and treat approach using VIA and thermal ablation across 10 health facilities in Kenya. Chapter 2 used qualitative methods to identify barriers and facilitators to the implementation of the SV-SAT+TA among 34 participants: 20 frontline health care providers, 10 health facility managers, and 5 policymakers. In-depth interviews were conducted and guided by the adapted Consolidated Framework for Implementation Research (CFIR) for LMICs. In Chapter 3, we applied the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) to systematically document and track adaptations to the TIBA implementation strategies across the 10 health facilities. FRAME-IS guided the development of the Excel tracking sheets. Data was collected monthly by Technical Assistants through site visits, direct observations, and field notes. Chapter 4 employed a convergent mixed-methods approach to evaluate barrier-strategy matching using surveys and small group discussions with 40 participants, mainly frontline healthcare providers and facility managers.

Results: Findings from Chapter 2 identified leadership engagement, the relative advantage of thermal ablation over cryotherapy, and self-efficacy among providers as drivers of successful SV-SAT+TA implementation. Conversely, lack of essential commodities, infrastructural limitations, shortage of trained staff, and recruitment challenges emerged as barriers to implementation. Building on Chapter 2, findings from Chapter 3 revealed that most adaptations occurred early in implementation and were primarily education (57%) and resource-related (21%). Adaptations mainly targeted provider adoption of the SV-SAT+TA, and the rate of adaptations declined over time. In Chapter 4, we found that 71% of the pre-identified barriers were successfully addressed through well-matched strategies focusing on improving clinic workflows, training, and community engagement. However, structural issues such as staffing, client follow-up remained inadequately addressed.

Conclusion: This dissertation provides critical insights into the contextual and system-level factors influencing the implementation of cervical cancer prevention interventions in Kenya. The lessons learned have a broad relevance for scaling and sustaining cervical cancer prevention efforts across LMICs.

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DEDICATION

To my late mum, Esther, your unwavering love, sacrifices, and prayers have carried me further than words can express. This achievement is for you.

To my sons, Brad Harvey Osano and Ira Davids Osano, you are limitless. Always remember you can do all things through Christ who strengthens you (Philippians 4:13)

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Chapter 1: Introduction

Unlike many other cancers, cervical cancer is preventable, detectable, and curable when identified at an early stage.¹ Yet, it continues to pose significant threats to women's health globally.² In 2022 alone, it is estimated that 662,044 women were newly diagnosed with cervical cancer, and approximately 350,000 deaths were reported.^{3,4} This burden is greatest in low- and middle-income countries (LMICs), with 94% of the mortalities reported in the Sub-Saharan African region.^{5,6} These preventable cases and deaths persist despite the availability of effective primary prevention through human papillomavirus vaccination (HPV) and secondary prevention through cervical cancer screening and treatment of precancerous cervical lesions.^{7,8}

In response to this public health burden, the World Health Organization (WHO) launched a global call in 2018 to eliminate cervical cancer with the mantra *"No woman should die from cervical cancer."*⁹ The 2020 global elimination strategy set ambitious but achievable targets for 2030: 90% of girls fully vaccinated by age 15, 70% of women screened with a high-performance test by ages 35 and 45, and 90% of women with cervical disease receiving appropriate treatment. Remarkable progress has been observed in high-income countries such as Australia, which is among the first globally to be on the pathway to achieving the set targets.¹⁰ Australia has reported that 83% of women aged 35-39 years have received at least one HPV test, 79.8% of women aged 45-49 have been screened at least twice, and 88.7% of women diagnosed with cervical precancer have received treatment.¹¹

Despite the global momentum, a pressing question remains: "Why is the burden of cervical cancer increasing in low and middle-income countries?" On average, only 19% of eligible women in LMICs get screened for cervical cancer compared to 63% in high-income countries.¹² This disparity stems from multiple health system and individual-level factors, including shortage of trained providers to deliver screening and treatment, inconsistent availability of essential supplies and equipment, and persistent logistical and supply chain challenges.¹³ Additionally, cultural beliefs such as myths and misconceptions about screening and fear of receiving a cancer diagnosis discourage women from seeking preventive services.¹⁴ Further contributing to the widening of these gaps is the standard practice for screening and treatment in most LMICs, i.e., the single visit, screen-and-treat approach with visual inspection with acetic acid (VIA) and cryotherapy, which has faced multiple implementation challenges, well documented in the literature.¹⁵⁻¹⁷ In Kenya, for example, the SV-SAT+ with VIA and Cryotherapy has resulted in low uptake. Only 17% of eligible women are screened, and just under one-third (30%) of those who screen positive for precancerous lesions receive treatment.^{18,19} These low rates are primarily due to logistical challenges associated with the supply chain for nitrous oxide gas used in cryotherapy, in addition to frequent stockouts of screening supplies such as gloves and acetic acid, shortage of trained providers, and lack of equipment.²⁰

As an alternative approach, the single-visit, screen and treat with VIA and thermal ablation (SV-SAT+TA) is a promising approach in overcoming these logistical barriers.^{21,22} However, critical implementation science questions remain, including determining which context-specific implementation strategies best address system-level and organizational factors and facilitate the streamlined introduction and scale-up of the SV-SAT+TA in diverse settings in Kenya. Applying implementation science methods to refine the SV-SAT+TA will generate valuable insights for scaling cervical cancer prevention not only in Kenya but also across similar LMIC contexts.

To address gaps in cervical cancer prevention in Kenya, our team designed a hybrid type III implementation trial to develop and test implementation strategies to inform the nationwide adoption and scale-up of the SV-SAT+TA for sustainable cervical cancer prevention services.²³ “*TIBA*,” a Swahili word for treatment, will be used in this dissertation to represent the SV-SAT+TA approach. TIBA is a five-year, prospective cluster-randomized stepped-wedge trial conducted across 10 health facilities in three successive waves in Kiambu, Embu, and Murang’a Counties in Central Kenya.

Nested within the TIBA trial, this dissertation explores how health systems can effectively adopt and scale the TIBA model in real-world settings. It uses a combination of qualitative and mixed methods approaches to identify implementation determinants, explore how health workers adapt implementation strategies, and evaluate how well barriers are matched to specific strategies, ultimately informing the development of more effective, contextually appropriate cervical cancer interventions.

In the first study (Chapter 2), I use qualitative methods guided by the adapted Consolidated Framework for Implementation Research (CFIR) for LMICs to identify drivers for implementation success and challenges for rolling out TIBA. In-depth interviews with policymakers, frontline healthcare providers, and health facility managers explored implementation determinants across multiple levels, forming the foundation for developing tailored implementation strategies at each participating facility.

The second study (Chapter 3) builds on the findings from Chapter 2 to identify and track context-specific implementation strategies to address barriers to the implementation of TIBA. Using the Framework for Reporting Adaptations and modifications to Evidence-based implementation strategies (FRAME-IS), we systematically document, track, and characterize adaptations to the implementation of TIBA, providing insights on how strategies evolve in real-world settings.

Finally, in the third study (Chapter 4), I apply convergent mixed approaches to evaluate the extent to which implementation strategies address the pre-identified barriers to TIBA implementation.

In summary, this dissertation aims to contribute valuable insights into how implementation science can enhance the delivery and sustainability of cervical cancer prevention services in resource-constrained settings, ultimately promoting population health and reducing barriers to accessing preventive care.

Chapter 2: Barriers and Facilitators to Implementing a Single-Visit, Screen-and-Treat Approach with Thermal Ablation for Cervical Cancer Prevention in Kenya

Introduction

Cervical cancer remains a major global threat to women's health, ranking as the fourth most common cause of cancer among women.²⁴ The World Health Organization (WHO) estimates that globally, approximately 660,000 women are diagnosed with cervical cancer, with about 350,000 deaths reported annually.^{25,26} Women in low- and middle-income countries (LMICs) account for 94% of the disease burden.⁵ In 2022, cervical cancer contributed to 12% of all cancer deaths in Kenya.²⁷ Despite the availability of preventive interventions such as the human papillomavirus (HPV) vaccination and routine screening and treatment of precancerous cervical lesions and early cancer,²⁸ their availability, affordability, and uptake remain limited in many LMICs. This is due to structural, operational, and behavioral barriers constraining providers' and patients' access to and utilization of services.^{9,29} Addressing these challenges requires a deeper understanding of implementation determinants to improve access and uptake of these preventive interventions, ultimately reducing the global burden of cervical cancer.

The standard practice for cervical cancer screening in LMICs, including Kenya, involves a single-visit, screen-and-treat approach (SV-SAT).³⁰⁻³² This strategy utilizes visual inspection with acetic acid (VIA) for screening, followed by immediate treatment of screen-positive lesions with either cryotherapy or loop electrosurgical excision procedure (LEEP), a method referred to as SV-SAT+Cryotherapy or LEEP.²³ The single-visit approach requires fewer resources compared to multistep processes such as screening with VIA or HPV DNA testing followed by a diagnostic evaluation (e.g., colposcopy or biopsy) and subsequent treatment. It enables broader population coverage and provides immediate treatment, reducing the need for repeat visits and minimizing loss to follow-up.³³ Since 2013, Kenya has adopted the SV-SAT+Cryotherapy or LEEP for eligible women aged 25-49 years³⁴ as outlined in the national guidelines. However, the availability of screening and treatment services remains limited, with substantial facility-level disparities. Screening is predominantly opportunistic in Kenya³⁵, and the SV-SAT+Cryotherapy strategy has resulted in low service uptake, with approximately 16% of eligible women screened and 22-39% of women diagnosed with precancerous lesions receiving treatment.^{20,36,37} These figures fall far short of the ambitious WHO target of 70% of women screened by 35 years of age and, again, at 45 years, and 90% of women with precancerous lesions treated.^{9,38} The low screening uptake in Kenya is attributed to factors such as lack of awareness, social influence, such as health care decisions made by partners, fear, high provider workload, lack of trained staff, limited availability of screening services, and insufficient essential supplies, including gloves and acetic acid.^{39,40}

The low treatment compliance is primarily associated with logistical and supply chain challenges, specifically the inconsistent supply of nitrous oxide, a critical component in cryotherapy treatment.²⁰ Additionally, the number of providers trained in LEEP is limited and concentrated in higher-level facilities, which has further hindered its effective use to increase treatment.^{12,41} These challenges have led to missed opportunities for screening, losses to follow-up, and incomplete treatment. As a result, 90% of women diagnosed with cervical cancer (approximately 5236 diagnosed annually) in Kenya present at an advanced stage.^{42,43} Recommended by the WHO as an alternative treatment for precancerous lesions,⁴⁴ thermal ablation (TA) provides a promising alternative to bridging the current gaps in the single-visit screen-and-treat initiatives for cervical cancer prevention in LMICs. In Kenya, TA is part of the

cervical precancer treatment interventions. Compared to cryotherapy, TA is portable, may have lower infrastructural challenges and maintenance costs, and is better suited for primary care settings.^{42,45}

Kenya is preparing for a national rollout of the SV-SAT+TA to enhance population-based cervical cancer screening and treatment. As part of this effort, we implemented a stepped-wedge, cluster-randomized trial that aims to develop and test implementation strategies to inform the nationwide scale of the SV-SAT+TA. We will use "TIBA," a Swahili word for treatment, to represent the SV-SAT+TA. Prior to the rollout, we conducted formative work with implementers (frontline healthcare providers and health facility managers) and policymakers to gather their perspectives on factors that could promote or hinder successful TIBA implementation. Understanding these implementation determinants at multiple levels is critical for effective planning, resource optimization, and achieving national cervical cancer prevention goals. These findings will provide actionable insights for the Kenyan Ministry of Health (MOH) and offer applicable lessons to other LMICs aiming to implement similar strategies, contributing to the global efforts to eliminate cervical cancer.

Methods

Setting

Kenyan Health System

The healthcare system in Kenya provides services across six levels of facilities. The county manages levels I-V, while level VI is managed at the national level.⁴⁶ Apart from government-led health facilities, Kenya's health systems also include faith-based health facilities, which contribute approximately 30% of health services.⁴⁷ They are overseen by faith-based organizations and health facilities operated with support from non-governmental organizations (NGOs). Cervical cancer screening across these levels is primarily opportunistic, occurring at reproductive health clinics and outpatient clinics. Complicated cases, such as suspicious cases for cancer or precancer treatment requiring LEEP services, are referred to higher-level facilities with the necessary equipment and trained personnel.

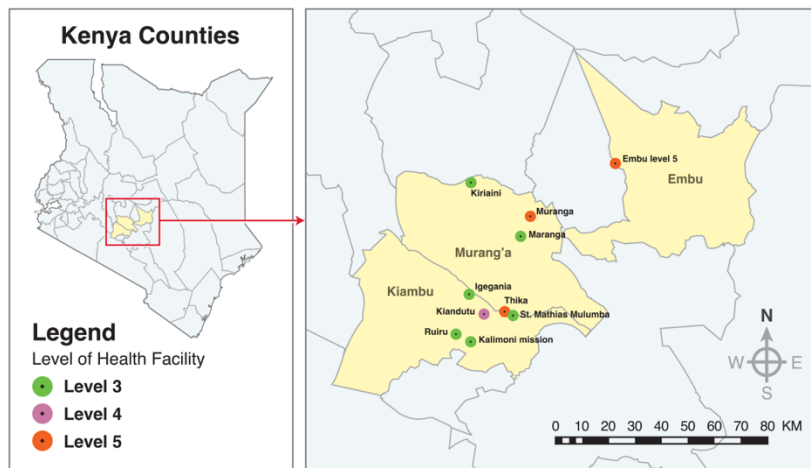
Study Setting

This study purposively sampled ten facilities across three levels (III, IV, V), including public and faith-based-managed facilities with varying levels of support from partner organizations. The study took place in Kiambu, Embu, and Murang'a counties in Kenya, which serve an estimated 4.1 million inhabitants (Figure 1). The heterogeneity of facilities engaged in the TIBA study (Table 1) provides a robust representativeness of the healthcare landscape in Kenya, bolstering the potential generalizability of our research findings and supporting the development of a scalable TIBA model for Kenya and other LMICs.

TABLE 1. HEALTH FACILITY CHARACTERISTICS

County and Health Facility Name	Health Facility Level			Management		Average monthly outpatient visits
	V	IV	III	Govt.	Faith Based	
Kiambu County						
Thika	✓			✓		58,458
Igegania		✓		✓		5137
St Matias Mulumba		✓			✓	6292
Ruiru		✓		✓		19,712
Kiandutu		✓		✓		2489
Kalimoni Mission		✓			✓	5551
Embu County						
Embu	✓			✓		37,331
Murang'a County						
Maragua		✓		✓		18,074
Murang'a	✓			✓		33,315
Kinaiini Mission			✓		✓	14,296

FIGURE 1. TIBA HEALTH FACILITIES



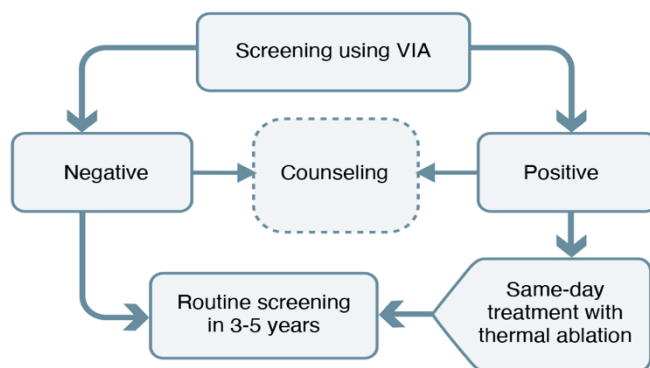
The TIBA Strategy

TIBA (Figure 2) is a dual-pronged implementation strategy targeting women of reproductive age (25-49 years) that consists of two steps:

- 1) Screening of the cervix using visual inspection with acetic acid (VIA)
- 2) Same-day treatment using thermal ablation.

TIBA is introduced to facility staff over six months with support from county-level advisors, and the target implementers are healthcare facility staff, including reproductive health clinic nurses (primary implementers), clinical officers, and medical officers.⁴⁸

FIGURE 2. TIBA STRATEGY



Study Design

This cross-sectional descriptive qualitative study applied in-depth interviews to collect data between 17/05/2022 and 08/08/2022, before the TIBA rollout. This study design provides an overview of the current situation while enabling the collection of contextually rich data on participant perspectives and experiences. It prioritizes stakeholder engagement, which is critical for facilitating intervention adoption and sustainability, thereby increasing the likelihood of successful implementation and scale-up.

Sampling and Participant Recruitment

Thirty nurses, clinical officers, and medical doctors were purposively sampled from 10 healthcare facilities across the three counties. Two categories of providers were recruited: frontline healthcare providers (n=20) and health facility managers (n=10). Four national-level public-sector policymakers from the Ministry of Health, the National Cancer Institute of Kenya, the National Cervical Cancer Program, the Kenyatta National Teaching Hospital oncology unit, and a Kenya Medical Education Trust representative were interviewed. Each of these individuals plays a critical role in influencing policy decisions on cervical cancer prevention and treatment nationally. Multiple strategies for participant recruitment were employed, including email outreach, phone calls, and in-person recruitment at the study facilities.

It is important to note that prior to this formative research, seven out of ten health facilities had been exposed to thermal ablation through training by other implementing partners. However, only two of these facilities actively applied thermal ablation in practice. As a result, only participants from these two health facilities had firsthand experience with thermal ablation, while others did not.

Theoretical Framework and Data Collection

The adapted Consolidated Framework for Implementation Research (CFIR) for LMICs⁴⁹ informed the development of semi-structured interview guides used to explore end users' (clinicians) and policymakers' perspectives on potential drivers of TIBA's future implementation success or failure. CFIR was selected for its pragmatic and proven approach to investigating barriers and facilitators and its successful application across diverse settings, making it highly relevant for this study.^{50,51} We prioritized constructs based on a review of the literature and the investigators' and study team members' prior knowledge and experience implementing similar strategies in Kenya and regionally. A total of 16 constructs across five domains were included in the question guide (Supplementary information): relative advantage, adaptability, complexity, evidence strength and quality, health system context, policies and guidelines, structural characteristics, networks and communication, implementation climate, readiness for implementation, knowledge and beliefs about the intervention, self-efficacy, individual stage of change, and patient's needs and resources. The interview guide was pilot tested with three potential end-users from health facilities and one representative from the policy realm. The pilot findings were employed to refine the interview guides.

Four qualitative research assistants (authors EO, PO, VO, and NBT) conducted the interviews. Each assistant had more than five years of experience conducting qualitative research with women of childbearing age in Central Kenya. They conducted in-depth interviews with 20 healthcare providers and nine health facility managers between May and August 2022. Twenty-nine interviews were conducted in private rooms within the health facilities, and five were done on Zoom due to scheduling constraints. Each interview lasted between 45-60 minutes and was conducted in English. Participants were reimbursed Ksh1000 (~ 8 USD) for transport costs; otherwise, no monetary fees were paid to participants. All interviews were audio recorded and transcribed verbatim. Thematic saturation was achieved with the planned number of participants across categories.^{52,53}

Analysis

The CFIR-guided codebook⁵⁴ was developed and used by a four-member team (authors, NBT, HAF, EO, and PO) to code transcripts using Dedoose software (dedoose.com).⁵⁵ Initially, all four team members simultaneously coded the same three transcripts: one each from a

frontline healthcare provider, a health facility manager, and a policymaker to assess the adequacy of the codebook. We began coding from a deductive approach, given the constructs that were obtained from the CFIR framework. However, there are a few codes that were inductively added. A series of six consensus meetings were held to review and discuss the coding results and make necessary refinements to the codebook. The final, refined codebook was used by a three-member team (authors HAF, EO, and PO), who incorporated identified complementary field notes to complete the coding of the remaining 31 transcripts. The analysis of the CFIR intervention domain compared thermal ablation to cryotherapy, and the other domains considered TIBA, i.e., the single-visit, screen, and treat approach with thermal ablation (SV-SAT+TA). This is because thermal ablation was the most novel component of the intervention from the participant's perspective. While the broader SV-SAT model was already familiar to many health workers, having been previously implemented using cryotherapy, thermal ablation was relatively new in this setting and still in the early stages of introduction. The unit of analysis was the health system level (national versus health facility). In addition, management (public sector versus faith-based) and size (< 3000 monthly visits = smaller health facilities, >5000-17999= moderately sized health facilities, and >18,000 monthly visits = larger) were considered as potential site-specific factors influencing TIBA implementation.

