WHITE PAPER

Scaling thermal ablation devices for cervical cancer prevention: experience from a multi-country Unitaid-supported program

A guide to procuring, introducing and effectively utilizing thermal ablation devices for cervical cancer prevention

Authors: Akanksha Doval, Anisa Ghadrshenas (Unitaid), Ciru Wanjiru Ndichu, Divya Sarwal*, Emily Crawford, Frehiwot Birhanu, Isaac Okiring, Jenala Nyangu, Kehinde Onasanya (Unitaid), Kevin Sawadogo, Lance Osiro, Layo Lawson, Marieme Diallo, Marvin Lubega, Memory Samboko, Nang'andu Chizyuka, Patricia Njiri, Prudence Haimbe, Ranveer Singh, Smiljka de Lussigny (Unitaid), Sophia Dunu, Sylvie Gaju, Tatenda Maparo, Timothy Tchereni

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Please reach out to dsarwal@clintonhealthaccess.org for any queries on this paper

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Executive summary

Cervical cancer remains a leading cause of cancer-related deaths among women in low-and-middle-income countries (LMICs), despite being largely preventable. Treatment of precancerous cervical lesions is a key pillar of the World Health Organization's (WHO) global strategy to eliminate cervical cancer, which targets 90% of women with identified precancerous lesions to receive treatment by 2030. However, access to precancer treatment in LMICs has been limited, largely due to dependence on cryotherapy—a technology constrained by high costs and operational challenges.

Thermal ablation (TA) is a highly effective, safe, portable, and cost-efficient alternative, and is endorsed by WHO. Thanks to Unitaid's investments in CHAI, the SUCCESS group, and the WHO, in collaboration with country governments, over 6,000 TA devices have been introduced and scaled across 28 countries, with more than 11,000 healthcare workers trained. Countries have adopted various deployment strategies—including tiered, universal, and demand-driven models—to integrate TA into their national programs.

The transition from cryotherapy to TA has reduced precancer treatment costs by 75% per patient, bringing costs down to approximately $4.10. These savings are due to lower consumable needs, fewer operational constraints, and broader usability by various healthcare cadres. Moreover, global access pricing agreements negotiated with two manufacturers—Liger Medical and Wisap—have reduced the cost of TA devices by ~45% compared to market prices, improving affordability and market stability. Further, healthcare providers have reported no significant differences between the two devices in terms of ease of use, effectiveness or satisfaction, suggesting that either device is suitable for countries looking to scale up TA use for treating precancerous lesions.

Key enablers of success include integration of TA into national guidelines, decentralized service delivery, robust training and supervision systems, strong community engagement and patient tracking systems to minimize women lost to follow-up. Countries' experiences confirm that TA can be effectively delivered by a wide range of healthcare providers, enabling task-shifting and broader service availability.

As countries accelerate toward WHO's elimination targets, TA represents a transformative solution to expanding access to cervical precancer treatment—offering a scalable, sustainable, and cost-effective path forward.

Abbreviations

ART - Antiretroviral therapy

CDSCO - Central Drugs Standard Control Organization

CHAI - Clinton Health Access Initiative

CIN - Cervical intraepithelial neoplasia

IFUs - Instructions for use

LMICs - Low-income and lower-middle-income countries

MCH – Mother and Child Health

NAFDAC - National Agency for Food and Drug Administration and Control

NCS - Nigeria Customs Service

PMS - Post-market surveillance

PSM - Procurement and supply chain

'SUCCESS' group - Scale Up Cervical Cancer Elimination with Secondary Prevention Strategy

TA - Thermal ablation

US$ - U.S Dollar

WLHIV - Women living with HIV

HPV - Human papillomavirus

WHO - World Health Organization

1. Background: The need for scalable solutions in cervical cancer prevention

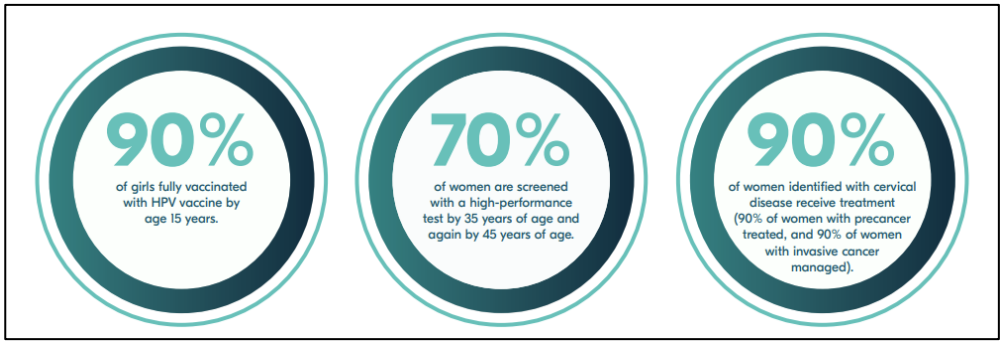
1.1 The global burden of cervical cancer