Ethical Approval

This study was approved by the Scientific and Ethics Review Unit of Kenya Medical Research Institute (SERU-KEMRI No. 4403) in Nairobi, Kenya, and the Human Subjects Institutional Review Board (STUDY00014200) at the University of Washington, Seattle, USA. All participants provided written consent to participate in interviews.

Results

Study Participants

Thirty-four participants were interviewed: nine from level V, 19 from level IV, and two from level III facilities. The majority of participants were nurses, n=23. (Table 2).

TABLE 2. PARTICIPANT CHARACTERISTICS

Cadre	Participants	
	Manager (n=14)	Provider (n=20)
Nurse	4	19
Clinical Officer	1	0
Medical Officer	2	0
Obstetrician and Gynaecologist	3	1
Policymakers	4	0

The CFIR domains of innovation characteristics and inner settings were most often cited as driving TIBA implementation success or failure. Within these two domains, five CFIR constructs, cost, complexity, relative advantage, leadership engagement, and self-efficacy, emerged as greater drivers of successful TIBA implementation across health system levels. In contrast, constructs on available resources, structural characteristics, and health system

context were identified as significant barriers. Additionally, constructs on policies, programs, and guidelines were reported to negatively and positively influence TIBA implementation.

Intervention characteristics-complexity, cost, and relative advantage

National Level

Policymakers felt thermal ablation was user-friendly and provided a relative advantage over cryotherapy due to its portability and lower setup and maintenance costs (TA does not require regular consumables). They also highlighted that TA, being chargeable in multiple ways, can treat more than 20 patients without the need to recharge. Its portability was reported to be suitable for outreach activities to communities with limited accessibility. These were perceived as facilitators for the successful implementation of TIBA.

“It is easier and less complex compared to cryotherapy. It does not require regular filling of the consumables. It's portable and can potentially improve linkage to care (Policymaker, 003).”

Despite these advantages, a policymaker stated that maintaining TA may be a potential challenge because hospital maintenance staff lack experience servicing the TA machines and, thus far, have not received this training.

“There is a need to orient the biomedical maintenance unit in the health facility, as they don't seem to understand the thermal ablator.” (Policymaker, 002)

Health Facility-Level

Providers and health facility managers working across facilities reinforced the national level's belief that thermal ablation was easier and thus offered a comparative advantage over cryotherapy. Specifically, informants reported that the TA machine was easy to assemble and time-efficient, requiring 30 seconds for treatment compared to approximately 10 minutes with cryotherapy. They reported other benefits such as portability, reduced storage space needs, fewer logistical and supply chain challenges, and its potential to minimize client distress because treatment could be completed more quickly relative to cryotherapy. Providers and managers felt that it was cheaper to operate TA as it only required batteries or solar compared to regularly purchasing gas for cryotherapy.

“It doesn't have many steps, and it's not complicated. Doing the treatment is not hard because it's just connecting the machine, and you do it.” (Nurse, 016)

Inner setting: Structural Characteristics

National Level

As a facilitator, the policymakers highlighted that each sub-county has trainers for cervical cancer screening and treatment who offer mentorship to providers to curb challenges with staff turnover. Additionally, cervical cancer screening and treatment sessions are included during the health facilities' continuous medical education (CMEs). These trainers and CMEs are key to TIBA's successful adoption and implementation.

“So, for the first entry, we usually train a minimum of two. We also have mentors who are trainers in clusters at the sub-county level.” (Policymaker, 002)

Health Facility-Level

Unlike at the national level, where structural supports were described to be in place, the health facilities identified structural issues as significant barriers to implementation. Some providers (primarily nurses) across the ten health facilities were trained in cervical cancer screening and TA treatment, and five facilities received donated TA machines and screening supplies, yet screening and treatment rates were low, as reported by providers. Inadequate space (commonly cited in smaller facilities) was highlighted as a significant challenge, resulting in long queues and compromised privacy and confidentiality for clients seeking services at integrated service delivery points. In larger level IV & V facilities with multiple screening points, some had only one TA machine, limiting clients and reducing overall treatment numbers.

“Our rooms are tiny, the ones the partners had the structure for the CCC (HIV treatment rooms.” (Clinical Officer, 009)

“It's hard for us now to link the screening to the treatment area because of the different service points. So, the screening can be done, but the treatment may be delayed or may not be done at all.” (Obstetrician-Gynaecologist, 003)

Additionally, shortage of trained staff, high staff turnover, and the perception of increased workload with TA were noted as challenges to TIBA implementation by providers and managers across the three facility levels. Larger-level health facilities were more impacted by staff turnover relative to smaller sites. Respondents recommended regular, routine provider training across cadres and mentorship to address this challenge. One respondent proposed to set specific days each week to offer cervical cancer services to better align care delivery with reduced staff workload.

“I'm the only nurse offering services. Right now, even with VIA VILI, sometimes I can't do it because I'm alone, the queue is very long, and we have a high workload.” (Nurse, 006).

“If we can allocate a specific day, we set aside and say that day is for cervical cancer screening and treatment, it will be effective and more efficient.” (Nurse, 001).

Readiness for implementation: Leadership engagement and available resources

National Level

National-level respondents felt the Kenyan health system was ready to implement TIBA. Readiness was attributed to the availability of expertise nationwide to support protocol implementation and national health leadership's expressed commitment to reviewing reproductive health policies and advocating for health financing for women's health.

“I think they [policymakers] are well-versed enough to advise and guide on developing appropriate guidelines. The policies are already there for screening, and there is relevant expertise to be able to guide that process.” (Policymaker, 004)

As noted by national-level respondents, the available resources to support TIBA included training and commodities. Cervical cancer screening and treatment training for health providers had been carried out in half of the counties (22 counties out of 47) nationwide, and partnerships exist with multilateral organizations such as the Global Fund to purchase cervical cancer-related commodities and provide cervical cancer training for the remaining half of counties in Kenya. Additionally, policymakers noted that cervical cancer prevention activities had been incorporated into existing program planning, such as family planning and HIV services, to improve efficiency and expand access. Finally, workflow algorithms, information,

education, and communication (IEC) materials, and guidelines were reported to have been developed by the Ministry of Health at the national level. These inputs were perceived as facilitators to effectively implementing TIBA.

“I am happy to report that we partnered with the Global Fund. As we speak, we've already integrated a lot of cervical cancer commodities, such as speculums, in this current cycle. We will also train another 22 countries using the Global Fund's support.” (Policymaker, 001).

Human resource constraints are a major challenge, especially at the county level. National-level respondents proposed collaborations with various implementing partners to support hiring additional staff, with the caveat that leveraging donor support was ultimately unsustainable.

“We know that counties have human resource challenges. If any partners can bring in additional personnel to support that service, that will be welcomed, although we don't promote it because it is not sustainable.” (Policymaker, 001).

Engaging political stakeholders was identified as necessary for securing more resources to expand cervical cancer screening and treatment nationally. However, this would require effective packaging and dissemination of information to politicians. Ensuring their support requires convincing them of the immense need for these preventive interventions for women and the feasibility of effectively reallocating resources to this area.

“A lot of strengthening is needed on the political side of policymaking to create the connection between this intervention and the ultimate goal of averting cervical cancer. Reframing the benefits of this intervention from a political perspective can ensure prioritization and resource allocation.” (Policymaker, 003)

Health Facility-Level

Most health facility managers reported a strong commitment to implement TIBA with the provided inputs of training, CMEs, and essential commodities for cervical cancer screening and treatment in partnership with the County government and donors. Their readiness was influenced by previous experiences implementing new tools and approaches.

“Well, I am very prepared. I have been in management for thirteen years, so trust me. We are prepared.” (Clinical Officer, 005).

However, one manager from a larger facility felt ill-prepared to implement TIBA due to shortages of trained staff and consumables, inadequate space, coupled with lack of support from the administration. The lack of support was linked to management's inability to provide resources for cervical cancer activities such as outreaches. The manager noted that these challenges have not yet been addressed, even with the use of cryotherapy, which had been in place before the introduction of thermal ablation.

“We have done many things, but without the administration's support, these projects always fail. I have even tried doing outreaches in this county in the past, but then they died because of a lack of support.” (Obstetrician-Gynaecologist, 006)

Most health providers, however, felt confident in their leadership's support and benefitted from implementing partners' support for other reproductive health initiatives to ensure the successful implementation of new approaches. However, there was a word of caution from

providers and managers regarding the need to train individuals engaged in service delivery rather than just managers. Policymakers also shared these concerns. In addition, providers noted that supportive supervision by the leadership was deemed crucial to enhancing provider competency and confidence.

“So currently, in the county, they are supportive of the treatment of precancerous lesions. They are partnering with different donors so that we can increase the screening of women in reproductive health clinics.” (Nurse, 005).

“Mostly, they train people who never see clients. For training and refresher courses, let them consider training people on the ground who review patients. Also, continuous on-the-job mentorship, supervision, and meetings are necessary to identify gaps and determine progress.” (Nurse, 009).

Regarding available resources, providers and managers emphasized that their readiness to implement TIBA was tied to addressing their facilities' pragmatic gaps in human resources, equipment, and other essential commodities such as gloves, speculums, and acetic acid. If these barriers were not addressed, successful implementation would likely be stymied. Forecasting, budgeting, and including these needs in annual work plans were identified as ways to ensure continuity in service provision.

“We need refresher training, the actual machine (TA), supportive supervision, and mentorship from the national government. If we can get staff employed, this will address the staff shortage.” (Nurse, 004).

“When doing the annual work plan, they can incorporate a budget for cancer screening, training, etc. It is possible and doable with proper planning.” (Nurse, 007).

Characteristics of Systems: Health System Context

National Level

Policymakers identified human resources, insufficient funding for cervical cancer preventive services, supply chain management, and infrastructure as the main health system factors that would hinder the successful implementation of TIBA. To achieve this, they proposed reducing donor dependency and ensuring adequate budget allocations for cervical cancer prevention activities at the County level.

“One is the buy-in and changing that attitude from funder- or partner-driven to county-led and county-driven. So, there is a lot of work that we need to do to ensure that the county budgets for this and that it is not seen as a partner initiative.” (Policymaker, 002)

Health facility-Level

Providers and managers, like the policymakers at the national level, identified human resources, logistical and supply challenges, and essential commodities for cervical cancer screening and treatment as key factors within the health system that hinder the successful execution of TIBA. These challenges included frequent staff transfers across health facilities without immediate replacement, staff changeovers, and lengthy procurement processes contributing to service interruptions.

“So, the procurement, I said, is a long process. When our gas [for cryotherapy] went off, we stayed for six months, and one of the partners bought for us that gas, the one that we are using currently.” (Nurse, 007)

“You find that the county has decided to reassign staff from here, affecting the implementation of services. You might introduce something, and we pick it, then in between, things fall apart with the staff changeover. I'm left now with nobody trained.” (Nurse, 008)

Other factors within the health system reported by providers and managers that may influence TIBA implementation negatively were unsupportive provider attitudes. Unsympathetic provider attitudes were reported to stem from work burnout, lack of motivation because of delayed salaries, and overall lack of workplace resources. These complaints were common, especially among providers in larger health facilities.

“I have noted that most healthcare workers have negative attitudes toward the screening. I think it is more from burnout, shortage of workers, being demotivated, and lack of resources.” (Clinical Officer, 005)

“Staff demotivation is at an all-time high; you find people staying for so long without salaries, even two months, and you expect them to work.” (Obstetrician-Gynaecologist, 006)

Faith-based facilities (more so than public facilities) highlighted challenges with securing agreement from patients to screen and treat for cervical cancer. These facilities charge more for screening and treatment, a deterrent for many lower-income women in the community. To address this challenge, faith-based facilities offered free educational outreach activities to create awareness and encourage women to attend screening and treatment of precancerous cervical lesions at their facilities. In contrast, public sector sites focus more on in-reach activities (e.g., recruiting from other departments within the same facility), as outreach in the communities poses logistical and financial challenges.

“There's a service cost for screening and treatment, affecting TIBA implementation. If the person has no money to pay, they will not receive the service.” (Nurse, 014-Faith-based health facility)

“Actually, in-reaches are less expensive than outreaches because you must be facilitated to go out.” (Nurse, 002- Public health facility)

Policies, programs, and guidelines

National Level

Existing policies, guidelines, and protocols on cervical cancer screening and treatment were recognized as facilitating implementation. They provided a structured framework for cervical cancer screening and treatment implementation, including strategies like TIBA, aligning with WHO-recommended best practices. Two policymakers acknowledged that HPV testing is the gold standard for cervical cancer screening. However, Kenya is widely implementing VIA due to limited resources to implement HPV testing, which requires access to an expensive DNA testing platform. Existing DNA testing capacity in Kenya is primarily from GeneXpert machines acquired through and prioritized for use by tuberculosis screening programs.

“We have national cancer screening guidelines in place, which serve to guide all stakeholders on screening and treatment.” (Policymaker, 001)

“What is recommended by these screening guidelines is HPV (Human Papillomavirus) DNA testing. We advocate for VIA because resources for pathology are limited.” (Policymaker, 003)

Despite the existing policies and guidelines, gaps in understanding how patients navigate referral pathways and follow-up procedures persist. These gaps lead to inefficiencies in service provision and missed opportunities for timely care and treatment, impeding progress toward cervical cancer elimination.

“Implementing population-based screening may be challenging because, despite having screening guidelines, there is no system to track which patients complete screening, follow up on results, or return for care.” (Policymaker, 004).

Health Facility-Level

Existing programs supported by implementing partners were seen as potentially helpful to TIBA implementation. These programs increased access to cervical cancer services by providing the facilities with screening supplies, training, equipment, and supportive supervision. This was common across health facility levels.

“We have had so many programs that the partners have been supporting, and they have been of great help because we have gone around to most of the periphery facilities to screen and try to mentor the ones there.” (Nurse, 007)

Cervical cancer screening and treatment guidelines were available onsite at all health facilities, except for two larger facilities with old and outdated versions. It was unclear why they did not have access to the updated version.

“We have a cervical cancer screening guideline that we are using, and that is what I am saying. I am not sure if it is 2016 or 2014, and you know things have changed. We should have an updated one.” (Nurse, 004)

A concern voiced by smaller health facilities regarding existing cervical cancer programs was the variation in program priorities among the implementing partners who provided cervical cancer screening and treatment supplies. For example, some partner-supported programs only allowed services for HIV-infected women. Staff felt this caused unnecessary and unethical disparities in access to services, was an inefficient use of resources, and would undermine the effective implementation of TIBA. Additionally, health facility managers reported that variable remuneration by program (HIV or non-HIV-specific) and county government for nursing staff could potentially negatively impact TIBA implementation and cause staff demotivation because they perform similar activities but are paid differently.

“Screening can be a bit tricky because the organization that is giving us the materials specifically provides for women living with HIV only.” (Nurse, 013)

“The nurse working in the CCC will deal with her patients, and those on the other side [regular clinics like MCH] will feel demotivated because they know the ones in the program are being paid more. Services need integration, whether they are supported programs or not.” (Nurse, 008)

Individual Characteristics: Self-Efficacy

Health Facility-Level

Most health facility providers and managers across sites expressed confidence in their ability to implement TIBA. This confidence was influenced by several key factors, including previous experience with cervical cancer screening and treatment (e.g., cryotherapy), support from management, knowledge, and skills related to thermal ablation, and a track record of successfully implementing other healthcare interventions. However, a minority of managers (n=2) reported less confidence because of limited knowledge and skills related to thermal ablation. These individuals also noted that staff were still learning and felt uneasy about how patients and staff would receive the intervention. One of them suggested that with good training, they would be confident in delivering TIBA instead of referring clients to larger sites (standard practice).

“I would not say I am very confident. You know it is a new thing. So, we are learning and eager to learn, but I cannot predict how the patients and health workers will take it, so I am eagerly waiting.” (Obstetrician-Gynaecologist 010)

Discussion

Our study identified nine key CFIR constructs frequently mentioned as the most influential drivers of TIBA implementation. Five constructs: cost, complexity, relative advantage, self-efficacy, and leadership engagement emerged as drivers of successful implementation. Previous research on cervical cancer screening and treatment programs with same-day screening using VIA and treatment with TA have demonstrated its suitability for low-resource settings, highlighting provider acceptability of TA due to its portability, ease of use, and affordability, which aligns with the positive reception of TIBA, as reported by the health providers, managers, and policymakers in our study. A study examining healthcare workers' experiences implementing screening and treatment for cervical cancer prevention in Malawi identified relative advantage, cost, and complexity as key positive influences for using TA.⁶² However, unlike our study, where leadership engagement was perceived as a strong positive driver of TIBA implementation, Moucheraud et al. reported it as a mixed factor with both weak positive and negative influences on TIBA implementation.⁶² As a building block of the WHO health system framework,⁶³ leadership plays a critical role in facilitating or hindering the implementation of new healthcare interventions. It may vary depending on the local context or structure of the healthcare system. Strong leadership engagement can drive motivation, mobilize and allocate resources, and ensure strategic alignment with organizational goals.⁶⁴ Our study adds evidence to the existing literature on barriers to implementing the TIBA strategy by identifying key CFIR constructs. We found available resources, structural characteristics, health system context, and gaps in policies, programs, and guidelines as key barriers to implementing TIBA. These findings align with recent systematic reviews conducted on barriers to the implementation of cervical cancer preventive services in LMICs.^{12,60,61}

A key finding in our study was the disconnect between the national and health facility-level perceptions of readiness to implement TIBA. The national-level respondents reported positive developments related to the CFIR constructs on the availability of resources and structural characteristics. These included comprehensive provider training conducted on cancer screening and treatment, incorporation of cervical cancer activities into the existing programs to improve efficiency and access, and the availability of information, education, and

communication (IEC) materials. In contrast, the health facility level participants continued to face significant challenges to successful implementation driven by shortages of trained staff, inadequate space, lack of equipment and essential commodities such as gloves, speculums, and acetic acid, and service integration challenges hindering access to cancer preventive services. This disconnect across system levels can lead to compromised care. Our findings mirror those of Paine et al., who used the Viable Systems Model (VSM) to explore health system disconnect in a specialist clinical service in New Zealand.⁶⁵ To address these issues, it is imperative to align strategic goals with the realities on the ground. Focused strategies such as cross-level conversations, implementation monitoring and evaluation, and equitable access to resources are necessary to ensure national-level priorities are effectively implemented at the sub-national (county) and facility levels.

The construct of health system architecture, specifically related to workforce gaps, procurement delays, and limited funding for cervical cancer preventive services, was a strong barrier to the effective implementation of TIBA. Participants in our study reported frequent staff changes without timely replacement, which led to disruptions in service delivery. Human resources represent a key health system pillar that is critical to delivering high-quality healthcare and achieving sustainable development goals.^{66,67} Staff redeployment affects healthcare system functioning and subsequently impacts patient care through loss of investment in human capital, reduced quality of care, and increased burden on remaining staff.^{68,69} The TIBA strategy relies heavily on skilled providers for screening (VIA) and treatment (thermal ablation); any personnel changes compromise timely and effective care. Healthcare organizations invest heavily in training to ensure a competent workforce for optimal patient care. Staff redeployment loses the value of the training investment in skill development, resulting in compromised care. Ministries of Health can address these gaps by collaborating with multiple stakeholders to conduct skill assessments that match the right staff to the right position before redeployment. In addition, onboarding and ongoing training targeting skill development for redeployed staff may help maintain competence across provider cadres in dynamic health systems.^{68,70} Respondents also reported that lengthy and unpredictable procurement processes contributed to shortages of essential commodities for cervical cancer screening, including gloves and acetic acid. Implementing TIBA is stymied if the commodities necessary for screening are unavailable. Health facility managers must prioritize the inclusion of cervical cancer commodities in annual budgetary planning and simultaneously strengthen procurement processes by supporting evidence-based forecasting of demand for screening and treatment supplies. Strengthening the internal tracking systems to monitor stock levels can help prevent shortages.⁷¹ Notably, these challenges in human resources, inadequate funding, and logistical and supply chain highlighted above are not unique to Kenya; they have also been reported in similar contexts such as Rwanda, Nigeria, Ethiopia, and Malawi.^{60,71–73}

Client recruitment for cervical cancer screening and treatment at the facility level was identified as a barrier to effective TIBA implementation, specifically in faith-based health facilities. Faith-based healthcare facilities and public health facilities recruitment varied, with faith-based facilities excelling in outreach efforts in the community. In contrast, public health facilities attracted more clients through routine site-level service provision and in-reach activities (recruitment from hospital wards or other service areas). Fewer women sought care at faith-based health facilities because they 1) charged higher fees for cervical cancer screening and treatment and 2) did not offer family planning services (a key entry point for cervical cancer screening at public sector facilities). Although previous studies have reported that faith-based facilities have higher patient satisfaction with services and are perceived to provide quality

care, these organizations often rely on user fees because they lack financial support from the government.^{76–80} In contrast, public hospitals serve a larger proportion of their communities, especially socioeconomically disadvantaged individuals, as services are more affordable and accessible.⁸¹ Better coordination and service sharing across faith-based and public health facilities could support the successful implementation of TIBA. For example, leveraging the outreach recruitment capabilities of faith-based health facilities with the improved accessibility and cost of treatment at public facilities could create a synergistic system whose sum is greater than its parts. Collaborative planning and communication between the management of facilities and resource sharing could support integrated service delivery and ensure a broader and more sustainable continuum of cervical cancer screening and treatment.