Cervical cancer is primarily caused by persistent infection with the human papillomavirus (HPV), a common sexually transmitted infection. If left untreated, persistent HPV infection leads to 95% of cervical cancer cases [1]. Cervical cancer is a preventable and curable disease, yet it continues to be a leading cause of cancer-related deaths for women globally. Women in low-income and lower middle-income countries (LMICs) are more likely to experience cervical cancer due to a lack of access to affordable and high-quality services for primary prevention, screening, and treatment. Of the 350,000 deaths from cervical cancer reported in 2022, over 90 percent occurred in LMICs. Women living with HIV (WLHIV) are at higher risk of illness and death from the disease.

Cervical cancer is preventable through multiple interventions: vaccinating 9–14-year-olds to protect against HPV and related cancers (primary prevention), screening women for cervical cancer (secondary prevention), and effectively treating precancerous lesions as well as early detection followed by timely, high-quality treatment for invasive cervical cancer (tertiary prevention). The World Health Organization (WHO) has classified these interventions as "best buys" or the most effective strategies with a cost-effectiveness of ≤ I$100 per healthy life year (HLY) gained in LMICs[2].

In August 2020, the WHO launched its first-ever Global Strategy for Cervical Cancer Elimination[3] to respond to this public health challenge. Elimination of cervical cancer will be achieved when all countries reach and maintain an incidence rate of 4 per 100,000 women. As of 2022, the average incidence rate across LMICs was 118 per 100,000 women[4]. Fig 1 highlights the WHO 2030 targets for each of the three pillars essential for achieving elimination.

Fig 1: WHO targets for cervical cancer elimination



[1] WHO cervical cancer factsheet, weblink here

[2] WHO Tackling NCDs - Best buys and other recommended interventions for the prevention and control of noncommunicable diseases, weblink here

[3] World Health Organization. "Cervical Cancer Elimination Initiative." Last modified November 17, 2020, Weblink here

[4] Globocan 2022 (version 1.1) - 08.02.2024- Age-Standardized Rate per 100 000, Incidence, Both sexes, in 2022- Countries classified as Lower-middle-Income and Low-income per World Bank

1.2 Evolution of thermal ablation as a preferred precancer treatment option

Access to cryotherapy, that was the standard treatment for precancerous cervical lesions, has been limited in LMICs due to cost and logistical challenges. Cryotherapy devices need nitrous oxide or high-quality carbon dioxide to operate, which can be difficult to procure in LMICs. Transporting the heavy tanks in uncertain conditions can be arduous.

WHO endorsed thermal ablation (TA) devices for treating precancerous cervical lesions in 2019[5], thus expanding the secondary prevention toolkit for cervical cancer.

TA devices offer equivalent clinical outcomes to cryotherapy and help overcome supply chain and access barriers faced by LMICs. Thermal ablation effectively treats eligible cervical intraepithelial neoplasia (CIN) or precancerous lesions, with documented success rates between 87 and 97 percent in low-resource settings [6,7,8].

Examples of quality-assured, portable and easy-to-use TA devices include Liger Medical and Wisap Medical Technologies GmbH. These devices use a heated metallic probe and can be operated by various cadres of healthcare professionals with some training. TA devices have lower costs than cryotherapy and they do not require refrigerant gas, reducing logistical barriers and operating costs while achieving equivalent clinical outcomes.

1.3 Unitaid-supported programs to improve access to screening and precancer treatment

In May 2018, Unitaid announced a US$70 million investment toward cervical cancer screening and precancer treatment for women in LMICs in response to the WHO call for the elimination of cervical cancer. A year later, in July 2019, the Clinton Health Access Initiative (CHAI), with funding from Unitaid, launched a multi-country program to increase access to screening and treatment for cervical pre-cancer in 10 countries[9]. Unitaid also funded related interventions under the SUCCESS[10] project covering Burkina Faso, Ivory Coast, Guatemala and the Philippines, and more recently under the SUCCESS2 project expanding efforts to additional countries.

Since the launch, the Unitaid investment, in partnership with CHAI, SUCCESS group and partner Governments has helped screen over 1.5 million women, with over 80 percent of screen-positive women receiving appropriate treatment across 14 countries. The program has trained over 11,000

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[5] WHO guidelines for use of thermal ablation for cervical pre-cancer lesions - Weblink

[6] WHO technical guidance & specifications of medical devices for screening and treatment of precancerous lesions - Weblink; Maza M, Schocken CM, Bergman KL, Randall TC, Cremer ML. Cervical Precancer Treatment in Low- and Middle-Income Countries: A Technology Overview. Journal of global oncology (2017); 3(4):400-8 - Weblink

[7] Randall TC, Sauvaget C, Muwonge R, Trimble EL, Jeronimo J. Worthy of further consideration: An updated meta-analysis to address the feasibility, acceptability, safety and efficacy of thermal ablation in the treatment of cervical cancer precursor lesions. Prev Med. 2019;Jan:118:81–91 - Weblink

[8] de Fouw M, Oosting RM, Rutgrink A, Dekkers OM, Peters AAW, Beltman JJ. A systematic review and meta-analysis of thermal coagulation compared with cryotherapy to treat precancerous cervical lesions in low- and middle-income countries. Int J Gynaecol Obstet. 2019 Oct;147(1):4-18. doi: 10.1002/ijgo.12904. Epub 2019 Jul 22. PMID: 31273785 - Weblink

[9] India, Kenya, Malawi, Nigeria, Rwanda, South Africa, Senegal, Uganda, Zambia, Zimbabwe

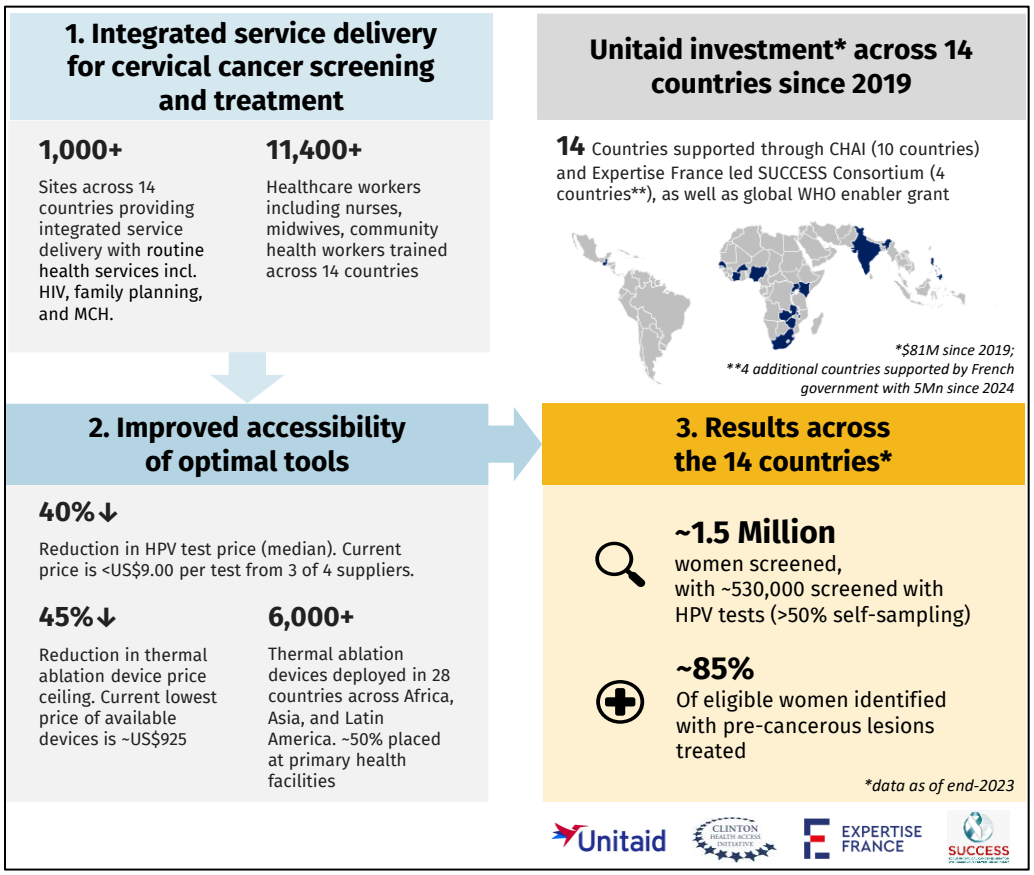
[10] SUCCESS group stands for 'Scale Up Cervical Cancer Elimination with Secondary Prevention Strategy'