Significant progress has been made over the years to combat HIV, cervical cancer, maternal and infant morbidity, and mortality with support from implementing partners and donors. However, silos have been created through these efforts, which have weakened the entire healthcare system.^{82,83} Participants in our study reported the need to balance program priorities driven by differing implementing partners. This lack of donor coordination was noted as an obstacle to effectively implementing TIBA. Participants highlighted negative sequelae from these siloes, including that some implementing partners only provided cervical cancer commodities for HIV-infected women and health worker discontent and demotivation was driven by pay differentials between program staff (who received supplements from implementing partners) and public health facility staff. Siloes within the health systems pose barriers to quality care and result in inefficient use of limited resources.^{82,84} Barr et al. similarly observed inefficiencies in the health system in Sierra Leone, attributing them to partner- and donor-driven vertical /siloed programs that operate in isolation from the broader health system.⁸⁵ To achieve optimal outcomes in implementing cervical cancer prevention strategies like TIBA, collaborative efforts between the MOH and implementing partners are necessary to ensure goal alignment. By adopting a more integrated, system-wide approach, stakeholders can avoid the creation of such inefficiencies within the health system and ensure equitable and efficient use of resources for sustainable cervical cancer prevention efforts.

Table 3 below summarizes how these key findings impact various aspects of TIBA implementation and offers guidance for other settings planning to adopt the strategy.

TABLE 3. SUMMARY OF KEY FINDINGS AND IMPLICATIONS

	Key Findings	Implications for TIBA Implementation	Guidance for other LMIC Settings
1	Relative advantage, cost, and complexity of thermal ablation	The relative advantages of thermal ablation, simplicity, and the potential for low maintenance requirements support its adoption	Consider the nationwide rollout of TA to overcome logistical challenges associated with cryotherapy
2	Disconnect between the national and health facility-level perceptions on readiness to implement TIBA	Misalignment in readiness at different levels can lead to implementation bottlenecks	Establish regular cross-level communication and monitoring to ensure strategic alignment
3	Leadership engagement	Strong leadership support facilitates implementation through motivation and resource mobilization	Identify point persons/champions at all health systems levels to drive implementation

4.	Structural and resource limitations, workforce gaps, and procurement delays	Lack of trained staff, essential commodities, and adequate space is a precursor to TIBA for implementation failure	Targeted investments in capacity building, staff retention, and essential commodities Streamline procurement services for cervical cancer screening services
5.	Client recruitment challenges	High out-of-pocket costs reduce service uptake among clients in faith-based/ private health facilities	Promote cross-referrals and service integration between faith-based and public health facilities
6.	Siloed and programmatic misalignment between implementing partners and the MOH	Misaligned priorities can lead to inefficient use of resources and demotivation among staff	Promote coordination between implementing partners and the MOH to integrate activities that align with implementing partners

Our study has two limitations. First, we did not consistently obtain relevant provider participant characteristics, such as years of experience with cervical cancer preventive services and familiarity with the use of thermal ablation for same-day treatment. The lack of this detailed participant data may limit our ability to fully understand how these factors influenced the perspectives shared, thus potentially limiting the interpretation of our findings. Secondly, the questions assessing constructs related to the intervention characteristics domain focused primarily on comparing thermal ablation with other treatment modalities rather than evaluating the comprehensive single-visit screen-and-treat approach with thermal ablation (SV-SAT+TA). As a result, insights into the intervention characteristics domain's constructs may not fully capture perceptions of the overall strategy.

We obtained data from multiple stakeholders, including policymakers, health facility managers, and frontline providers offering reproductive health services across various health facility levels, providing a comprehensive understanding of the implementation context. This strengthens our findings' robustness and applicability to policy and practice, making them more transferable to the Kenyan health context and other LMICs.

Conclusion

This study aimed to identify implementation determinants of TIBA for cervical cancer prevention before the implementation trial, aiming to increase adoption. Participants highlighted key factors such as leadership engagement and the relative advantages of thermal ablation within the single-visit, screen, and treat approach. Notably, the lower start-up and maintenance costs and thermal ablation's lower complexity than cryotherapy emerged as critical benefits. However, a lack of essential commodities for screening and treatment constrained human resources, and logistical and supply challenges emerged as drivers of implementation failure. Reducing silos within the healthcare system and fostering synergy between different health facility levels and management structures is crucial for strengthening the health system. A coordinated, integrated, system-wide approach involving all stakeholders is critical to ensuring the successful implementation of TIBA.

Chapter 3: Applying FRAME-IS to Characterize Provider-led Adaptations to a Cervical Cancer Prevention Intervention in Kenya

Introduction

Integrating evidence-based implementation strategies in real-world settings characterized by complex contextual realities is often challenging. This complexity is heightened by misaligned organizational priorities and constrained resources, often necessitating modifications or adaptations.⁸⁶ Adaptations are deliberate alterations to an intervention or an implementation strategy aiming to achieve fit within a context while maintaining fidelity to the core components.^{87,88} Evidence-based interventions and strategies are often adapted, adopted, or abandoned based on various factors, including indications of low effectiveness, emerging barriers and facilitators, and other multi-level influences.⁸⁹⁻⁹¹ Therefore, documenting and reporting strategy adaptations is critical to providing insights into what is more or less important for enhancing strategy effectiveness and sustainability, providing a foundation for replication in similar contexts.^{86,92-94}

While we know why adaptations occur,^{95,96} less is understood about their evolution, underlying patterns, and their long-term impact. These knowledge gaps limit our ability to learn from real-world implementation to optimize strategies for scale-up. This challenge is especially evident in cervical cancer prevention. Despite the availability of effective preventive interventions, the burden of cervical cancer remains on the rise in low- and middle-income countries⁹⁷ due to inconsistent implementation of these preventive measures, primarily attributed to limited resources and infrastructure.^{98,99} Although most of these interventions have demonstrated success, there is limited evidence concerning context-specific adaptations made to enhance their fit and impact on clinical and implementation outcomes. This challenge is not unique to cervical cancer prevention interventions but extends to several effectiveness and implementation trials.^{87,100,101}

Existing tools, such as the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS), among others, provide a structured process for tracking strategy adaptations.^{87,100,102} FRAME-IS has been used to track adaptations to strategies for implementing mHealth interventions,¹⁰³⁻¹⁰⁵ pediatric guidelines, and mental health interventions,^{92,93,103,106} yet its application remains limited in the context of cervical cancer prevention. This emphasizes the need for more empirical work to understand how strategy adaptations influence implementation.

To address these gaps, we applied FRAME-IS to capture and disseminate strategy adaptations made during the implementation of a single-visit, screen-and-treat approach with thermal ablation (SV-SAT+TA) for cervical cancer prevention in Kenya. The SV-SAT+TA is a bundled evidence-based intervention (EBI) composed of visual inspection with acetic acid (VIA) and same-day treatment with thermal ablation being implemented through a stepped-wedge cluster randomized trial in 10 health facilities in Kenya.¹⁰⁷⁻¹¹⁰ Henceforth, "TIBA," a Swahili word for treatment, will represent the single-visit, screen-and-treat approach with thermal ablation. We report how FRAME-IS was used to document strategy adaptations within TIBA, providing insights necessary for its optimization and scale-up within the Kenyan health system.

Methods

Study setting and design

This longitudinal sub-study characterizing adaptations to implementation strategies is nested within a larger hybrid type III implementation trial aiming to develop and test implementation strategies for TIBA to enhance cervical cancer screening and treatment of precancerous lesions in Kenya (NCT05472311).²³ TIBA was implemented across 10 health facilities in Kenya, using a three-wave stepped wedge design.

The reproductive health facilities implementing TIBA are medium to larger in size, i.e., Levels four and five,^{111,112} and are located in Kiambu, Embu, and Murang'a Counties in Kenya.

Conceptual Framework

The Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies was employed in this sub-study to assess changes in TIBA implementation over time. FRAME-IS provides a structured, systematic approach to documenting adaptations and modifications to implementation strategies, promoting consistent reporting.¹¹³ The framework is composed of seven modules, four of which are considered core (Figure 3). The core modules cover four main areas: a brief description of the implementation strategy (Module 1), what was modified, such as content, evaluation, content, or training (Module 2), the nature of the modification (Module 3), and the goal and level of the rationale for the modification (Module 4).

FIGURE 3. FRAME-IS CORE MODULES

Module 1: BRIEFLY DESCRIBE THE EBP, implementation strategy, and modification(s) The EBP being implemented is: _____ The implementation strategy being modified is: _____ The modification(s) being made is/are: _____ The reason(s) for the modification(s) is/are: _____	Module 3: What is the NATURE of the content, evaluation, or training modification? ☐ Tailoring/weakening/refining ☐ Changes in packaging of materials ☐ Adding elements ☐ Removing/skipping elements ☐ Shortening/condensing (pacing/timing) ☐ Lengthening/ extending (pacing/timing) ☐ Substituting ☐ Reordering of implementation modules or segments ☐ Spreading (breaking up implementation content over multiple sessions) ☐ Integrating parts of the implementation strategy into another strategy (e.g., selecting elements) ☐ Integrating another strategy into the implementation strategy in primary use (e.g. adding an audit/feedback component to an implementation facilitation strategy that did not originally include audit/feedback) ☐ Repeating elements or modules of the implementation strategy ☐ Loosening structure ☐ Departing from the implementation strategy ("drift") followed by a return to strategy within the implementation encounter ☐ Drift from the implementation strategy without returning (e.g., stopped providing consultation, stopped sending feedback reports) ☐ Other (write in here): _____	Module 4, Part 1: What is the GOAL? ☐ Increase reach of the EBP (i.e. the number of patients receiving the EBP) ☐ Increase the clinical effectiveness of the EBP (i.e. the clinical outcomes of the patients or others receiving the EBP) ☐ Increase adoption of the EBP (i.e. the number of clinicians or teachers using the EBP) ☐ Increase the acceptability, appropriateness, or feasibility of the implementation effort (i.e. improve the fit between the implementation effort and the needs of those delivering the EBP) ☐ Decrease costs of the implementation effort ☐ Improve fidelity to the EBP (i.e. improve the extent to which the EBP is delivered as intended) ☐ Improve sustainability of the EBP (i.e. increase the chances that the EBP remains in practice after the implementation effort ends) ☐ Increase health equity or decrease disparities in EBP delivery ☐ Other (write in here): _____
Module 2: WHAT is modified? ☐ Content Modifications made to content of the implementation strategy itself, or that impact how aspects of the implementation strategy are delivered ☐ Evaluation Modifications made to the way that the implementation strategy is evaluated ☐ Training Modifications to the ways that implementers are trained ☐ Context Modifications made to the way the overall implementation strategy is delivered. For Context modifications, specify which of the following was modified: ☐ Format (e.g. group vs. individual format for delivering the implementation strategy) ☐ Setting (e.g. delivering the implementation strategy in a new clinical or training setting than was originally planned) ☐ Personnel (e.g. having the implementation strategy be delivered by a systems engineer rather than a clinician/facilitator) ☐ Population (e.g. delivering the implementation strategy to middle managers instead of frontline clinicians) ☐ Other context modification: write in here: _____	Module 3, OPTIONAL Component: Relationship to fidelity/core elements? ☐ Fidelity Consistent/Core elements or functions preserved ☐ Fidelity Inconsistent/Core elements or functions changed ☐ Unknown	Module 4, Part 2: What is the LEVEL of the rationale for modification? ☐ Sociopolitical level (i.e. existing national mandates) ☐ Organizational level (i.e. available staffing or materials) ☐ Implementer level (i.e. those charged with leading the implementation effort) ☐ Clinician or Teacher level (i.e. those implementing the EBP) ☐ Patient or Other Recipient level (i.e. those who will ideally benefit from the EBP) ☐ Other (write in here): _____

Adapted from CJ Miller, 2021

Three optional/supplementary modules (Figure 4) provide additional details, including modification timing and whether the modification was planned or reactively adopted (Module 5), which participants were involved in the decision to modify (Module 6), and the extent or spread of the modification (Module 7).

We selected FRAME-IS because it is among the first and most widely employed tools developed to track adaptations to implementation strategies. Our data collection tool was informed by FRAME-IS modules 1 to 5, and we included additional sections to capture contextual factors, thus providing a comprehensive understanding of each adaptation.

FIGURE 4. FRAME-IS SUPPLEMENTARY MODULES

Module 5, Part 1: WHEN is the modification initiated? ☐ Pre-implementation/planning/pilot phase ☐ Implementation phase ☐ Scale up (i.e. when the EBP is being spread to additional clinics/settings within your system) ☐ Maintenance/Sustainment ☐ Other (write in here): _____	Module 6: WHO participates in the decision to modify? ☐ Political leader(s) ☐ Program Leader, Manager, or Administrator ☐ Funder ☐ Implementer or implementation strategy expert ☐ Researcher ☐ Clinician(s) or teacher(s) who are being asked to use the EBP being implemented ☐ Community members ☐ Patients or other recipients who will be the ultimate target of the EBP being implemented ☐ Other: write in here: _____	Module 7: How WIDESPREAD is the modification? (i.e. for whom/what is the modification made?) ☐ Individual patient or other recipient for whom the EBP is being implemented ☐ Group of patients or other recipients for whom the EBP is being implemented ☐ Patients or other recipients that share a particular characteristic (e.g. all patients from a specific language background) ☐ Individual clinician or teacher charged with implementing the EBP ☐ Clinic/unit ☐ Organization ☐ Network system/community ☐ Specific implementer/facilitator ☐ Implementation/facilitation team
Module 5, Part 2: Is modification PLANNED? ☐ Planned/Proactive (proactive adaptation) ☐ Planned/Reactive (reactive adaptation) ☐ Unplanned/Reactive (modification) ☐ Other (write in here): _____	Optional: Indicate who makes the ultimate decision: _____	

Adapted from CJ Miller, 2021

Data Collection

FRAME-IS guided the development of an Excel-based tracking tool for documenting adaptations to TIBA strategies in response to implementation barriers. These barriers to implementing TIBA and potential implementation strategies were identified during a baseline stakeholders' workshop and through formative qualitative interviews with providers and health facility managers at each of the 10 health facilities. Each health facility was then asked to prioritize three to five key barriers to address during the implementation of TIBA, based on feasibility assessment to ensure the chosen strategies were practical and achievable within their context.

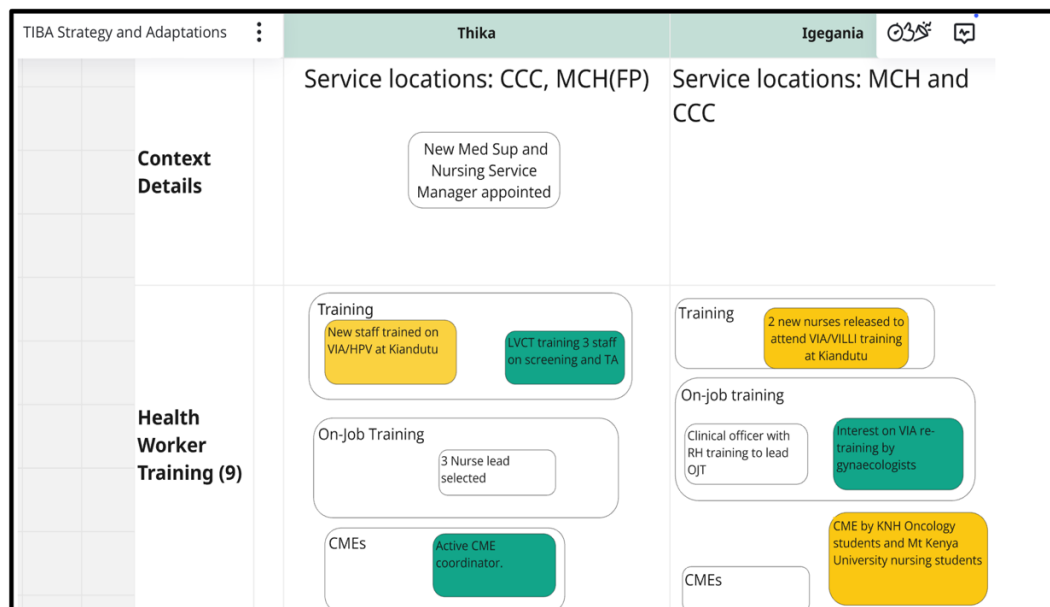
From these discussions, a list of 18 potential strategy options (Appendix) was generated collaboratively by the facility representatives and subsequently refined by the research team. Health facilities then applied these strategy options to address the specific barriers prioritized at each site.

Data was collected monthly between March 2023 and September 2024 across the 10 health facilities, with each health facility being observed for six consecutive months during the implementation phase. The data collection occurred during technical assistants' support visits, phone calls, and monthly meetings with health providers and their managers across the three implementation waves. The data was entered into the Excel-based tracking sheet. The data entered entailed whether the strategy component was ultimately adapted, adopted, or abandoned, a description of each adaptation, adaptation type, by whom, when it was initiated, whether it was ad hoc or planned, and the goal of the adaptation. We elicited feedback on adaptations over time through discussions with the providers and health facility managers. Additional data on contextual factors related to the strategy adaptation, barriers, and facilitators were also collected. We created a Miro board (<https://miro.com>) to synthesize findings and compare site adaptations. This visual whiteboard captures strategy components (clear boxes), site-specific contextual factors (green), and adaptations (yellow) that were updated monthly (Figure 5). Adaptations were considered adopted if used at two consecutive observation points.

An extraction tool aligned with the FRAME-IS modules with modifications to module 2 (What was modified-context category) of the framework to expand the categories of the adaptation types (education, resources, data management, communication, service reorganization, and community engagement) was applied by five authors (HAF, VI, BMK, AK, and SN) to systematically extract and organize the data for analysis. During the extraction phase, the five

authors convened two brief meetings to assess the consistency and accuracy of their interpretations of their characterization of the adaptations. Additionally, we categorized the adaptations into two periods, i.e., early adaptations (1-3 months after the site initiated the intervention) and late adaptations (from months 4-6).

FIGURE 5. MIRO BOARD



A section of the TIBA Miro board

The extracted data was reviewed by an independent coder (MC) to assess the consistency and reliability of the coding process. Three discussion meetings were held between the lead author, the independent coder, and one of the project's investigators (SG) to review convergence, reconcile discrepancies, and reach a consensus on the characterization of the adaptations.

Analysis

We used descriptive statistics to summarize the study sites' characteristics and describe trends and patterns in adaptation types over time and across the health facility levels. Adaptation rates were computed per facility per 3 or 6-month period. Due to the small counts of adaptations in our analysis, we used an exact Poisson test to compare whether the adaptation rates varied across the health facility level, which we grouped as level four vs five. The test produces a rate ratio, a 95% confidence interval, and a p-value. For the same reason, we also applied the exact Poisson test to compare whether the adaptation rates significantly changed across the two time periods (early vs late). However, the exact Poisson test does not take into account the pairing in the data across time points and is, therefore, conservative. Analyses were performed using R version 4.5.0 and "poisson. exact" R package.

Ethical considerations

Ethics approval was granted by the Scientific and Ethical Review Committee of the Kenya Medical Research Institute (SERU-KEMRI No. 4403) in Nairobi, Kenya, and the Human Subjects Institutional Review Board (STUDY00014200) at the University of Washington, Seattle, USA.

Results

Overall, 70% of health facilities were Level four (n=7), and 30% were Level five (n=3). Most (80%, n=8) of the health facilities were located in urban areas and were publicly managed (70%, n=7). Two hundred and sixty health providers, including nurses, clinical officers, and gynecologists, were trained on cervical cancer screening using VIA and treatment with thermal ablation, with 58% (n=152) of the providers from Level four health facilities. Approximately 18%(n=46) of the providers trained offered screening and treatment services during the study period across both site levels. Table 4 provides a summary of the characteristics of the participating health facilities.

TABLE 4. CHARACTERISTICS OF PARTICIPATING CLINICS

Characteristic	All (n, %)	Level Four (n, %)	Level Five (n, %)
No. of health facilities	10 (100%)	7(70%)	3(30%)
Management Type			
Government	7(70%)	4(57%)	3(100%)
Faith-based	3(30%)	3(43%)	0(0%)
Location			
Urban	8(80%)	5(71%)	3(100%)
Rural	2(20%)	2(29%)	0(0%)
No. of providers trained in offering Cervical Cancer screening and treatment (TIBA)	260(100%)	152(58%)	108(42%)
No. of providers offering Cervical Cancer screening and treatment (TIBA)	46(100%)	24(52%)	22(48%)

We had one level three facility, which was grouped with level four facilities based on comparable characteristics.

Module 2: What was modified

We modified the category names of module 2 of FRAME-IS to support a more tailored categorization of the adaptation types seen in our work. A total of 28 adaptations were identified, of which two adaptation types were unique. Over half of the adaptations (57%, n=16) were related to education, targeting patients or providers, followed by resource-related adaptations (21%, n=6), for example, changes to essential commodity acquisition. Table 5 provides the detailed distribution of the adaptation types, with the education category representing the most significant proportion.

TABLE 5. SUMMARY OF ADAPTATION TYPES

FRAME-IS Categories	Adaptation Types	Count	Proportion	Examples of adaptations
Training	Education	16	57%	New staff trained on screening and treatment at nearby health facility
Context	Resources	6	21%	Essential commodities like speculums supplied by implementing partners due to procurement delays.
Context	Service Reorganization	4	14%	Services moved from the MCH clinic to the outpatient department
Context	Community Engagement	1	4%	In-reach activity supported by implementing partners
Training	Data Management	1	4%	SOPs developed by implementing partners to guide documentation in the register

FIGURE 6. HEAT MAP VISUALIZING ADAPTATION TYPES ACROSS HEALTH FACILITIES

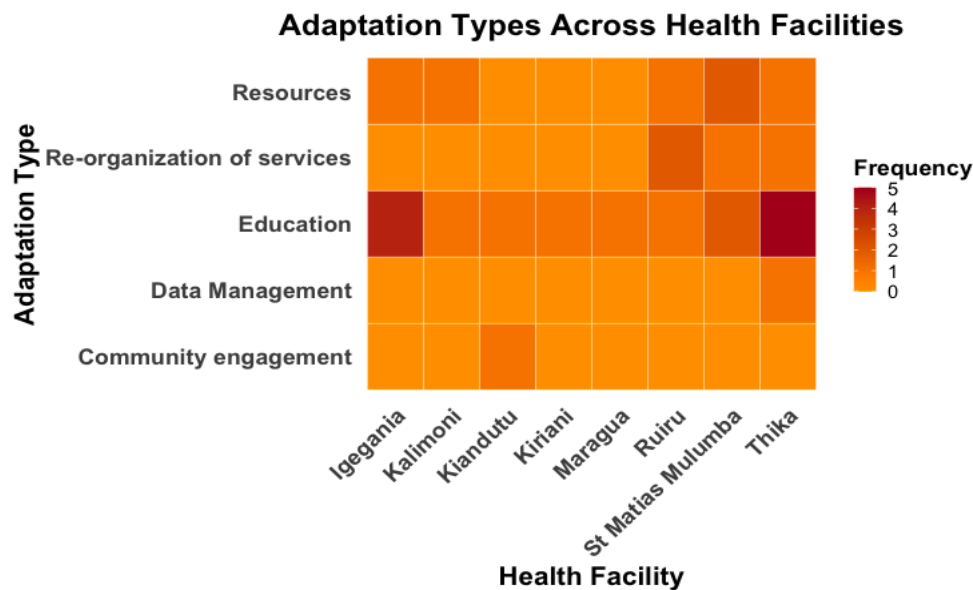


Figure 6 visualizes the distribution of adaptation types across the 8 health facilities that made adaptations. Overall, there is a variation in the adaptation types, suggesting that some facilities were more focused on certain adaptations than others.

Module 3: Nature of Adaptations

Almost half of the adaptations (46%, n=13) focused on tailoring provider education related to cervical cancer. For example, new staff who missed training sessions at their own facility were allowed to attend training on cervical cancer screening at nearby health facilities to increase the adoption of the TIBA intervention at their facilities. The training strategy was tailored depending on the staffing challenges at each site. Furthermore, many educational adaptations were enhanced by adding new components (29%, n=8), including the creation of alternative patient pathways for individuals ineligible for thermal ablation and supplementary resources such as links to the International Agency for Research on Cancer (IARC) that offered in-depth information on cervical cancer to bolster provider competency.

Module 4: Goals and Levels for Modifications

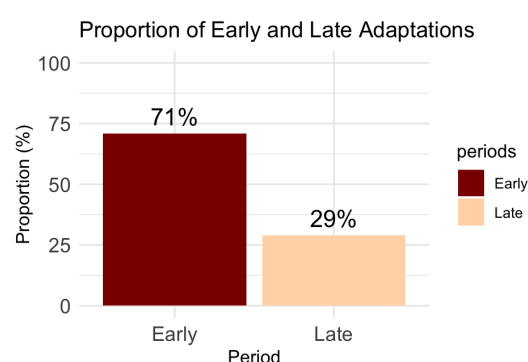
Of the 28 adaptations, 43% (n=12) aimed to increase the adoption of TIBA by expanding the number of clinicians offering cervical cancer screening with VIA and treatment with thermal ablation through provider training. An additional 36% (n=10) focused on increasing reach, i.e., the number of patients receiving TIBA. This was achieved by increasing the number of cervical cancer service delivery points, providing essential screening commodities, and targeting in-reach and outreach activities. Eighteen percent (n=5) targeted improving fidelity through supportive supervision, and one (3%) adaptation aimed to improve clinical effectiveness.

Most adaptations (46%, n=13) targeted the organizational level, emphasizing the leadership role in resource mobilization to ensure continuity in cervical cancer delivery. Approximately 39% (n=11) targeted the clinician level, addressing gaps in provider skills, which aligned with the goal of increasing the number of providers implementing TIBA. Adaptations at the patient level were less frequent (14%, n=4), but those focused on expanding TIBA reach.

Module 5: Timing of the Modifications and their Level of Planning

All the adaptations occurred during the implementation phase, and the majority occurred in the early phase (71%, n=20) (Figure 7). Over half of the adaptations (57%, n=16) were planned. A substantial proportion of unplanned adaptations were mainly implemented in response to clinical training needs among new staff and delays in the procurement of essential commodities. 75% (n=21) of adaptations were adopted, and none were abandoned. However, given our definition of an adopted adaptation (two consecutive observation points), the majority (seven) of the adaptations not adopted after the first round of implementation were one-time ad-hoc changes mainly intended to address skill gaps among providers of cervical cancer screening and treatment.

FIGURE 7. PROPORTION OF ADAPTATION TIMING



Change in adaptation rates across time and across health facility levels

Table 6 below summarizes adaptation rates across time and Levels four and five health facilities.

TABLE 6. CHANGE IN ADAPTATION RATES ACROSS TIME AND ACROSS HEALTH FACILITY LEVELS

Adaptation Types	Over Time		By level
	Month 1-3 (rate per 3-months)	Month 4-6(rate per 3-months)	Months 1-6 (rate per 6-months)
Resources			
Level V	1 (0.33)	0 (0.00)	1 (0.33)
Level IV	3 (0.43)	2 (0.29)	5 (0.72)
Total	4 (0.40)	2 (0.20)	6 (0.60)
Data Management			
Level V	1 (0.33)	0 (0.00)	1 (0.33)
Level IV	0 (0.00)	0 (0.00)	0 (0.00)
Total	1 (0.10)	0 (0.00)	1 (0.10)
Education (Provider and Patient)			
Level V	2 (0.67)	3 (1.00)	5 (1.67)
Level IV	10 (1.43)	1 (0.14)	11 (1.57)
Total	12 (1.20)	4 (0.40)	16 (1.60)
Community Engagement			
Level V	0 (0.00)	0 (0.00)	0 (0.00)
Level IV	0 (0.00)	1 (0.14)	1 (0.14)
Total	0 (0.00)	1 (0.10)	1 (0.10)
Reorganization of services			
Level V	1 (0.33)	0 (0.00)	1 (0.33)
Level IV	2 (0.29)	1 (0.14)	3 (0.43)

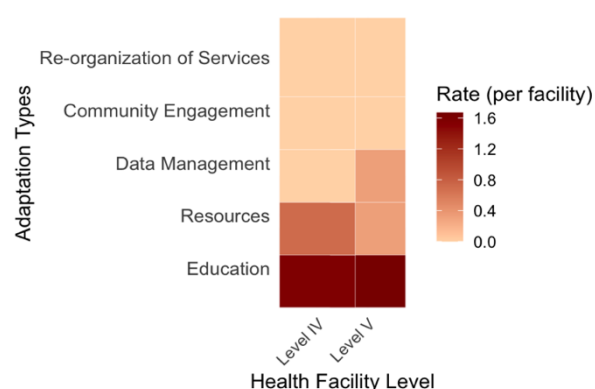
Total	3 (0.30)	1 (0.10)	4 (0.40)
Total			
	Over Time		By level
	Month 1-3	Month 4-6	Months 1-6
Level V	5 (1.67)	3 (1.00)	8 (2.67)
Level IV	15 (2.14)	5 (0.71)	20 (2.85)
Total	20 (2.0)	8 (0.80)	28 (2.80)
p-value	0.02		0.89

Key: *n* (adaptation rate per clinic per 3 or 6-month period as indicated), *n*=10 (total no. of health facilities), *n*=7 (no. of health facilities in level four), *n*=3 (no. of health facilities in level five). Level four contains one level three health facility

We observed an overall rate of 2.67 adaptations per facility over a six-month period in Level five facilities, compared to 2.85 adaptations per clinic over the same period in Level four facilities (rate ratio = 0.93 (95% CI = 0.39-2.08, *p* = 0.89), indicating no statistically significant difference in adaptation rates between the facility levels. Figure 8 visualizes adaptation rates across health facility levels.

During the early phase, we observed an overall rate of 2.0 adaptations per facility, compared to 0.80 adaptations per facility in the late phase (rate ratio =2.50, 95% CI = 1.12–6.02, *p* = 0.02), indicating a statistically significant decrease in adaptations over time.

FIGURE 8. ADAPTATION RATES COMPARING LEVEL FOUR AND FIVE HEALTH FACILITIES



Discussion

Our study provides key insights into patterns of strategy adaptations necessary to enhance fit and optimize cervical cancer prevention, particularly in LMICs. Guided by FRAME-IS, we identified 28 adaptations, most of which focused on provider and patient education, followed by resource adaptations. The primary goals of these adaptations were to increase provider adoption of TIBA and reach (the number of women being screened and treated for precancerous lesions), with most of the adaptations occurring in the early phase of implementation and being planned. Adaptation rates were consistent across health facility levels, though significantly higher in the early implementation phase, highlighting early enthusiasm to enhance strategy fit. Education-related adaptations aimed at tailoring strategies to staff needs and local contexts, and they remained common across the time periods (early and late periods).

We observed an overall rate of 2.0 adaptations per facility in the early phase, compared to 0.80 adaptations per facility in the late phase (rate ratio =2.50, 95% CI = 1.12–6.02, *p* = 0.02),

indicating a statistically significant decrease in adaptations over time. Early adaptations occur as initial challenges and misalignments with context are more apparent, resulting in proactive adjustments to improve the fit of an intervention or strategy.¹¹⁴ For example, in our study, challenges such as high provider workload, staff transfers between departments and clinics, and onboarding new staff are findings reported in the literature^{115–117} that led to the tailoring of provider education. These adaptations, occurring early in the implementation phase, primarily focused on the action target (health providers) by offering flexible training opportunities at nearby health facilities and additional mentorship from implementing partners to ensure adoption, fidelity to the clinical task, and broader use (reach). Addressing challenges through tailored context-specific adaptations ensures better alignment with the contextual realities, enhancing strategy effectiveness and sustainability.^{118,119} We hypothesize that the frequent adaptations during the early phase were necessary as TIBA fit within the health facility setting. Over time, these adaptations were successfully integrated into the health facility's routine, marking a stabilization phase during the later phase, hence the decline in the adaptation rate over time. It is also possible that there was a decline in organizational enthusiasm.

We found no significant differences in the adaptation rates across the health facility levels. However, following Geng et al.¹²⁰ recommendation to consider the "dose" of an adaptation, tracking both the frequency and intensity of specific adaptations, such as provider education, could offer deeper insights into site-level variation that may otherwise go unrecognized.

Most of our adaptations were planned as recommended in the literature¹²¹ and targeted the organizational level. This allowed the health facilities to maximize the fit of the strategies through collaborative meetings and goal setting among key stakeholders, including frontline staff/implementers, health facility managers, and implementing partners, ensuring aligned priorities and resources. The approach minimized disruptions in service delivery, emphasizing the importance of meaningful stakeholder engagement in ensuring the success of an intervention.^{93,122,123}

Interestingly, two health facilities did not report any adaptations to the implementation strategies. Both were Level five health facilities located in urban areas and did not face challenges with essential commodities for cervical cancer screening, as they received support from larger implementing partners and procured these commodities through their health facilities, unlike the other sites. One of the facilities also provided training on cervical cancer screening and treatment to health providers in peripheral health facilities. This initiative aimed to reduce the number of women referred to their facility for screening and precancer treatment. It sought to increase the broader adoption of TIBA among providers and expand its reach within the region. Additionally, leadership support in these two facilities was evident, and a positive and receptive attitude was observed among providers offering cervical cancer preventive services. Perhaps these two health facilities, in addition to their leadership support, possessed a high level of adaptive capacity¹²⁴ and had a functioning system in place, possibly explaining the lack of strategy adaptations. While leaders from all the facilities were involved in the strategy development phase, contributions from these active leaders may have led to the strategy having better fit when introduced, so requiring less adaptation. Further exploration is

needed to examine how the clinical and implementation outcomes differed between these facilities and others with strategy adaptations.

Lessons learned when applying FRAME-IS

FRAME-IS was valuable in documenting and tracking adaptations to the TIBA strategy during the implementation phase. It provided a clear view of how TIBA was optimized within the various health facilities.

Determining whether an adaptation occurred was challenging when the original strategy implementation plan lacked sufficient detail. Proctor's recommendation for naming, defining, and operationalizing implementation strategies would help ensure consistency in documenting strategy adoptions and adaptations.

FRAME-IS does not provide guidance on adopted strategy adaptations. We defined "adopted adaptations" as those changes that were consistently implemented over two months. We also incorporated a section in the data collection tool to capture emerging barriers and facilitators, providing actionable guidance for strategy adjustments.

FRAME-IS characterizes adaptations into four main categories, i.e., context, content, training, and evaluation, as outlined in module 2. However, during preliminary coding, we encountered challenges applying these categories, as they were not mutually exclusive, and the terminology used was unfamiliar to Technical Assistants and would subsequently be challenging to health providers during dissemination. To address this, we expanded the context and training adaptation types into six categories: community engagement, data management, resources, education, communication, and reorganization of services, which were terminologies familiar and easily interpreted among the health providers in our context. Despite these revisions, we still faced challenges coding certain adaptations. For example, patient education can logically fit under the "community engagement" and "education" categories. Similar challenges have been reported by other authors^{93,103} who addressed these challenges by incorporating additional modules to provide in-depth information on the specific adaptations, implementing a numbering system to map changes to other modules, and adding supplementary coding categories. These refinements can be considered by the authors of FRAME-IS if there is a future update to the framework.

This study had limitations. First, we have not assessed the impact of these adaptations on the implementation and clinical outcomes, which would have provided insights into which adaptations were effective in optimizing TIBA. However, this does not undermine the validity of our findings, as we provided useful information on the adaptation types and examined the trends and patterns of these adaptations during TIBA implementation. Secondly, the study's technical assistants obtained information on the adaptations through monthly conversations with providers and their managers, which may have potentially introduced recall and social desirability biases. Finally, due to time constraints, we could only track adaptations during the active implementation phase, not the maintenance phase. Perhaps tracking adaptations beyond the implementation phase would have provided additional insights into the sustainability patterns of the adaptations.

Strengths

FRAME-IS has previously been applied in Kenya to track adaptations to a mobile health strategy¹⁰³; however, our study is the first to report its application in the context of cervical cancer preventive intervention. We prospectively collected data on these adaptations, offering valuable learning opportunities on optimizing the framework's use while making real-time adjustments to the data collection tool to enhance data quality. We compared adaptation rates across health facility levels and examined how these adaptations evolved. This comparison provided useful information on immediate adaptations needed to support the successful implementation of TIBA.

Conclusion

We demonstrate the capability of FRAME-IS in documenting and tracking strategy adaptations, highlighting the critical role of education adaptations as the most frequently needed modifications to optimize cervical cancer preventive interventions. Over time, we observe a reduction in these adaptation rates, indicating a potential stabilization or strategy fit. Based on our experiences applying the framework, we offer recommendations targeting refinements to module 2 categories, adding new modules to link strategy adaptations to outcomes, and improving data capture of contextual factors influencing the implementation of the adapted strategies.

Future studies should focus on evaluating the impact of these adaptations on both implementation and clinical outcomes, exploring the “dose” of adaptations, and determining an ideal duration for tracking them. Furthermore, establishing an “adaptome,” a knowledge base, or a collection of implementation strategy adaptations[8,42] would allow the collection of contextualized data that can be easily adapted, facilitating scaling and replication of strategy adaptations in different settings.

Chapter 4: An evaluation of barrier-strategy matching for a cervical cancer prevention intervention in Kenya: A convergent mixed methods study

Introduction

Advances in cervical cancer prevention have significantly led to reductions in incidence and mortality, particularly in high-income countries.¹²⁶ However, the global burden remains substantial, with low- and middle-income countries (LMICs) bearing the greatest impact.^{98,127} In 2022, approximately 350,000 cervical cancer-related deaths were reported, 94% of which occurred in LMICs primarily due to limited availability and suboptimal utilization of preventive services such as Human papillomavirus (HPV) vaccination and screening.^{128–130} Therefore, context-specific implementation strategies are needed to effectively implement these evidence-based preventive interventions to reduce global inequities in cervical cancer prevention.¹³¹

Implementation strategies are key in ensuring improvement in the adoption, implementation, and sustainability of evidence-based interventions (EBIs).^{132,133} However, their impact is often limited by misalignment or a mismatch between the selected strategies and the barriers they are designed to address.^{134–136} Several implementation strategies have been employed to improve screening and precancer treatment uptake in cervical cancer prevention. These include educational interventions, the establishment of mobile clinics, and financial incentives, among others.^{137,138} Similar to other interventions, these strategies are frequently selected without a systematic approach, insufficient contextual understanding, and inadequate stakeholder engagement.^{139,140} As a result, resources may be wasted on ineffective strategies, and the intervention may fail to achieve its intended outcomes. This highlights a critical gap; there is limited evidence on whether deployed implementation strategies in cervical cancer prevention interventions actually address the barriers they are intended to overcome. As Mosquera et al. recommend, assessing the fit between barriers and strategies is essential to improving implementation effectiveness.¹⁴¹

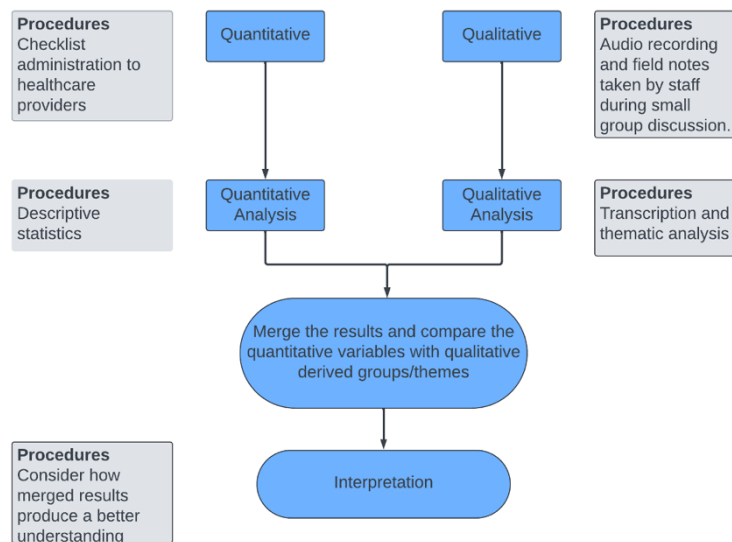
To address this gap, we evaluated whether the deployed implementation strategies addressed barriers to implementing the single visit, screen, and treat approach with thermal ablation (SV-SAT+TA) using a convergent mixed methods approach.