healthcare workers, established mentorship and supervision structures, and strengthened health and lab systems for service integration. Program countries have incorporated optimal tools, including HPV tests and TA devices into their national guidelines, enabling long-term access to these innovations for women.

With Unitaid's investments together in CHAI, SUCCESS group and WHO Enabler grants, more than 6,000 TA devices are now available at public health facilities in 28 countries in Asia, Africa, and South America[11] . The scale of this investment enabled Unitaid and CHAI to negotiate an access pricing agreement with two key TA manufacturers, reducing cost of TA devices by ~45% compared to market price and stabilizing the market. A TA device costs under $1,000, significantly lowering the cost of treating precancerous lesions when compared to cryotherapy - See here for TA pricing factsheet undergoing a revision for the current year, and also refer to section 2.3.

Unitaid has also recently released a comprehensive landscape on cervical cancer prevention technologies, highlighting both existing tools and promising innovations to improve early detection and treatment of precancerous lesions.

Fig 2: Unitaid-supported program to expand access to secondary prevention of cervical cancer



[11] List of 28 countries where TA devices have been made available with Unitaid's investment – India, Kenya, Malawi, Nigeria, Rwanda, Senegal, South Africa, Uganda, Zambia, Zimbabwe, Cambodia, Peru, Barbados, El Salvador, Paraguay, Burkina Faso, Ivory Coast, Guatemala, Philippines, Cameroon, Eswatini, Liberia, Myanmar, Tanzania, Ethiopia, Papua New Guinea, Lesotho, Botswana

1.4 Scaling thermal ablation devices for precancer treatment

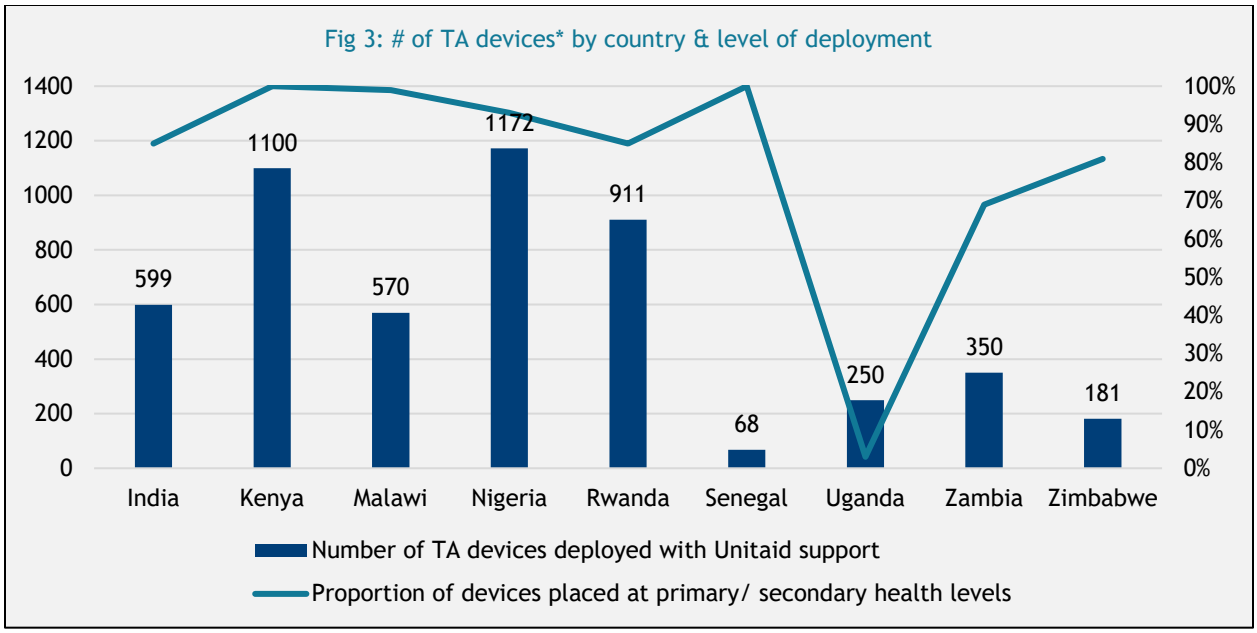
In 2022, CHAI published a whitepaper outlining the program's initial experience with rolling out TA devices in partnership with the governments of India, Kenya, Malawi, Nigeria, Rwanda, Senegal, Uganda, Zambia, and Zimbabwe. It explored the benefits of adopting TA in these settings, highlighting key advantages such as:

- **TA devices are easy to use**. They can be run on battery power, allowing them to be used at primary health facilities and in outreach settings.
- **TA devices can be operated by various healthcare workers** following training, expanding the pool of providers who can safely and effectively offer treatment. This increases access even in lower-level health facilities.
- **TA is straightforward to roll out**, requiring a simple procurement process, basic training, and standard pricing. The devices don't require ongoing maintenance beyond regular disinfection after each use, as outlined in the manufacturer's instructions for use (IFUs). Probes can be replaced if they become nonfunctional or break.
- **TA reduces loss to follow-up** in women who need treatment because it is effective and can be conducted the same day a woman receives her results.
- **TA is less expensive than cryotherapy**, allowing countries to expand treatment access affordably.

The program observed these benefits across multiple countries, with only a few reported challenges. The program's success demonstrates the importance of TA in supporting countries in achieving their cervical cancer elimination goals by 2030.

By mid-2024, Ministries of Health in all ten Unitaid-CHAI supported countries had included TA devices in their national screening and treatment guidelines and/ or clinical curriculum for treating precancerous cervical lesions. They had also secured the necessary approvals for their use in national programs.

Notably, health authorities have placed over 85 percent of deployed devices at primary (48 percent) or secondary (37 percent) health facilities, shifting treatment from centralized tertiary care. Before the introduction of TA devices, women had to travel long distances for cryotherapy at district or provincial hospitals, leading to a low treatment completion rate. This resulted in missed opportunities to prevent the progression of a precancerous lesion to invasive cancer.



**This accounts for only a portion of the total devices procured with Unitaid's support, that had been deployed in countries shown in the graph by mid-2024*

This paper serves as a practical guide for national cervical cancer programs seeking to adopt and scale TA devices for the treatment of eligible precancerous lesions. It provides detailed guidance on planning, implementing, and sustaining TA devices within cervical cancer secondary prevention programs. Additionally, it outlines the costs associated with treatment, key budget considerations, and insights from project countries to enhance patient uptake and improve access to precancer treatment for women. The paper is divided into two main sections:

- **Key enablers for scale-up of precancer treatment using TA devices**, including: integration into health systems, training and clinical mentorship programs, access and procurement, and post-market surveillance to collect valuable insights for scale-up.
- **Guidance to optimize TA service delivery and systems to increase treatment rates**, including: community sensitization and engagement with women, client tracking and referral to minimize loss to follow-up, and ongoing troubleshooting and support to device users.

2. Key enablers for scale-up of precancer treatment using TA devices

Introducing a new medical device and a new way to treat precancerous cervical lesions requires several preparatory initiatives before a device is even procured. This section summarizes the preparatory steps including integrating TA into health systems, training and capacity building of health care workers, and access and procurement considerations. Many countries introducing TA take the opportunity to implement complementary initiatives, including strengthening their health information systems to enable the collection of quality data on screening and treatment, track adverse events, and ensure screen-positive women receive appropriate treatment and/or referral services.

2.1 Integrating TA into health systems

2.1.1 Adopting TA into clinical guidelines

To integrate TA as a treatment method, public health programs need to include it in their national clinical guidelines, in line with WHO's guidance for managing cervical precancerous lesions. Additionally, clinical training materials for managing cervical precancers need to be updated to include TA procedures. These steps are essential prerequisites before integrating TA devices into a national program on cervical cancer prevention.

2.1.2 Integrating devices in existing delivery channels

Unitaid-CHAI-supported countries have prioritized placing TA devices at existing service delivery points that offer cervical cancer screening services. These locations typically include ART (antiretroviral therapy) clinics, family planning centers, and mother and child health (MCH) facilities across all levels of healthcare—primary, secondary, and tertiary. The program has demonstrated that, with adequate training, TA treatment can be effectively performed by a diverse range of healthcare workers, including gynecologists and medical officers (India), midwives (Senegal, Uganda), nurses (Kenya, Rwanda, Zimbabwe), and community health extension workers (Nigeria). This supports its use across different healthcare settings and enables task-shifting to lower-level cadres.