Methods

Study design and setting

To evaluate how well the implementation strategies address the pre-identified barriers to TIBA's implementation in Kenya, this longitudinal sub-study utilizes a convergent parallel mixed methods design (Figure 9).¹⁴² The rationale for this approach is rooted in the research question that seeks to determine whether the strategies matched the pre-identified barriers (quantitative) and to explore perspectives on how and why these barriers were addressed successfully, partially, or not at all, as well as contextual factors that influenced strategy implementation (qualitative). Barrier-strategy match was defined as the selection of implementation strategies most effective in addressing specific barriers to adopting the single-visit, screen, and treat approach with thermal ablation (SV-SAT+TA). This study's philosophical assumptions were guided by the pragmatic worldview.¹⁴³ The quantitative and qualitative data were collected at the same time to converge both data sets to understand the research question better. Equal weight was given to each data type (QUAN+QUAL), i.e., each data type was considered equally important for answering the research question.

FIGURE 9. CONVERGENT MIXED METHODS DESIGN



This sub-study, conducted in Kenya, is nested within the main trial that aims to develop and evaluate implementation strategies to inform nationwide scale-up of a single visit, screen-and-treat approach with visual inspection with acetic acid (VIA) and thermal ablation for sustainable cervical cancer prevention services.²³ TIBA, a Swahili word for “treatment,” is used for this trial to represent the single-visit, screen and treat approach with thermal ablation. TIBA is a cluster-randomized stepped wedge design being conducted across 10 reproductive health clinics in Kenya across three successive waves, each with an intensive phase lasting six months, followed by 18, 12, and 6 months of maintenance phases, respectively.²³ The Kenyan healthcare system is tiered, comprising six levels of care, from Level I (community health units, which are the smallest) to Level VI (national referral hospitals), designed to handle increasingly complex cases. TIBA is implemented across Levels III, IV, and V health facilities located in Kiambu, Murang’a, and Embu Counties, which are either managed by faith-based organizations or the Ministry of Health (MOH). The average monthly outpatient clinic attendance in Level III is approximately 2,500, in Level IV, 5,000-8,000, and in Level V, over 15,000.¹⁴⁴

Study participants

A purposive sample of health care providers offering cervical cancer prevention services at the 10 reproductive health clinics was included in the study. This sample comprised nurses, gynecologists, clinical officers, laboratory technologists, and health facility managers. Five providers, including the health facility managers, were recruited from each clinic by word of mouth and phone calls to participate in the assessment. However, the number of participants per facility ranged from 3 to 5 participants due to work-related commitments. In total, 40 participants participated in the assessment.

Study measures and data collection procedures

We utilized a structured survey that contained two sections: one assessing the extent to which the pre-identified barriers were addressed, and the other section capturing new barriers that emerged during the implementation process. The pre-identified barriers to the implementation of TIBA were identified during a stakeholders’ meeting before the roll-out of the trial. The participants in the stakeholders’ meeting included representatives of health care providers from the health facilities, county health management teams (CHMT), policymakers from the Ministry of Health (MOH), and representatives from the Kenya National Cancer Institute (NCI).

However, for this evaluation, only healthcare providers from the 10 health facilities were included, as they were directly involved in implementing the strategies.

Prior to the roll-out of TIBA, implementation strategies were matched to the barriers at the facility level. This process involved the health facility providers, in collaboration with the research team, selecting context-relevant barriers and strategies they considered feasible to implement.

The quantitative section required the participants to indicate whether each pre-identified barrier applied to their health facility and whether it was successfully, partially, or not addressed. Barriers were defined as follows:

Successfully addressed barriers: The barrier was initially present, but it was fully resolved or no longer hindered implementation, based on the participant's perception.

Partially addressed barrier: The barrier was one that was present, and the strategy applied reduced its impact, but did not fully eliminate it, as some challenges remained.

Not addressed: The strategy had little or no effect, and the barrier continued to impede implementation efforts.

This approach was also applied to the section capturing emerging barriers to TIBA implementation.

Upon completion of the quantitative phase, a small group discussion was immediately co-led by a technical assistant and a qualitative research assistant, both experienced in clinical and qualitative research, respectively. The small group discussions elicited participants' perspectives on how and why barriers were successfully, partially, or not addressed. These 50-minute discussions were conducted in English at the end of each implementation wave and were audio recorded.

Analysis

Quantitative

Descriptive statistics were used to summarize the characteristics of participating clinics using R software, with comparisons made between government-led and faith-based facilities. Pre-identified barriers reported by participants were ranked and compared across the two facility management types. For each barrier, we reported the proportion of respondents who perceived it as successfully addressed, partially addressed, or not addressed. To determine the overall classification for the barriers, we applied the majority "rule" approach, where barriers were classified as "successfully addressed," "partially addressed," or "not addressed" based on the response category by the majority of the respondents. This classification was then used to determine the overall barrier-strategy match by summing the number of barriers successfully, partially or not addressed across the sites. In a case where there was an equal rating between the categories, consensus on the classification was based on the review of the qualitative data and discussion between the lead author and the data collection team.

Flow diagrams were used to visually map the relationship between the reported barriers, corresponding implementation strategies, and the relevant WHO health systems Framework building blocks. This approach enabled the identification of key health systems domains targeted by the implementation strategies.

Qualitative

The qualitative data from each of the 10 facilities were transcribed verbatim. The framework analysis method^{145,146} was inductively applied by two authors (HAF and SCM) to identify emerging themes. This process consisted of seven stages: transcription, familiarization with the

data, coding, developing an analytical framework, applying the analytical framework, charting the data into the framework matrix, and interpretation. During the familiarization stage, the authors reviewed one transcript jointly and developed the analytic framework after discussing and agreeing on the codes. The remaining nine transcripts were divided between the two authors, who applied the subsequent stages of the framework analysis, including charting the data into the matrix and interpreting the results.

Integration of quantitative and qualitative data

Integration involved merging the results from both the quantitative and qualitative data after separate analysis, allowing for a comparison that provides a more comprehensive understanding than either the quantitative or qualitative results alone. At the interpretation and reporting stage, integration was achieved through a narrative approach. Where applicable, we will highlight any differences that may have emerged across various management types (government-led vs faith-based) to provide contextual nuance.

Ethical Consideration

This study received approval from the Scientific and Ethics Review Unit of the Kenya Medical Research Institute (SERU-KEMRI No. 4403) in Nairobi, Kenya, as well as the Human Subjects Institutional Review Board (STUDY00014200) at the University of Washington in Seattle, USA. All participants provided written informed consent to take part in the survey and interviews.

Results

We collected survey responses and conducted interviews with forty participants across 10 health care facilities. The majority of the health facilities (70%, n=7) were publicly managed. Among the forty participants, 77% were female (n=31), 95% (n=38) were frontline health care workers, with nurses representing the majority (78%, n=31) of healthcare providers offering cervical cancer preventive services. Table 7 provides a summary of the participant and clinic characteristics.

TABLE 7. PARTICIPANT DEMOGRAPHICS AND CLINIC CHARACTERISTICS

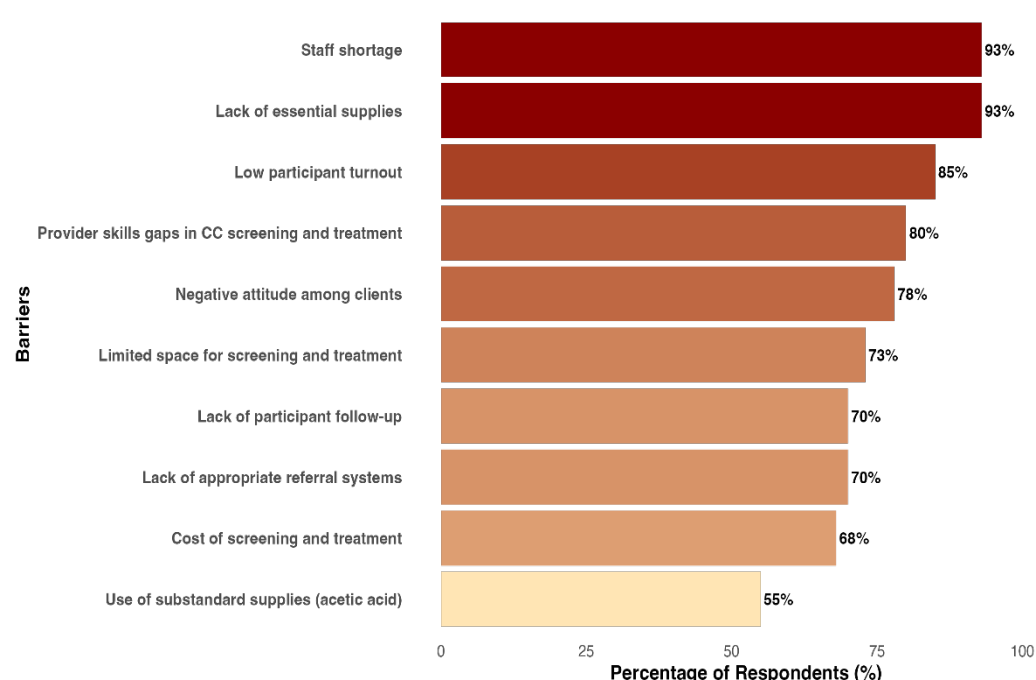
Characteristics	All (n, %)	Public/Government (n, %)	Faith-based (n, %)
No. of health facilities	10	7	3
Location			
Urban	8 (80%)	6 (86%)	2 (67%)
Rural	2 (20%)	1 (14%)	1 (33%)
No. of participants	40	29	11
Sex			
Male	9 (23%)	4 (14%)	5 (45%)
Female	31 (77%)	25 (86%)	6 (55%)
Cadres			
Nurses	31 (77%)	24 (80%)	7(70%)
Clinical Officers	6 (15%)	5(17%)	1(10%)
Medical Officers/Gynecologists	1(3%)	0	1(10%)
Laboratory Technologists	2 (5%)	1(3%)	1(10%)
Participant Roles			
Frontline healthcare worker	38 (95%)	28(97%)	10 (91%)
Health facility Manager	2(5%)	1(3%)	1(9%)

Quantitative Results

During the stakeholders' workshop, a total of 21 barriers were pre-identified by participants as factors that would negatively influence the implementation of TIBA (Table 8). The majority of the barriers (81%, n=17) were health system-related, reported across multiple facilities. The most frequently reported barriers included staff shortages, identified by 93% of the respondents, and lack of essential commodities for screening and treatment of precancerous lesions, also reported by 93% of the respondents. These two barriers ranked as the top two implementation challenges.

Among patient-related barriers, low participant turnout (85%) and negative attitude towards cervical cancer screening (78%) were commonly reported. These were mainly driven by beliefs and fears surrounding the screening process, and ranked third and fifth, respectively (Figure 10).

FIGURE 10. RANKING OF THE TOP TEN BARRIERS IDENTIFIED ACROSS HEALTHCARE FACILITIES



There were no differences in the barriers observed when comparing the two health facility levels, i.e., Level IV and V. However, when comparing barriers across facilities with different management levels (Figure 11), the cost of cervical cancer screening and treatment, as well as low participant turnout, were commonly reported in faith-based health facilities compared to public health facilities. The higher cost of cervical cancer preventive services in faith-based health facilities led to a lower participant turnout, as most of the women could not afford these services.

The barrier assessment results show that (71%, n=15) of the barriers were successfully addressed, 10% (n=2) were partially addressed, and 19% (n=4) were not addressed. Figures 12 and 13 categorize the barriers into two groups: (1) Staff and clinic flow barriers and (2) Health system, infrastructure, and patient access barriers, illustrating the proportion of respondents who reported barriers that were successfully, partially, or not addressed. A summary of the assessment table is also provided as supplementary Table 9.

FIGURE 11. COMPARISON OF BARRIERS BETWEEN FAITH-BASED AND PUBLIC HEALTH FACILITIES

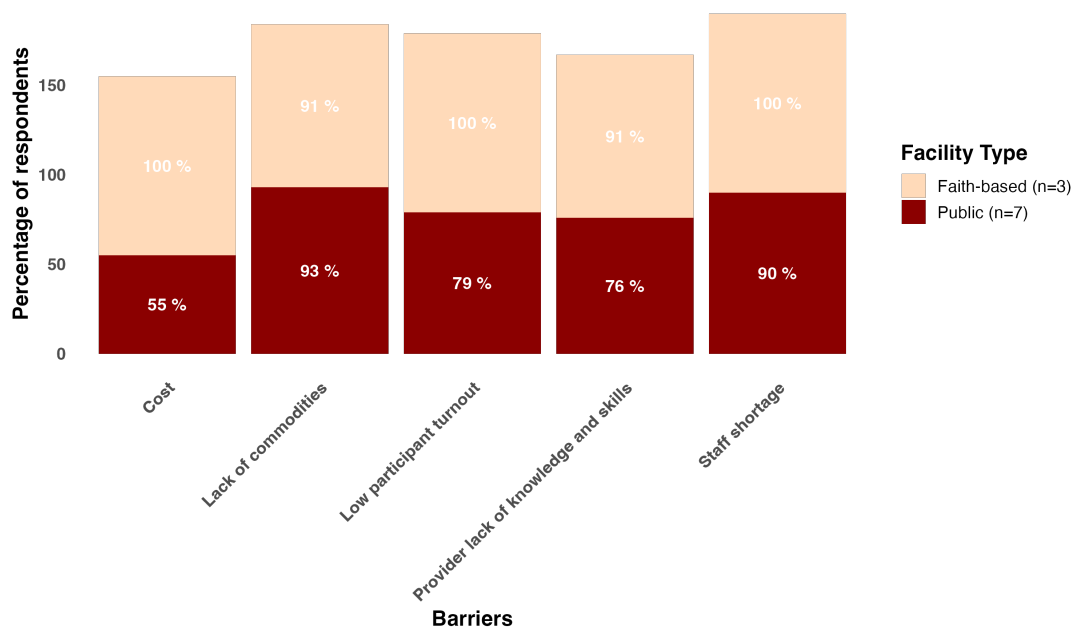
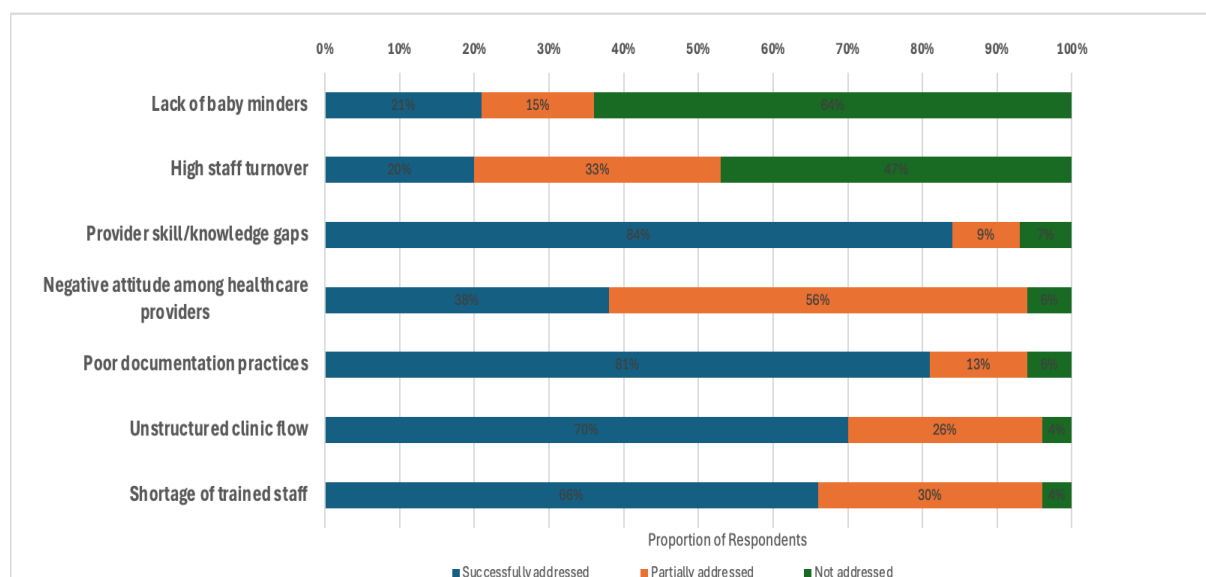


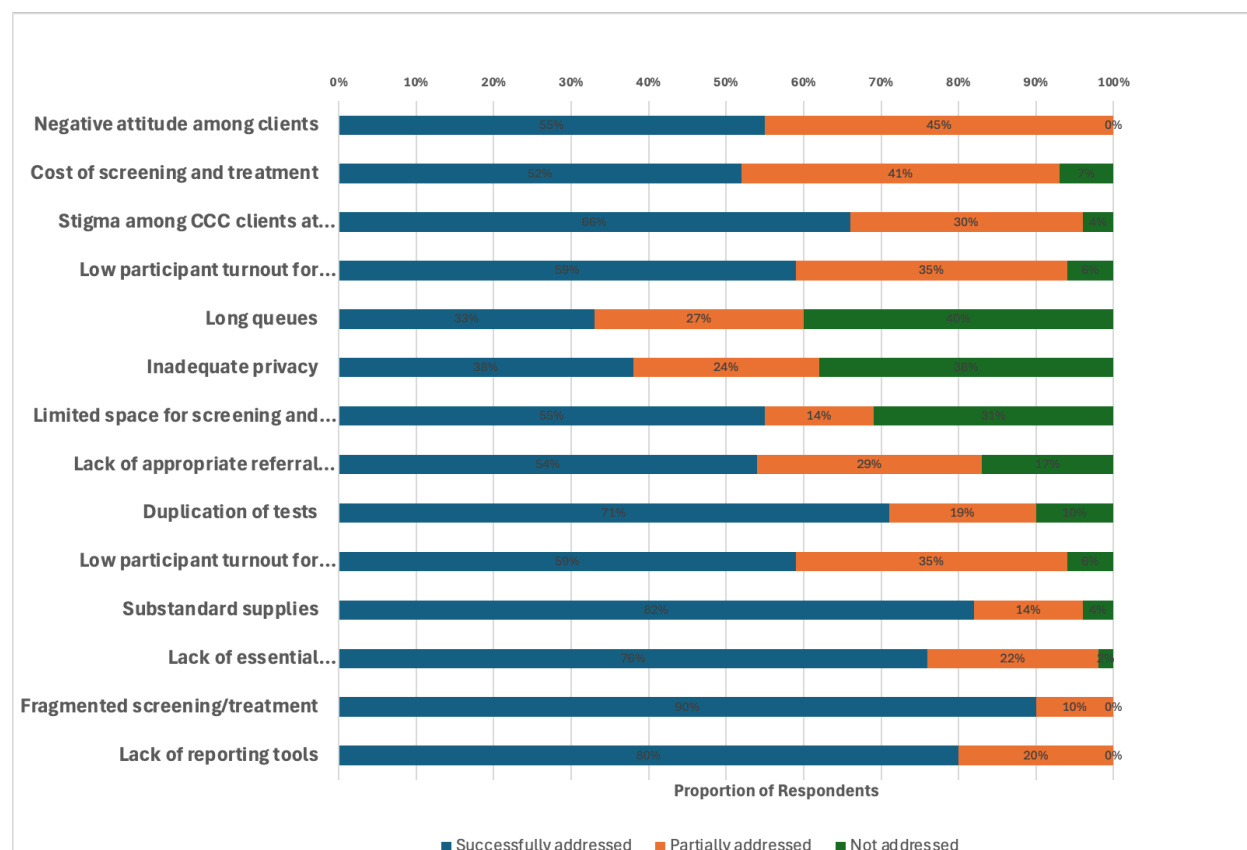
FIGURE 12. PROPORTION OF RESPONDENTS REPORTING STAFF-RELATED AND CLINIC WORKFLOW BARRIERS ADDRESSED SUCCESSFULLY, PARTIALLY, OR NOT



A range of implementation strategies was applied to address the barriers reported by health providers. For example, clinic workflows were redesigned to reduce bottlenecks and improve patient flow, including the establishment of dedicated rooms for cervical cancer screening and treatment. Care coordination was strengthened by introducing patient navigators/customer care representatives to guide patients through the clinics, and health provider capacity was built through regular training sessions and continuous medical education (CME).