Key considerations for TA device placement include – 1) Infrastructure and staffing: ensuring the availability of basic infrastructure, such as a private space and an examination table, along with trained healthcare workers capable of performing the procedure; 2) Training and capacity building: Once suitable sites are identified, provide hands-on training to staff on TA treatment protocols, benefits, and procedures for managing potential device malfunctions.

2.1.3 Allocation/ deployment strategy for TA devices

Countries have adopted various approaches to deploy and scale up the use of TA devices, and national programs should assess which strategy best fits their specific needs and context. Common models include:

- **Tiered deployment approach**: India and Kenya implemented a phased approach to TA device deployment, starting with tertiary and nodal secondary-level institutions that served as referral centers. The initial deployment enabled experienced clinicians to efficiently serve large catchment areas. In the second phase, these trained providers transferred their skills to

medical officers and nurses, supporting the expansion of TA device use to primary and secondary healthcare facilities and promoting decentralized access.

- **Universal distribution model:** In countries like Zimbabwe, the national program adopted a universal coverage strategy by equipping all screening sites with TA devices, ensuring precancer treatment services were accessible at every level of care. As of mid-2023, 96 percent of project sites offering screening services in the nine Unitaid-CHAI supported countries were equipped with TA devices.
- **Demand-driven allocation strategy:** Some countries prioritized deploying TA devices in high-volume facilities and locations with substantial treatment backlogs. By targeting high-demand sites, these programs maximized the impact of TA devices while addressing gaps in access and service delivery.

2.1 Integrating TA into health systems – Highlights

- Adopt TA into clinical guidelines and training materials, aligned to WHO recommendations.
- Integrate TA devices in existing service delivery points that offer cervical cancer screening services - ART, family planning, MCH clinics etc.
- Adopt appropriate TA allocation/ deployment strategy – tiered deployment approach, universal distribution, demand-driven allocation.

2.2 Training and clinical mentorship programs

2.2.1 Training of health workers

Training on device operation and management is essential for both effective treatment and device longevity. It should cover procedure preparation, proper cleaning and disinfection of the TA device, and the protocol for reporting issues or complaints. It is valuable to have multiple types of training materials, such as reference guides, instructions for use, videos, simulations, checklists, and/or live sessions with the manufacturers. Please find links to training videos on how to operate Liger's HTU110 thermo-coagulator here, and Wisap's C3 device here.

Training healthcare workers to accurately identify which precancerous lesions are suitable for ablative treatment and which require referral for excisional procedures is crucial to ensuring successful patient outcomes. Evidence suggests that 60-70 percent of women found with cervical precancers can be treated using ablative methods[12], with some studies suggesting this proportion could reach up to

[12] Per National Cancer Institute (article link) & Farida Selmouni et al, Lessons Learnt From Pilot Cervical Cancer Screening and Treatment Programmes Integrated to Routine Primary Health Care Services in Benin, Cote d'Ivoire, and Senegal. *JCO Glob Oncol* **8**, e2200051(2022) - Weblink

90%[13,14,15]. Effective management of these lesions at the precancerous stage presents a significant opportunity to prevent progression to cervical cancer. WHO guidelines offer technical guidance on eligibility for ablative treatment and provide screening and treatment algorithms for both ablative and excisional procedures.

It is crucial to optimize the health worker training model to avoid operational and budgetary burdens. CHAI and partner governments have employed a cascade model for training for its efficiency. In a cascade model, master trainers, who operate regionally, receive comprehensive training and clinical practice on using TA devices. They are then tasked with training and mentoring health workers in their respective regions. The theory portion of the training is cascaded further virtually - a cost-effective means of instruction adopted and improved upon during the COVID-19 pandemic when mobility and gatherings were limited. Health workers are then assessed through unit tests or other objective means to test their knowledge before the in-person clinical practicum.

2.2.2 Ongoing capacity building with clinical mentorship and supportive supervision

Beyond the upfront training, secondary prevention programs for cervical cancer prioritize continuous quality improvement through routine clinical mentorship. Mentorship, which involves structured assessment of clinical skills and personalized attention, plays a critical role in ensuring quality of care. Clinical mentors are often also regional consultants for complex clinical cases. Mentorship fosters communication between the mentors and mentees, improving service quality, and strengthening the referral network for cervical cancer prevention and treatment, and other disease areas. Further, countries have noted that periodic supportive supervision at sites, conducted by trainers or mentors, enhances the effective use of devices and reinforces healthcare workers' knowledge and skills.

In addition to these preparatory steps, it is essential to strengthen health systems for patient tracking and reporting, thus ensuring timely care for screen-positive women found eligible for treatment (see section 3.2).

2.2 Training and clinical mentorship – Highlights

- Provide theoretical and practical training for health workers on device operation, lesion identification, and ablative treatment.
- Support continuous quality improvement through clinical mentorship to optimize device use and treatment services.
- Conduct periodic supportive supervision by trainers/mentors to enhance device use and reinforce healthcare workers' knowledge

[13] Clara Yolanda Stroetmann, Muluken Gizaw, Rahel Alemayehu, Abigiya Wondimagegnehu, Friedemann Rabe, Pablo Santos, Bariki Mchome, Blandina Theophil Mmbaga, Adamu Addissie, Eva Johanna Kantelhardt, Adherence to Treatment and Follow-Up of Precancerous Cervical Lesions in Ethiopia, *The Oncologist*, Volume 29, Issue 5, May 2024, Pages e655–e664 - Weblink

[14] Feasibility of thermocoagulation in a screen-and-treat approach for the treatment of cervical precancerous lesions in sub-Saharan Africa Manuela Viviano , Bruno Kenfack, Rosa Catarino, Eveline Tincho, Liliane Temogne, Anne-Caroline Benski, Pierre-Marie Tebeu, Ulrike Meyer-Hamme, Pierre Vassilakos and Patrick Petignat - Weblink

[15] Lawson, O., Ameyan, L., Tukur, Z. *et al.* Cervical cancer screening outcomes in public health facilities in three states in Nigeria. *BMC Public Health* **23**, 1688 (2023) - Weblink

2.3 Enhancing TA access, facilitating procurement and budgeting for total treatment costs

Before the Unitaid-supported programs, TA devices were not widely used at scale. To expand their availability and accessibility, Unitaid and CHAI conducted a market analysis in 2019, identifying two two global manufacturers of quality-assured portable TA devices - Liger Medical and Wisap Medical Technologies GmbH. Following this, Unitaid and CHAI negotiated global price agreements with these manufacturers, reducing costs for designated purchasers[16] by an average of 45 percent (across the two brands) compared to market prices.

Since this negotiation, price agreements remain in place (this factsheet is currently undergoing a revision to reflect the revised validity) and can be accessed by procurers directly by contacting manufacturers or through the UNICEF-SD procurement route. The market has stabilized, and the manufacturers have assured supply of these devices amidst steady demand.

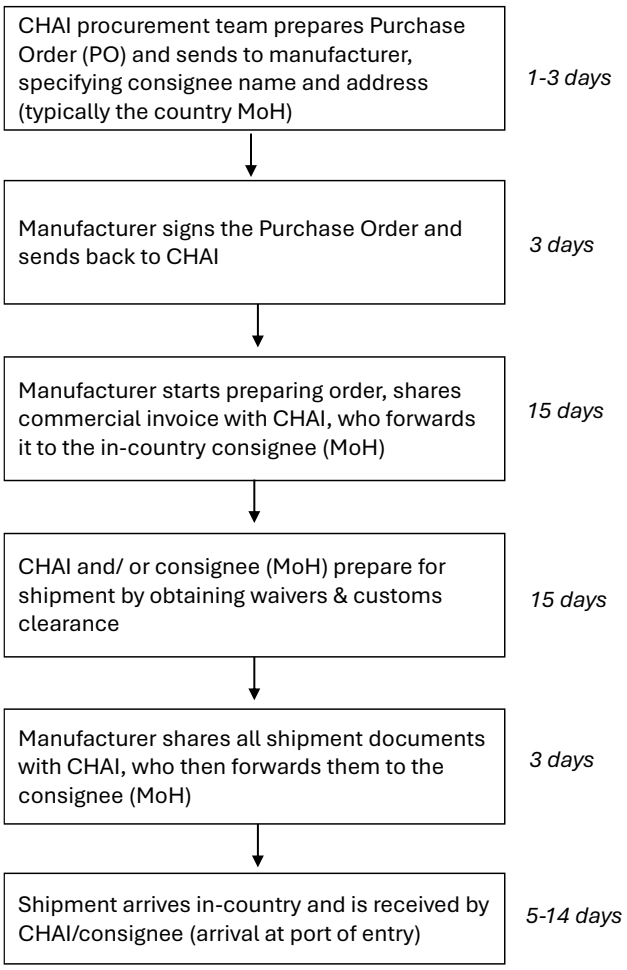
The following sections cover procurement logistics, regulatory approval and anticipated cost of treatment using TA devices.