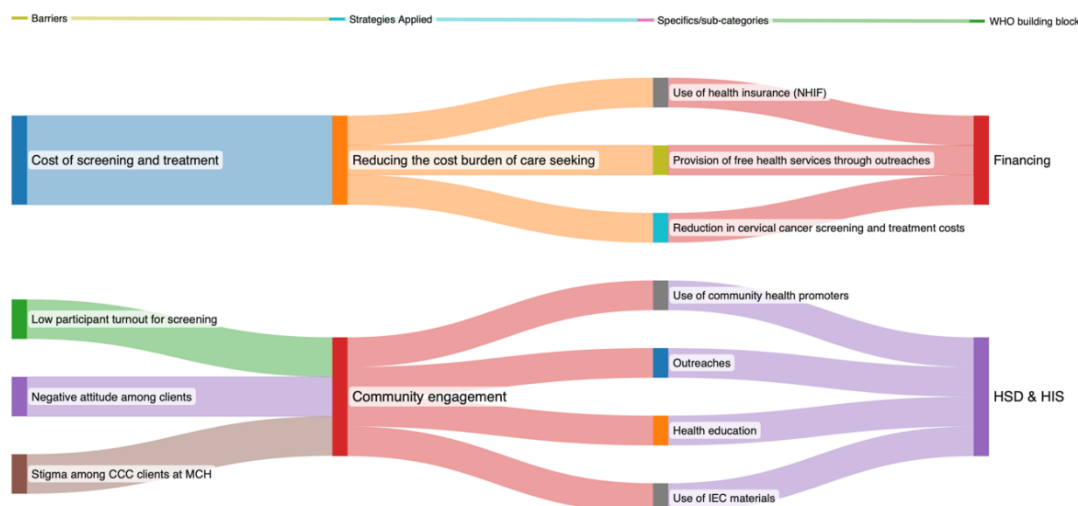
Additionally, some strategies addressed multiple barriers simultaneously. For example, the dual strategy of health care provider training and mentorship on cervical cancer screening and treatment helped address multiple barriers more efficiently. In this case, shortage of trained providers, provider knowledge gaps and skills on screening and treatment, use of substandard acetic acid for screening, poor documentation of cervical cancer preventive services, and duplication of screening tests were tackled with the aforementioned approach.

FIGURE 13. PROPORTION OF RESPONDENTS REPORTING HEALTH SYSTEM, INFRASTRUCTURE, AND PATIENT ACCESS BARRIERS ADDRESSED SUCCESSFULLY, PARTIALLY, OR NOT



Strategies were mapped to the WHO health systems framework and building blocks. These strategies primarily targeted the health service delivery and health workforce building blocks, which are key health system inputs aiming at improving health and efficiency.¹⁴⁷ These areas addressed key barriers such as gaps in provider knowledge, staffing shortages, and inefficiencies in clinic workflows. The mapping also highlighted target actions in essential medicine, e.g., ensuring availability of essential commodities, leadership and governance, and financing (reduction in screening and treatment costs). Additionally, community engagement emerged as a critical strategy for addressing barriers related to low screening uptake and stigma. Figures 14 and 15 provide a summary of these strategies and their subcategories.

FIGURE 14. FLOW DIAGRAM MAPPING IMPLEMENTATION STRATEGIES TO WHO HEALTH SYSTEMS BUILDING BLOCKS FOR ADDRESSING PRE-IDENTIFIED PATIENT-LEVEL BARRIERS



Key: HSD-Health service delivery
HIS-Health information system

Qualitative Results

Theme 1: Improving service accessibility and optimizing clinic processes

Health care providers reported that barriers related to clinic operations, such as unstructured clinic (patient movement back and forth between registration and clinic rooms) flow, limited space for screening and treatment, fragmented approach to care, lack of essential commodities, and the cost of cervical cancer preventive services, were successfully addressed. This contributed to improved service accessibility and a more streamlined clinic process that was achieved through:

Use of customer care representatives/patient navigators to guide patients through the health system by providing direction and information on the cost and location of services offered.

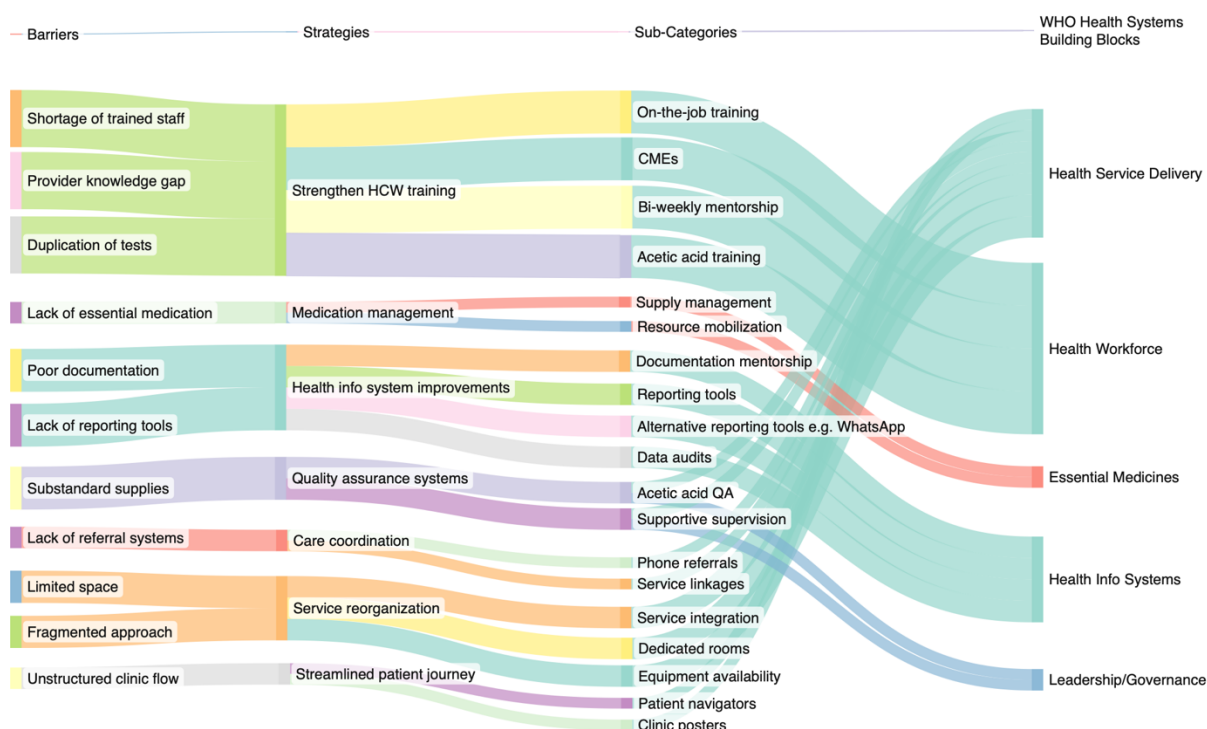
“We have a customer care lady who actually talks to patients every morning, she tells them about every section of the hospital” (Nurse, government-led facility)

- a) Establishment of dedicated clinic rooms and integration of cervical cancer screening and treatment into the clinic services. The three faith-based health facilities established dedicated rooms, whereas most of the public health facilities integrated cervical cancer screening into routine clinic services such as maternal-child health and HIV clinics. However, service integration in most public health faced challenges, including delays in the provision of other services.

“We currently have a room for cervical cancer screening, exclusively for that purpose” (Clinical Officer, faith-based facility)

“In the comprehensive care clinics (CCC), we have only one room for screening, which is also used for Operation Triple Zero (OTZ) classes. During OTZ sessions with children, screening cannot take place.” (Clinical Officer, government-led facility)

FIGURE 15. FLOW DIAGRAM MAPPING IMPLEMENTATION STRATEGIES TO WHO HEALTH SYSTEMS BUILDING BLOCKS FOR ADDRESSING PRE-IDENTIFIED HEALTH SYSTEM LEVEL BARRIERS



- a) Availability of essential commodities and equipment for cervical cancer screening and treatment. Eight facilities that reported a lack of essential supplies and commodities, having been fully addressed, received donations of thermal ablaters and essential supplies such as gloves, acetic acid, and speculums from implementing partners. Additionally, three facilities reported leadership support, which helped ensure that the required commodities were purchased by their respective health facilities. These ensured there were no gaps in the provision of cervical cancer preventive services.

"The hospital management increased supplies such as cotton wool, clean gloves, and we were also able to get the lighting lamp. We also got support from the people's Program; they were able to give us additional lighting lamps and a screening chair. " (Clinical Officer, government-led facility)

- b) Provision of free cancer screening and treatment services in some hospitals, along with reduced service charges and cost waivers. Given that the cost of cervical cancer preventive services was a challenge to the majority of the women, health facilities implemented various strategies to address this issue. Some health facilities organized free outreaches (mostly faith-based health facilities) targeting women who were unable to visit the facility due to financial constraints. Additionally, one faith-based facility reduced service charges after receiving donations of essential commodities for screening. The free services and cost waivers were applied in public health facilities.

"The services were made free, and even the gloves that we used to tell them to buy are now available in the hospitals," (Nurse, government-led facility)

"Thanks to the free donations that we've been receiving, we've been able to offer these services at a lower cost. "(Nurse, faith-based facility)

Although most participants reported that cost was a major barrier that had been successfully addressed, this was not the case in all the faith-based health facilities, as these sites rely on patient service charges to purchase the commodities. Additionally, women who screened positive for precancerous lesions or were suspected to have cancer and required additional tests and procedures, such as biopsy sample collection or Loop Electrosurgical Excision Procedure (LEEP) treatment, still experienced financial constraints, as these additional services were charged.

Theme 2: Capacity building to enhance provider knowledge, skills, and quality of cervical cancer preventive service delivery

Health provider training on screening using VIA and treatment of precancerous lesions with thermal ablation, conducted during the roll-out of TIBA across the health facilities, significantly enhanced providers' knowledge and skills, while also improving their overall competency. This training was supplemented by additional opportunities for professional development, including monthly continuous medical education (CME) sessions, provision of job aids, technical assistance by the study, and on-the-job training for new staff in the reproductive health clinics.

"The KEMRI team came in and trained us and gave us support and job aids." (Nurse, government-led facility)

"First of all, it was done through the initial training; besides that, there was continuous on-job mentorship." (Laboratory Technician, faith-based facility)

However, some facilities reported that staff shortages and lack of training among other personnel hindered service provision, despite the initial training that had been offered. This was an emerging barrier during the implementation phase.

"In terms of sustaining it, we don't have a specific person stationed there to attend to mothers. The management can consider adding staff who will be stationed there so that these mothers, when they come during their MCH clinics, can be attended to". (Nurse, faith-based facility)

To further improve the quality of cervical cancer prevention services, mentorship was provided on the right formulation of acetic acid for screening. Most of the health facilities had previously relied on acetic acid sold in stores, which did not meet the required standard, and negatively affected the accuracy of the screening process. Training in this process addressed barriers related to a lack of provider knowledge on cervical cancer screening and treatment, as well as influenced the shortage of trained providers.

"Through training, we've learned the importance of using the right formulation of acetic acid with an expiry date that delivers results. Previously, we used 4-6% acetic acid, a garden vinegar bought from the supermarket, but now we can properly prepare and ensure the correct acetic acid concentration for screening." (Nurse, government-led facility)

Challenges related to a lack of reporting tools and poor documentation were addressed through the provision of reporting tools, mentorship on proper documentation by the health records and information officers, and regular data audits during supportive supervision.

"We have had frequent supportive supervision, and the registers have been reviewed several times. The main issue was usually poor documentation, despite screening being

conducted. However, most of these documentation issues have now been addressed."
(Clinical Officer, government-led facility)

Theme 3: Strengthening community engagement and communication for cervical cancer prevention

Health facilities that identified negative attitudes among clients and low participant turnout for screening as barriers addressed these challenges by successfully conducting routine health talks and sensitization at the clinics. This was achieved by the distribution of information and communication (IEC) materials, such as posters, and involving community health promoters to mobilize eligible women for cervical cancer screening services. Negative attitude towards screening was associated with fear of screening and receiving a positive result and lack of knowledge about cervical cancer. Additionally, outreach activities within various communities also played a key role in increasing women's participation in the screening.

"Outreaches have been conducted and the number of women accessing services has increased." (Clinical Officer, government-led facility)

"Previously, these participants were unable to come to the facility for screening due to fear and other concerns. However, after the training, we were able to provide health education to help alleviate their fears and encourage participation." (Nurse, faith-based facility)

Themes emerging from barriers partially addressed and not addressed included staffing challenges, workforce instability, and lack of appropriate infrastructure and support systems.

Theme 1: Staffing challenges and workforce instability

High staff turnover was mainly reported in faith-based health facilities. The transition was driven by better opportunities elsewhere. This led to the disruption in service delivery. Unfortunately, this barrier could not be addressed as it was beyond the control of the providers. In contrast, public health facilities experienced more staff changeovers. Staff changeovers were partially addressed by minimizing the movement of trained staff on cervical cancer screening and treatment staff between departments. However, in certain circumstances, such as acute staff shortage, it was inevitable to avoid the changeovers from reproductive health clinics to other departments within the hospital.

"One significant challenge we still face is staff turnover. The reason is that many healthcare workers, when opportunities arise to work in public health facilities, often move to the public sector. (Medical Officer, faith-based facility)

"Sometimes it is circumstances that force us to move a staff from one area to the next. It is beyond us. (Nursing manager, government-led facility)

Theme 2: Lack of infrastructure and support systems for continuity of care

Appropriate support structures, such as baby-minder facilities, were reported unavailable, and as such, the barrier was not addressed. The participants also reported inadequate space in the screening rooms to set up a cot for the babies while mothers were being screened. This issue cut across both public-led and faith-based health facilities, and it was believed to discourage women with young children from accessing screening services as they were concerned about childcare and potential security risks by leaving their children with strangers at the waiting bay.

"When a mother is being screened and there is no one to hold their baby, and then also considering our setup is within a slum, you cannot be sure if the person holding the baby

will go away with the baby. When we are doing mobilization, we encourage them to come with their neighbors or friends. (Nurse, government-led facility)

Inconsistent participant follow-up, largely due to a lack of logistical support from the hospital management, was partially addressed. Providers often relied on their personal phones and support from implementing partners to make follow-ups, which created gaps in the continuity of care and subsequently decline in patient engagement and retention. This challenge was primarily common among women who screened positive and were not amenable to thermal ablation, or were suspicious for cancer, referred for further tests and procedures such as LEEP. Additionally, participants from one facility reported losing patient contact information within their data systems, which made follow-up efforts difficult. This challenge was yet to be resolved.

"There should be a phone in the screening rooms that should be used to contact these patients. When we need to follow up with clients, whether they missed a follow-up or completed treatment, we have to use our personal phones." (Nurse, government-led facility)

"There are limitations, like transport, which is not provided; you use your cash or airtime, but you are not reimbursed." (Cytologist, government-led facility)

Overall, the survey and interview data corresponded. The divergence observed in the qualitative responses was mainly related to emerging barriers rather than the pre-identified ones. These emerging barriers were not addressed, impacting TIBA implementation. For example, women with precancerous lesions covering more than 75% of the cervix and not eligible for thermal ablation did not receive timely LEEP treatment. This delay was attributed to both a shortage of gynecologists trained in LEEP and reluctance among those trained to perform the procedure. The reluctance stemmed from differing opinions on management approaches, as many gynecologists preferred performing LEEP only for patients with confirmed positive findings on pap smear or colposcopy, rather than solely relying on VIA results. Table 8 provides a summary of these emerging barriers.

TABLE 8. EMERGING BARRIERS DURING TIBA IMPLEMENTATION

Barrier	Description
Inconsistent supply of alternative screening modalities across health facilities	Alternative tests such as HPV and pap smear testing kits were inconsistently available.
Staff changeovers	Transfer of staff trained in cervical cancer screening and treatment to other departments hindered continuity in cervical cancer preventive services.
Incomplete treatment for women with larger cervical precancerous lesions	Women with larger precancerous lesions greater than 75% not amenable to thermal ablation did not receive treatment as gynecologists were reluctant to perform LEEP
Cost of referral procedures such as LEEP	High costs associated with procedures like LEEP created barriers among women who screened positive for precancer to access the service.
Gaps in provider skills and expertise	Some healthcare providers had challenges in differentiating positive lesions from conditions such as cervicitis and ectopy.
Staff capacity strain due to high participant volumes during outreach services	Staff faced challenges in managing high participant turnouts during outreaches due to shortage of providers, which impacted service delivery.

Match between barriers and strategies

The implementation strategies deployed during TIBA implementation matched the barriers identified by the key stakeholders (healthcare providers, health facility managers, and policymakers) during the stakeholders' workshop. As a result, these strategies successfully addressed 71% of the pre-identified barriers, with greater success in improving accessibility to cervical cancer screening and precancerous lesion treatment and enhancing provider skills. It is also important to note that there were strategy adaptations that occurred during the implementation phase. However, these adaptations are detailed in a separate paper.

Discussion

We assessed whether the implementation strategies deployed were aligned with the pre-identified barriers to implementing TIBA. The majority (81%) of the reported pre-identified barriers were health system-related. Overall, the implementation strategies were well matched to the barriers, as most (71%) were successfully addressed. Several strategies were applied to address these barriers, with some addressing multiple barriers simultaneously. Key themes related to successful barrier-strategy matching included targeted improvements in service accessibility, streamlining and optimizing clinic processes, investing in health provider capacity building through training, and strengthening community engagement and communication. Approximately 10% of the barriers were partially addressed, while 19% were not addressed. The barriers partially addressed and those not addressed were primarily associated with structural problems, including staffing challenges, workforce instability, infrastructural limitations, and lack of support systems for participant follow-up. These issues require long-term investments and system-level changes, beyond the health providers' control. For example, while training can improve provider skills, staff shortages and high turnover cannot be resolved immediately, as the process of recruiting new staff involves lengthy administrative processes, which are also influenced by other factors. In this study, the pre-identified barriers to implementing TIBA, including shortage of trained providers, lack of essential commodities, poor documentation, among others (a full list of the 21 barriers is provided as supplementary material), are not unique to this context. These challenges have been widely reported in similar settings implementing cervical cancer prevention services in countries like Nigeria, Zambia, Malawi, Rwanda, and countries in Latin America.^{60,148–150} To address these barriers, several implementation strategies, also highlighted in the literature, were employed, including provider training and mentorship, availability and management of essential commodities, supplies, and equipment, supportive supervision, community engagement through routine health education, and community outreaches.¹⁵¹ We mapped these strategies to the WHO health systems framework, and most strategies primarily targeted health service delivery, while others addressed key health system inputs such as health workforce and access to essential commodities, aiming at improving overall health system performance and efficiency.¹⁴⁷ These findings suggest that a “one-size-fits-all” approach may not be sufficient in addressing contextual challenges.¹⁵² For instance, in this study, some faith-based health facilities addressed the barrier of cost by reducing charges when they received donations of screening commodities or by offering free outreaches. In contrast, some public-led health facilities provided free routine screening and treatment services along with cost waivers for additional tests required.

Notably, some strategies addressed multiple barriers simultaneously. For example, provider training and mentorship on cervical cancer screening and treatment addressed provider knowledge gaps and skills, reduced the shortage of trained providers, improved documentation, ensured use of standard/required acetic acid formulation, and minimized duplication of screening tests. These findings have two key implications. First, they suggest that some implementation strategies, such as improving health worker skills, can have a ripple effect in improving several areas of care, including screening quality, treatment consistency, and

reliability of care.^{153,154} Second, it underscores the interconnected nature of barriers, highlighting the need for a holistic approach in making adaptable changes in health service delivery, particularly in resource-constrained settings, to optimize the use of available resources.^{155,156} It is important to note that, while most of the health providers reported having successfully addressed challenges related to the availability of cervical cancer essential commodities and equipment, these were largely addressed with support from implementing partners. Considering the recent USA funding cuts, which have impacted several vertical programs in LMICs, including cervical cancer prevention efforts,⁴ have led to delays in screening and precancer treatment. These delays could potentially lead to devastating outcomes, hindering global efforts towards cervical cancer elimination. To build resilient and sustainable health systems, LMICs must prioritize the development and implementation of national plans for cervical cancer prevention. This can be achieved through domestic resource mobilization, strengthening planning and prioritization processes, and gradually transitioning away from reliance on volatile donor assistance.^{157,158}

Pre-identified barriers, partially addressed or not addressed, were related to health systems gaps beyond the health provider's control. These included infrastructural challenges such as a lack of baby minder spaces due to space limitations, high staff turnover, especially in faith-based health facilities, and a lack of participant follow-up due to logistical and data system challenges. These barriers, common in other LMICs,^{159,160} derail progress toward cervical cancer elimination by creating missed opportunities for timely interventions and leading to inefficient resource use, especially when trained providers are relocated or transferred to other departments or health facilities.¹⁶¹ Addressing these challenges through improved infrastructure, better staff retention strategies, and enhanced participant follow-up is crucial for advancing cervical cancer prevention.¹⁶²

Additional barriers emerged during the implementation of TIBA. These included incomplete treatment for screen-positive women not eligible for treatment with thermal ablation, often due to cost constraints or reluctance from health providers (especially gynecologists). Challenges also arose in differentiating positive lesions from other cervical conditions, such as cervicitis and ectopy, particularly among newer staff who had not undergone initial training despite technical assistance provided by the study team during the intensive implementation phase. While initial VIA trainings and technical assistance offered by implementing partners can support early implementation, they are often short-term. Without structured and sustained opportunities for retraining, ongoing mentorship, and supportive supervision created by the health management teams, there is a clear risk of declining diagnostic skills among providers.¹⁶³ Therefore, alongside continued in-person mentorship, integrating VIA mentorship through telemedicine platforms could offer a viable option to improve the quality of screening and expand service reach.^{163,164}

Screening alone is ineffective without timely and appropriate linkage to treatment.^{162,165} In this study, the single-visit, screen-and-treat approach was not feasible for women with lesions more than 75% and extending to the ectocervix, as they required LEEP treatment. However, access to LEEP was hindered by several factors, including a lack of LEEP equipment, a shortage of trained providers on LEEP, and out-of-pocket costs, which were a limitation for most women. These findings have been documented,^{166,167} and our study additionally highlights that some gynecologists were reluctant to perform LEEP for women who screened positive for VIA, despite national guideline recommendations for precancer treatment.¹⁶⁸ Instead, they preferred performing LEEP on patients with positive findings on pap smear or colposcopy. Non-adherence to guidelines has been associated with delays in treatment, disease progression,

and an increase in health expenditure.^{169,170} To strengthen cervical cancer prevention efforts, there is an urgent need to expand the pool of trained LEEP providers and implement task sharing for LEEP services with ongoing supervision and mentorship. Additionally, quality improvement interventions are needed to ensure guideline adherence and timely access to treatment for screen-positive women.

A key strength of this study is its mixed methods design, which allowed integration of quantitative data to examine barrier-strategy matching, alongside qualitative insights that provided a deeper understanding of drivers behind successful, partial, and unsuccessful strategy implementation. This comprehensive approach enhanced the validity of our findings. However, the study should be interpreted considering some limitations. Of the ten health care facilities included, survey data and participant perspectives were obtained from only two health facility managers. As a result, we may have missed certain insights from a broader management perspective that could have influenced strategy implementation. Additionally, this study was designed to obtain data primarily from health care providers. Including perspectives from women who received cervical cancer prevention services could have provided more insights into the extent to which patient-level barriers were matched across these health facilities, as well as contextual factors that influenced their experiences.

Conclusion

In this study, the majority of the pre-identified barriers were successfully matched to the deployed implementation strategies, which mainly targeted improving health service delivery, workforce capacity, and community engagement. Applying the appropriate strategy to address barriers is associated with a higher probability of achieving the desired outcomes and maximization of the intervention's impact. Despite the overall success, important gaps remain, particularly related to structural challenges, such as staffing instability, infrastructural limitations, gaps in provider skills, and lack of support systems for continued care in cervical cancer prevention. These findings highlight the need for a more adaptable, context-specific strategies and sustained investments in health systems strengthening, with minimal reliance on external donor support, to achieve resilient and effective cervical cancer prevention programs in resource-constrained settings.

Implications

- Multiple strategies were applied to address barriers across health facilities. Although some strategies were similar, their application varied depending on context, for example, faith-based vs public health facilities. Adaptations to context enhance strategy effectiveness. Hence, flexibility and context-specific implementation are critical for success.
- Some implementation strategies addressed multiple barriers simultaneously. The interconnected nature of barriers highlights the need for a holistic approach, which is key in optimizing resource use, particularly in resource-constrained settings. Integrated strategies may be more impactful in accelerating implementation success than isolated ones.
- Essential commodity management and equipment availability (thermal ablaters) were largely supported by implementing partners. With donor cuts, we are experiencing service disruptions like treatment delays. Strengthening sustainable health systems through local ownership is critical to building resilient and self-reliant cervical cancer prevention services.

- Emerging provider skills gap in screening using VIA.
Initial trainings are short-term (for example, VIA) and there is a risk of declining diagnostic skills if not followed by a structured retraining and sustained mentorship.
- Screening is ineffective without timely treatment.
Delays in receiving LEEP treatment were reported due to equipment shortages, few trained providers and out-of-pocket costs.
Gynecologists' reluctance and non-adherence to guidelines further delayed treatment.
There is a need to expand the pool of LEEP-trained providers, implement task sharing, and strengthen quality improvement and supervision.

TABLE 9. SUMMARY OF BARRIER ASSESSMENT AS REPORTED BY PROVIDERS

	Barriers	Successfully addressed	Partially addressed	Not addressed
1	Unstructured clinic flow (movement of clients back and forth between registration, service delivery points and cashier's office)	16	6	1
2	Shortage of trained staff on cervical cancer screening and treatment (SOPs), job aids, and cervical cancer screening and treatment guidelines	25	11	1
3	Lack of essential medication supplies and equipment	28	8	1
4	Low participant turnout for screening	20	12	2
5	Provider knowledge gap and skills on cervical cancer screening and treatment	27	3	2
6	High staff turnover	3	5	7
7	Limited space for screening and treatment	16	4	9
8	Cost of screening and treatment	14	11	2
9	Negative attitude among healthcare providers	7	10	1
10	Negative attitude among clients	17	14	0
11	Poor documentation of cervical cancer preventive services	13	2	1
12	Fragmented approach to screening and treatment	18	2	0
13	Stigma among comprehensive care clinic clients at MCH	25	11	1
14	Substandard supplies especially acetic acid (Facilities use white vinegar bought from the stores)	18	3	1
15	Lack of baby minders	3	2	9
16	Lack of participant follow-up	10	14	4
17	Lack of appropriate referral systems	15	8	5
18	Long queues	5	4	6
19	Inadequate privacy (screening room used for other services, students present when services are being offered)	8	5	8
20	Duplication of tests (VIA positive participants sent for pap smear)	15	4	1
21	Lack of reporting tools	8	2	0

No. of barriers successfully addressed=15, partially addressed and not addressed =4.

TABLE 10. STRATEGIES AND SUB-CATEGORIES MAPPED TO WHO HEALTH SYSTEMS BUILDING BLOCKS

Barriers	Strategies applied and sub-categories	WHO health systems framework and building blocks
1. Unstructured clinic flow (movement of clients back and forth between	Streamlined patient journey (admission to screening, to treatment, to follow up).	Health service delivery

registration, service delivery points and cashier's office)	• Use of customer service representatives/patient navigators to assist patients/client with directions	
2. Shortage of trained staff on cervical cancer screening and treatment (SOPs), job aids, and cervical cancer screening and treatment guidelines 3. Provider knowledge gap and skills on cervical cancer screening and treatment 4. Duplication of tests VIA positive participants sent for pap smear)	Strengthen mechanisms for health worker training/mentoring and coaching. • On the job training • Continuous medical education (CMEs) • Bi-weekly mentorship • Training on acetic acid formulation	Health workforce
5. Lack of essential medication supplies and equipment	Better availability and management of essential medications, supplies and equipment. • Supply and commodity management • Resource mobilization from implementing partners	Access to essential medicine
6. Low participant turnout for screening 7. Negative attitude among clients 8. Stigma among comprehensive care clinic clients at MCH	Community engagement, service communication, sensitization related to cervical cancer screening and treatment. • Use of community health promoters • Outreaches • Health education • Use of IEC materials	Health service delivery and health information systems
9. Poor documentation of cervical cancer preventive services 10. Lack of appropriate reporting tools	Improvements regarding recording and management of routine health information. • Mentorship on documentation • Provision of reporting tools • Use of alternative reporting channels e.g. WhatsApp • Data audits	
11. Substandard supplies especially acetic acid. (Facilities use white vinegar bought from the stores)	Improvements to supervision and quality assurance • Quality assurance of acetic acid use • Supportive supervision	Health service delivery and leadership/ governance
12. Lack of appropriate referral systems	Effective coordination among healthcare providers for referring for further management • Phone calls	Health service delivery

	• Linkage to other services	
13. Cost of screening and treatment	Efforts to mitigate financial burden of care seeking • Use of health insurance (NHIF) • Provision of free health services through outreaches • Reduction in cervical cancer screening and treatment costs	Financing
14. Limited space for screening and treatment. 15. Fragmented approach to screening and treatment	Improvements to the organization of care (e.g., colocation of multiple services in one setting) • Integration of CC preventive services in clinics • Dedicated rooms for screening • Availability of thermal ablation and Loop Electrosurgical Excision Procedure (LEEP) services	Health service delivery

Chapter 5: Conclusion

This dissertation applied implementation science methods to provide valuable input for optimizing the delivery of cervical cancer prevention services in Kenya, while also offering lessons that are applicable to other LMICs. Specifically, it aimed to (1) identify key determinants influencing the implementation of TIBA; (2) characterize provider-led strategy adaptations; and (3) evaluate barrier-strategy matching to improve the effectiveness and sustainability of cervical cancer prevention efforts.

In chapter two, we examined barriers and facilitators to TIBA implementation. Among the most significant challenges was the disconnect between the national and health facility levels regarding perceived readiness for implementation. While the national level highlighted progress in resource availability and infrastructural development, the health facility level reported persistent challenges driven by inadequate resources, such as shortages of trained staff and lack of essential commodities. The differing perceptions of implementation readiness between those at the national level and those working on the frontline ultimately undermine the quality of service delivery. Additional barriers identified included recruitment challenges in faith-based facilities, structural limitations, and lack of coordination between implementing partners and the Ministry of Health (MOH) creating siloes that weakened the system. Conversely, leadership engagement and the perceived relative advantage of thermal ablation over cryotherapy were key facilitators. There is a need for cross-level communication, equitable resource allocation, and stronger implementation monitoring systems. The findings in this chapter provided foundational insights for the development and evaluation of implementation strategies in the subsequent chapters.

In chapter 3, we applied the FRAME-IS framework to systematically document provider-led adaptations to TIBA implementation. Education adaptations, such as training newly onboarded health providers at nearby facilities, were the most common, followed by resource-related adaptations. These adaptations were often in response to site-specific challenges, such as the absence of designated training leads. On the other hand, resource-related adaptations were mainly in response to delays in the procurement of essential commodities, prompting implementing partners to facilitate the required commodities. Most adaptations occurred in the early phase of implementation and were planned, reflecting a proactive approach to increasing provider adoption of TIBA and expand service reach. While education-related adaptations remained common across both early and later phases, other types, such as service reorganization, community engagement, and resource adjustments, declined over time, likely due to their integration into routine practice. Adaptation rates were higher during early implementation, indicating strong initial momentum to enhance strategy-context fit. These findings emphasize the role of short-term adaptations in enabling trialability and highlight the proactive role of providers in addressing implementation gaps through context adaptations.

In chapter 4, we assessed how well strategies matched pre-identified barriers. Overall, most strategies were appropriately matched and successfully addressed contextual barriers. Importantly, we found out that some strategies address multiple barriers simultaneously, reinforcing the need for holistic approaches that optimize the use of available resources in resource-constrained settings. Despite the overall success, critical gaps remain, including staffing challenges, infrastructural limitations, reliance on implementing partners for essential commodities, emerging gaps in provider skills, and weak systems for follow-up care. We recommend targeted investments in health system strengthening with minimal reliance on donor support to ensure sustainability.

Together, this dissertation presents a systematic approach from the identification of implementation bottlenecks to the evaluation of the appropriateness of strategy deployment in enhancing the effectiveness and sustainability of cervical cancer prevention efforts in LMICs.

Next steps

This dissertation lays the groundwork for future research directions.

Our assessment of adaptations was limited to the intensive implementation phase, during which technical support was actively provided. However, it remains unclear how these adaptations evolve beyond the maintenance phase when technical support is withdrawn. Future studies should explore the patterns of these adaptations over time and identify factors that drive or hinder their sustainability.

Additionally, evaluating the impact of these adaptations on both clinical and implementation outcomes will provide valuable insights into their effectiveness and inform the design of adaptive and sustainable strategies for cervical cancer prevention.

HPV testing is recommended as a more sensitive screening method. However, it remains financially unsustainable in Kenya. VIA is the best alternative at the moment; however, the TIBA intervention has shown the need for consistent training, which is a huge investment in the long run due to frequent disruptions within the health system, like staff transitions through changeovers and turnovers. Research and policy discussions should consider investing in strategies that can sustain provider-directed or self-collected HPV sampling.

APPENDICES

Appendix 1: Interview Guides

Health Care Provider IDI

Instructions:

- This in-depth interview (IDI) is intended to obtain strategic information from frontline health care workers on the potential use of thermal ablation (TA) in lieu of ablative treatment through cryotherapy in the clinical protocol for managing pre-cancerous cervical lesions. This protocol is known as ‘single-visit approach with screen-and-treat’ (SVA-SAT).
- The objective of the IDI is to elicit views and insights from frontline health care workers about factors that will affect the *adoption, implementation, and sustainment* of TA within the SVA-SAT protocol in the clinic where they work.
- Key informants are staff of health care facilities that routinely implement the SVA-SAT protocol, which currently involves use of ablative treatment through cryotherapy. Informants are nurses, clinical officers, and doctors by profession.
- The interviewer should use, and adapt, if necessary, the lines of inquiry below to elicit participants’ views on:
 - The characteristics of TA compared to those of cryotherapy,
 - Patient needs and preferences,
 - The overarching health system and policy environment,
 - The service delivery environment, including their team, and
 - Their capacities, motivations, and intentions.

ID of data collector:

Date:

Name of Key Informant:

Job Title of Key Informant:

Facility and county where Key Informant is employed:

Number of Years Key Informant has been in that job:

Location of the interview:

Duration of the interview (minutes):

Introduction:

[READ ALOUD – INTERVIEWERS CAN PARAPHRASE]: Thank you for taking the time to participate in this in-depth interview on the factors that may help or hinder the incorporation of thermal ablation into the protocol for managing pre-cancerous cervical lesions, i.e., single-visit approach screen-and-treat. As you are aware, the Ministry of Health is considering adapting its policy and guidelines on this topic to encourage use of thermal ablation. Whereas evidence

from other countries indicates this may be a good idea, we are conducting this study to generate a high quality and comprehensive evidence base on this intervention for the Kenya context, which will inform the MOH policy decision. We are interested in your perceptions of this intervention, the factors that you think may help or hinder health care workers and teams tasked with adopting thermal ablation in the workplace, implement it effectively and make it a sustainable component of sexual and reproductive health care for women in the community.

This interview will take approximately 35-45 minutes. With your permission, I would like to record the interview on a digital recorder [show the participant the digital recorder]. The recording will be kept securely and confidentially, and only used for the research purposes described in the informed consent form [show the participant the form, which s/he has already signed]. Do I have your permission to record this interview?

INTERVIEWER SHOULD CONFIRM WITH THE KEY INFORMANT THAT S/HE HAS PERMISSION TO RECORD THE IDI ON A RECORDED DEVICE. IF RESPONDENT CONSENTS, THE INTERVIEWER CAN START RECORDING NOW. RECORD THE TIME AT WHICH THE INTERVIEW BEGINS.

START TIME OF IDI: _____

Interview:

1. The Intervention

Interviewer should ask about the participants' views and experiences with respect to the following aspects of TA. As interviewer listens, s/he should make note of barriers and facilitators that the participant mentions.

1.1 Relative advantage

i) Compared to cryotherapy what would you say are the benefits and risks of using TA for clinically managing precancerous cervical lesions?

PROBE

- ➔ *Benefits that could arise from use of TA?*
- ➔ *Risks or drawbacks of using TA?*
- ➔ *Current problems that using TA can help to solve?*
- ➔ *Problems that might get worse if TA is adopted?*

1.2 Adaptability

i) In your opinion, what changes or alterations to TA may be necessary so that it can be effective in the clinic where you work?

PROBE

- ➔ *How feasibility will it be to make these adaptations?*
- ➔ *Any aspect of TA that will not require adaptation?*

1.3 Complexity

i) In your opinion, how complicated is the use of TA?

1.4. Evidence strength and quality

i) What evidence or proof is needed about TA to get you and other health care workers that implement SVA-SAT to support adoption of TA rather than cryotherapy?

1.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed already, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

2. The Health system and policy context

Interviewer should elicit the participants' views and experiences with respect to the following aspects of TA at SVA-SAT.

2.1 Patients needs and preferences

i) How well do you think TA will meet the needs of women screening for cervical cancer in your facility?

Probe:

- ➔ *Do you think women will find TA preferable compared to cryotherapy?*
- ➔ *Less preferable? Why?*

2.2 Health systems context

i) Reflecting on the factors in the health system that seem beyond your control, is there anything that might affect TA implementation?

2.3 Policies and guidelines

i) Are there any policies, programs or guidelines ongoing at this time that might affect the use of TA for managing precancerous cervical lesions

Probe:

- ➔ *What are they?*
- ➔ *How might they affect implementation?*

2.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about patient needs, health system factors and policies and guidelines, are there any other factors that affect whether TA can be implemented well where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

3. The service delivery environment and team

3.1 Structural characteristics

i) In your opinion, how will the organization of services and care at the facility you work at affect the implementation of TA during SVA-SAT?

Probe:

- ➔ *What about current staffing arrangements?*
- ➔ *The skill mix among the staff?*
- ➔ *Do you think any changes regarding organization of services, staffing arrangements and skills will be needed?*

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3.2 Networks and communication

i) How would you describe working relationships and communication among staff where you work?

Probe:

- ➔ *Are relationships between teams and units within the health facility strong or weak?*
 - *How might this affect the introduction of TA?*
- ➔ *How is information communication among staff?*
 - *How might this affect introduction of TA?*

3.3 Implementation climate

i) In your opinion, is there a strong need for this intervention? Why?

ii) In your opinion, how well does the introducing of TA for use in SVA-SAT fit in with existing work processes and practices where you work?

ii) Can you describe how the intervention will be integrated into current processes?

3.4 Readiness for implementation

i) What kind of support or actions are needed from your leaders where you work to make this intervention successful?

Probe:

- ➔ Do you expect this from your leaders? Why?
- ➔ Other needs – e.g., training, materials, information – do you expect to receive them as needed? Why?

3.5 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about the service delivery environment, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

4. Individual capacities, attitudes, intentions

4.1 Self Efficacy

i) How confident are you that you have the skills you need to implement SVA-SAT with TA? Why?

4.2 Knowledge and beliefs about the intervention

i) Do you think that using TA with SVA-SAT will work well where you work? Why (not)?

4.3 Individual stage of change

i) How prepared are you to implement the intervention? Why (not)?

4.4 Barriers and facilitators

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i) Thank you for the rich information. In addition to what we have discussed about your individual knowledge and attitudes about the intervention, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

Thank you for participating in this interview. I have no further questions. Before we end the interview, is there anything you'd like to add?

[If yes, listen and continue recording, if no, stop recording and end interview].

END TIME OF IDI: _____

Health Facility Manager IDI

Instructions:

- This in-depth interview (IDI) is intended to obtain strategic information from health facility manager on the potential use of thermal ablation (TA) in lieu of ablative treatment through cryotherapy in the clinical protocol for managing pre-cancerous cervical lesions. This protocol is known as ‘single-visit approach with screen-and-treat’ (SVA-SAT).
- The objective of the IDI is to elicit views and insights from health facility manager about factors that will affect the *adoption, implementation, and sustainment* of TA within the SVA-SAT protocol in the clinic where they work.
- Key informants are managers of health care facilities in which the SVA-SAT protocol, which currently involves use of ablative treatment through cryotherapy, is routinely implemented.
- Regarding objective (a), the interviewer should use, and adapt, if necessary, the lines of inquiry below to elicit participants’ views on:
 - The characteristics of TA compared to those of cryotherapy,
 - Patient needs and preferences,
 - The overarching health system and policy environment,
 - The service delivery environment, including their team, and
 - Their capacities, motivations, and intentions.

ID of data collector: _____

Date: _____

Name of Key Informant: _____

Job Title of Key Informant: _____

Facility and county where Key Informant is employed: _____

Number of Years Key Informant has been in that job: _____

Location of the interview: _____

Duration of the interview (minutes): _____

Introduction:

[READ ALOUD – INTERVIEWERS CAN PARAPHRASE]: Thank you for taking the time to participate in this in-depth interview where I will ask you what you think about adoption of thermal ablation as a technique to treat pre-cancerous cervical lesions, i.e., single-visit approach screen-and-treat. The Ministry of Health would like information from you and your colleagues about this because it is considering whether it should encourage use of TA for this purpose. Existing evidence from other countries indicates that thermal ablation may be effective and appropriate to treat pre-cancerous cervical lesions. To help inform the MOH policy decision, we are conducting this study to provide high quality and comprehensive evidence about this intervention in the Kenyan context. We are interested in your ideas and perspectives about this intervention, the factors that you think may help or hinder health care teams to adopt TA in the workplace and implementing it well.

This interview will take approximately 30-45 minutes. With your permission, I would like to record the interview on a digital recorder [show the participant the digital recorder]. The recording will be kept securely and confidentially, and only used for the research purposes described in the informed consent form [show the participant the form, which s/he has already signed]. Do I have your permission to record this interview?

INTERVIEWER SHOULD CONFIRM WITH THE KEY INFORMANT THAT S/HE HAS PERMISSION TO RECORD THE IDI ON A RECORDED DEVICE. IF RESPONDENT CONSENTS, THE INTERVIEWER CAN START RECORDING NOW. RECORD THE TIME AT WHICH THE INTERVIEW BEGINS.

START TIME OF IDI: _____

Interview:

1. The Intervention

Interviewer should ask about the participants' views and experiences with respect to the following aspects of TA. As interviewer listens, s/he should make note of barriers and facilitators that the participant mentions.

1.1 Relative advantage

i) Compared to cryotherapy what would you say are the benefits and risks of using TA for clinically managing precancerous cervical lesions?

PROBE

- ➔ *Benefits that could arise from use of TA?*
- ➔ *Risks or drawbacks of using TA?*
- ➔ *Current problems that using TA can help to solve?*
- ➔ *Problems that might get worse if TA is adopted?*

1.2 Adaptability

i) In your opinion, what changes or alterations to TA may be necessary so that it can be effective in the clinic where you work?

PROBE

- ➔ *How feasibility will it be to make these adaptations?*
- ➔ *Any aspect of TA that will not require adaptation?*

1.3 Complexity

- i) From your perspective as a health facility in-charge, how complicated is the use of TA?

1.4. Evidence strength and quality

- i) What evidence or proof is needed about TA to get you and other health facilities' in-charges that implement SVA-SAT to support adoption of TA rather than cryotherapy)?

1.4 Barriers and facilitators

- i) Thank you for the rich information. In addition to what we have discussed already, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

2. The Health system and policy context

2.1 Patients needs and preferences

- i) How well do you think TA will meet the needs of women screening for cervical cancer in your facility?

Probe:

- ➔ *Do you think women will find TA preferable compared to cryotherapy?*
- ➔ *Less preferable? Why?*

2.2 Health systems context

- i) Reflecting on the factors in the health system that seem beyond your control, is there anything that might affect TA implementation?

2.3 Policies and guidelines

- i) Are there any policies, programs, or guidelines ongoing at this time that might affect the adoption and delivery of TA for managing precancerous cervical lesions?

Probe:

- ➔ *What are they?*
- ➔ *How might they affect implementation?*

2.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about patient needs, health system factors and policies and guidelines, are there any other factors that affect whether TA can be implemented well where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

3. The service delivery environment and team

3.1 Structural characteristics

i) In your opinion, how will current organization of services and care in the facility that you manage affect the implementation of TA during SVA-SAT?

Probe:

- ➔ *What about current staffing arrangements?*
- ➔ *The skill mix among the staff?*
- ➔ *Do you think any changes regarding organization of services, staffing arrangements and skills will be needed?*

3.2 Networks and communication

i) How would you describe working relationships and communication among staff where you work?

Probe:

- ➔ *Are relationships between teams and units within the health facility strong or weak?*
 - *How might this affect the introduction of TA?*
- ➔ *How is information communication among staff?*
 - *How might this affect introduction of TA?*

3.3 Implementation climate

i) In your opinion, do you think the environment in your facility will be supportive for introducing TA? Why?

Probe:

- ➔ *Will TA fit in existing work processes and practices?*
- ➔ *Can you describe how you think TA will be integrated into existing work processes?*

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3.4 Readiness for implementation

i) What kind of support or actions are needed from you, as health facility in-charge, to make this intervention successful?

Probe:

- ➔ *Are you ready to do these things? Why?*
- ➔ *Other needs your staff might have (training, materials, information)? Are you prepared to make them available? Why?*

3.5 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about the service delivery environment, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

4. Individual capacities, attitudes, intentions

4.1 Self Efficacy

i) How confident are you that you have the skills you need to manage the introduction of SVA-SAT with TA in the facility that you manage? Why?

4.2 Knowledge and beliefs about the intervention

i) Do you think that using TA with SVA-SAT will work well where you work? Why (not)?

4.3 Individual stage of change

i) How prepared are you to manage the intervention? Why (not)?

4.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about your individual knowledge and attitudes about the intervention, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

Thank you for participating in this interview. I have no further questions. Before we end the interview, is there anything you'd like to add?

[If yes, listen and continue recording, if no, stop recording and end interview].

END TIME OF IDI: _____

Policymaker IDI Guide

Instructions:

- This in-depth interview (IDI) is intended to obtain strategic information from policy makers on the potential use of thermal ablation (TA) in lieu of ablative treatment through cryotherapy in the clinical protocol for managing pre-cancerous cervical lesions. This protocol is known as 'single-visit approach with screen-and-treat' (SVA-SAT).
- The objective of the IDI is to elicit views and insights from policymakers about factors that will affect the *adoption, implementation, and sustainment* of TA within the SVA-SAT protocol in the clinic where they work.
- Key informants are policymakers in counties in which the SVA-SAT protocol, which currently involves use of ablative treatment through cryotherapy, is routinely implemented. Or key informants may be staff of the national Ministry of Health that are responsible for overseeing implementation of cervical cancer policies and guidelines.
- Regarding objective (a), the interviewer should use, and adapt, if necessary, the lines of inquiry below to elicit participants' views on:
 - The characteristics of TA compared to those of cryotherapy,
 - The overarching health system and policy environment,
 - The implementation context
 - Their capacities, motivations, and intentions.

ID of data collector:

Date:

Name of Key Informant:

ID of Key Informant:

Job Title of Key Informant:

Level of health system where Key Informant is employed (if county, put name of county):

Number of Years Key Informant has been in that job:

Location of the interview (e.g., office, phone, clinic):

Duration of the interview (minutes):

Introduction:

[READ ALOUD – INTERVIEWERS CAN PARAPHRASE]: Thank you for taking the time to participate in this in-depth interview where I will ask you what you think about adoption of thermal ablation as a technique to treat pre-cancerous cervical lesions, i.e., single-visit

approach screen-and-treat. The Ministry of Health would like information from you and your colleagues about this because it is considering whether it should encourage use of TA for this purpose. Existing evidence from other countries indicates that thermal ablation may be effective and appropriate to treat pre-cancerous cervical lesions. To help inform the MOH policy decision, we are conducting this study to provide high quality and comprehensive evidence about this intervention in the Kenyan context. We are interested in your ideas and perspectives about this intervention, the factors that you think may help or hinder health care teams to adopt TA in the workplace and implement it well.

This interview will take approximately 30-45 minutes. With your permission, I would like to record the interview on a digital recorder [show the participant the digital recorder]. The recording will be kept securely and confidentially, and only used for the research purposes described in the informed consent form [show the participant the form, which s/he has already signed]. Do I have your permission to record this interview?

INTERVIEWER SHOULD CONFIRM WITH THE KEY INFORMANT THAT S/HE HAS PERMISSION TO RECORD THE IDI ON A RECORDED DEVICE. IF RESPONDENT CONSENTS, THE INTERVIEWER CAN START RECORDING NOW. RECORD THE TIME AT WHICH THE INTERVIEW BEGINS.

START TIME OF IDI: _____

Interview:

1. The Intervention

1.1 Relative advantage

i) As a policy maker, what would you say are the benefits and risks of choosing TA, instead of cryotherapy, as the first line treatment for clinically managing precancerous cervical lesions?

PROBE

- ➔ *Benefits that could arise from use of TA?*
- ➔ *Risks or drawbacks of using TA?*
- ➔ *Current problems that using TA can help to solve?*
- ➔ *Problems that might get worse if TA is adopted?*

1.2 Adaptability

i) From your perspective, what changes or alterations to TA may be necessary so that it can be rolled out and implemented well in the health system?

PROBE

- ➔ *How feasibility will it be to make these adaptations?*
- ➔ *Any aspect of TA that will not require adaptation?*
- ➔ *Any adaptations to make it sustainable? Scalable?*

1.3 Complexity

i) From your perspective as a policymaker, how complicated do you think it would be to make TA the first line treatment for precancerous cervical lesions?

PROBE

- ➔ *Complicated in terms of roll out and integration in health system?*
- ➔ *Complication in terms of scale up and sustainability?*

1.4. Evidence strength and quality

i) What evidence or proof is needed about TA to get you and other policymakers to support adoption of TA rather than cryotherapy)?

PROBE

- ➔ *Safety concerns?*
- ➔ *Effectiveness?*
- ➔ *Costs and sustainability?*

1.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed already, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *Affect whether TA can be rolled out well?*
- ➔ *Whether TA can be sustained?*
- ➔ *Whether TA can be scaled up?*

2. The Health system and policy context

2.1 Health systems context

i) Reflecting on the factors in the health system, is there anything that might affect TA implementation?

PROBE

- ➔ *Supply chain?*
- ➔ *Human resource shortages?*
- ➔ *Financial resources?*

2.3 Policies and guidelines

i) Are there any policies, programs, or guidelines ongoing at this time that might affect the adoption and delivery of TA for managing precancerous cervical lesions?

Probe:

- ➔ *What are they?*
- ➔ *How might they affect implementation?*
- ➔ *Policies, programs, guidelines that might affect sustainability? Scaling up?*

2.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about patient needs, health system factors and policies and guidelines, are there any other factors that affect whether TA can be implemented well where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

3. Implementation context

3.1 Implementation climate

i) In your opinion, do you think the health systems environment will be supportive for introducing TA? Why?

Probe:

- ➔ *Will TA fit in existing work processes and practices?*
- ➔ *Can you describe how you think TA will be integrated into existing work processes?*

3.2 Readiness for implementation

i) What kind of support or actions are needed from you, as a policymaker, to make this intervention successful?

Probe:

- ➔ *Are you ready to do these things? Why?*
- ➔ *Other needs your facilities might have (training, materials, information)? Are you prepared to make them available? Why?*

3.3 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about the service delivery environment, are there any other factors that affect whether TA can be effective?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

4. Individual capacities, attitudes, intentions

4.1 Self Efficacy

i) How confident are you that you have the skills you need to (help) lead the process of changing policy and guidelines on cervical cancer treatment? Why?

4.2 Knowledge and beliefs about the intervention

i) Do you think that using TA with SVA-SAT will work well in the health system? Why (not)?

4.3 Individual stage of change

i) How prepared are you to help change policies and guidelines regarding cervical cancer treatment? Why (not)?

4.4 Barriers and facilitators

i) Thank you for the rich information. In addition to what we have discussed about your individual knowledge and attitudes about the intervention, are there any other factors that affect whether TA can be effective where you work?

Probe for factors that affect:

- ➔ *How consistently and broadly TA is adopted?*
- ➔ *Quality of implementation?*
- ➔ *Whether or not TA implementation can be sustained?*

Thank you for participating in this interview. I have no further questions. Before we end the interview, is there anything you'd like to add?

[If yes, listen and continue recording, if no, stop recording and end interview].

END TIME OF IDI: _____

Appendix 2: CFIR Constructs Assessed

Table 2: CFIR Constructs included in the question guide

DOMAN	CONSTRUCTS	SAMPLE QUESTIONS
Intervention Characteristics	Relative advantage	What demonstrates that TIBA is better or worse than existing programs?
	Adaptability	What kind of alterations will be needed to make TIBA work effectively?
	Complexity	How complicated is thermal ablation?
	Evidence strength and quality	What kind of evidence are you aware of that shows whether or not TIBA will work in your setting?
Inner Setting	Structural Characteristics	How will the infrastructure of your organization (social architecture, age, maturity, size or physical layout) affect TIBA implementation? What infrastructural changes will be needed to accommodate TIBA?
	Networks and communication	What is the general communication and relationships in the organization?
	Readiness for implementation Leadership engagement Available resources	What level of support have you received or heard from your leaders to make implementation successful? Do you expect to have sufficient resources to implement TIBA?
	Implementation climate	What is the general level of receptivity in your organization to implementing SVA-SAT+TA?
Characteristics of Individuals	Self-efficacy	How confident are you that you will be able to deliver TIBA?
	Individual stage of change	How prepared are you to implement TIBA?
	Knowledge and beliefs about innovation	What do you know about TIBA, and do you think it will be effective in your setting?
Characteristics of Systems	System architecture/health system context	What health system factors may affect TIBA implementation?
	Policies, programs and guidelines	What policies, programs, and guidelines may affect TIBA implementation?
Outer Setting	Patient needs and resources	How well do you think TIBA will meet the needs of women screening for cervical cancer and treatment in your facility?

Appendix 3: Quotes

Supplementary Material: Quotes

CFIR Domain	Constructs	Quotes
Intervention Characteristics	Complexity, relative advantage and cost.	<i>“It is easier and less complex compared to cryotherapy. It does not require regular filling of the consumables. It's portable and can potentially improve linkage to care.” (PM 003)</i> <i>“It doesn't have many steps, and the steps are not complicated. The treatment is not hard, because it's just connecting the machine, and you do it.” (HP 016)</i> <i>“The fact that it is quite simple to use and the fact that it is also easy, like assembling it. It is easier and it is something that you can carry. It is not bulky.” (HP 001)</i> <i>“There is a need to orient the biomedical maintenance unit in the health facility, as they don't seem to understand the thermal ablator.” (PM, 002)</i>
Inner Setting	Structural Characteristics	<i>“So, for the first entry, we usually train a minimum of two. We also have mentors who are trainers in clusters at the sub-county level.” (PM, 002)</i> <i>“Our rooms are very small—especially the ones provided by the partners. The CCC (HIV clinic) rooms are also quite cramped”. (HP 009)</i> <i>"Linking screening to treatment is difficult due to separate service points—screening may happen, but treatment is often delayed or missed."(HP, 003)</i>

		<i>"I'm the only nurse offering services. Right now, even with VIA VILL, sometimes I can't do it because I'm alone, the queue is very long, and we have a high workload." (HP, 006).</i> <i>"If we can allocate a specific day, we set aside and say that day is for cervical cancer screening and treatment; it will be effective and more efficient." (Nurse, 001).</i>
	Readiness for implementation: Leadership engagement and available resources	<i>"Policymakers are well versed and can guide guideline development—screening policies exist, and the expertise is there."(PM, 004)</i> <i>"We're already engaging the program to ensure these services are included in the next financial cycle. People understand the need for integration and the cancer burden, so they're willing to support." (PM,001)</i> <i>"We know that counties have human resource challenges. If any partners can bring in additional personnel to support that service, that will be welcomed, although we don't promote it because it is not sustainable." (PM, 001).</i> <i>"Policymaking needs stronger political backing to link the intervention to cervical cancer prevention. Reframing its benefits politically can help ensure prioritization and funding." (PM, 003)</i> <i>"Well, I am very prepared. I have been in management for thirteen years, so trust me. We are prepared." (HP, 005).</i> <i>"We have done many things, but without the administration's support, these projects always fail. I have even tried doing outreaches in this county in the past, but then they died because of a lack of support." (HP, 006)</i> <i>"The county is very supportive of treating precancerous lesions and is partnering with donors to expand screening among women of reproductive age."(HP 005)</i> <i>"Mostly, they train people who never see clients. For training and refresher courses, let them consider training people on the ground who review patients. Also, continuous on-the-job mentorship, supervision, and meetings are necessary to identify the gaps and determine progress." (HP, 009).</i> <i>"There should be ongoing mentorship, supervision, leadership, and evaluation—plus planning open days and meetings to identify gaps and track progress." (HM 009)</i> <i>"When doing the annual work plan, they can incorporate a budget for cancer screening, training, etc. It is possible and doable with proper planning." (HP, 007).</i>
Characteristics of systems	Health system context	<i>"One is the buy-in and changing that attitude from funder- or partner-driven to county-led and county-driven. So, there is a lot of work that we need to do to ensure that the county budgets for this and it is not seen as a partner initiative." (PM, 002)</i> <i>"The main limitation is financial. With funding, we can secure commodities, reporting tools, and staff. We have the knowledge,</i>

		training materials, and tools—resources would allow us to actualize." (PM 001) "So, the procurement, I said, is a long process. When our gas [for cryotherapy] went off, we stayed for six months, and one of the partners bought for us that gas, the one that we are using currently." (HP, 007) "You find that the county has decided to reassign staff from here, affecting the implementation of services. You might introduce something, and we pick it, then in between, things fall apart with the staff changeover. I'm left now with nobody trained." (HP, 008) "I have noted that most healthcare workers have negative attitudes towards the screening. I think it is more from burnout, shortage of workers, being demotivated, and lack of resources." (HP, 005) "Staff demotivation is at an all-time high; you find people staying for so long without salaries, even two months, and you expect them to work. (HP, 006) "There's a service cost for screening and treatment, affecting TIBA implementation. If the person has no money to pay, they will not receive the service." (HP, 014) "Actually, in-reaches are less expensive than outreaches because you must be facilitated to go out. (HP, 002)
	Policies, programs and guidelines	"We have national cancer screening guidelines in place which serve to guide all stakeholders on screening and treatment (PM, 001) "What is recommended by these screening guidelines is HPV (Human Papilloma Virus) DNA testing. We advocate for VIA because resources for pathology are limited." (PM, 003) "Implementing population-based screening may be challenging because, despite having screening guidelines, there is no system to track which patients complete screening, follow up on results, or return for care." (PM, 004). "We have had so many programs that the partners have been supporting, and they have been of great help because we have gone around to most of the periphery facilities to screen and try to mentor the ones there." (HP, 007) "The main limitation is financial. With funding, we can secure commodities, reporting tools, and staff. We have the knowledge, training materials, and tools—resources would allow us to actualize." (PM, 001) "Human resource management is decentralized, leading to frequent staff transfers that disrupt service delivery. This threatens effective implementation. Additionally, unlike treatment, cervical cancer screening isn't yet institutionally funded, making cost a key policy barrier." (PM 003)

		<i>"We have a cervical cancer screening guideline that we are using, and that is what I am saying. I am not sure if it is 2016 or 2014, and you know things have changed. We should have an updated one." (HP, 004)</i> <i>"Screening can be a bit tricky because the organization that is giving us the materials specifically provide for women living with HIV only." (HP, 013)</i> <i>"The nurse working in the CCC will deal with her patients, and those on the other side [regular clinics like MCH] will feel demotivated because they know the ones in the program are being paid more. Services need integration, whether they are supported programs or not." (HP, 008)</i>
Individual Characteristics	Self-efficacy	<i>"I would not say I am very confident. You know it is a new thing. So, we are learning and eager to learn, but I cannot predict how the patients and health workers will take it, so I am eagerly waiting." (HP, 010)</i> <i>"We've done this before with VIA/VILI. Once trained, we can handle the treatment—we're skilled nurses and midwives. It's just a matter of training, then we're ready." (HP 004)</i>

Appendix 4: Implementation Strategies

1.Streamlined patient journey (admission to screening, to treatment, to follow up).
2. Improved referral processes (communication, documentation, client-support, etc.)
3. Better availability and management of essential medications, supplies and equipment.
4. Streamline payment mechanics.
5. Other efforts to mitigate financial burden of care-seeking.
6. Dissemination of pertinent guidelines and standards (includes SOP).
7. Enhancements to the mangement of human resources.
8. Changes to service delivery environment to address client needs (e.g. privacy)

9. Strengthen mechanisms for health worker training/mentoring and coaching.
10. Improvements to supervision and quality assurance
11. Availability of job aids and similar resources for health workers.
12. Community engagement, service communication, sensitization related to cervical cancer screening and rx.
13. Improve quality of counseling and information provision to clients.
14. Support to clients to retain them in system of care (e.g., support for follow up, linkages to other SRH services)
15. Improvements to the organization of care (e.g., colocation of multiple services in one setting)
16. Improved collaboration between sectors and implementation partners.
17. Advocacy to county (other high level) authorities for a more enabling environment.
18. Improvements regarding recording and management of routine health information.

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