2.3.1 Procurement logistics

Designated purchasers can procure TA devices directly from manufacturers, through in-country distributors where available, or via the UNICEF-SD platform. Between 2020 and 2024, CHAI supported the procurement of over 5,700 TA devices—sourced both directly from Liger and Wisap and through the UNICEF-SD platform—for Ministries of Health across several countries, following a structured procurement process (see Fig 4). On average, the direct procurement route took about 1.5 months from order placement to in-country delivery.

[16] Public sector buyers noted in the agreement include ministries of health and parastatal procurement agencies of LMICs specified in the pricing agreements; international donors such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria, President's Emergency Plan for AIDS Relief (PEPFAR), United States Agency for International Development (USAID); and United Nations organizations.

Fig 4: Procurement process for TA devices (direct from manufacturer)



2.3.2 Securing regulatory authorization for use in-country

The use of TA devices in-country may require regulatory approval or authorization from relevant national authorities. This process is often separate from, and in addition to, manufacturer/ distributor-led product registration. CHAI has assisted manufacturers suppliers and Ministries of Health in navigating local regulatory requirements across various countries. For example, in India, the Central Drugs Standard Control Organization (CDSCO) requires approval through a locally registered entity to import TA devices. CHAI worked with device manufacturers and local distributors to secure the necessary regulatory approvals.

In many countries, procurers can request an import duty waiver from the relevant authorities by meeting specific conditions. For example, in Zimbabwe, authorities issue a waiver for goods deemed necessary for the operation of Ministry of Health programs. In Nigeria, clearing devices at the customs port of entry involves two applications: one to the Nigeria Customs Service (NCS) for an Import Duty Exemption Certificate and another to the National Agency for Food and Drug Administration and Control (NAFDAC).

2.3.3 Cost of treatment using TA devices

Understanding the total cost of delivering treatment with TA—encompassing both one-time initial costs and ongoing operational expenses—is crucial for countries newly adopting this treatment method (either alongside or in place of cryotherapy) and for those looking to scale up services. The following sections outline the various costs associated with TA treatment and offer a comparison with cryotherapy. These estimates are based on data obtained from Kenya, Senegal, Zambia, and Zimbabwe.

Startup costs for service delivery with TA devices

Programs that wish to adopt TA as a treatment method must take two key startup costs into account: device procurement and training costs.

1. Device procurement

When planning the budget for TA device procurement, the upfront device purchase cost and procurement and supply chain (PSM) costs for bringing the device to in-country sites should be considered. The total landed procurement cost is approximately **US$1,180 per device or US$0.59 per woman treated**.

This cost is based on device prices as of Dec 2024 from Liger and Wisap (device cost including four probes), estimates on device replacement outside the warranty period, and PSM charges needed to import the device from manufacturer's locations to CHAI-Unitaid supported countries. We have assumed that a single TA device can deliver approximately 2,000 treatments over its lifetime when operated according to the manufacturer's IFUs and disinfected following the recommended protocol. Please see Annex 1 for all assumptions.

We recommend that facilities keep extra batteries[17] on site, along with a voltmeter, to diagnose any battery issues if a battery is not fully charged or malfunctions during the procedure. Please note that these costs aren't included in the device cost cited above.

Understanding device and probe longevity in an implementation research settings will be useful for governments to more accurately budget for TA devices based on the treatment needs and volumes in different catchment areas.

2. Training costs

A cascade training model, where master trainers receive comprehensive training and clinical practice with TA devices before training health workers in their regions, is estimated to cost approximately **US$146 per healthcare worker, or US$0.07 per woman treated**.

Routine clinical mentorship and supportive supervision are essential for continuous quality improvement and better service delivery. However, since these are shared costs across multiple government programs, they have not been included in the cost estimate above.

Ongoing costs for TA treatment delivery

The two primary ongoing costs for using TA devices to deliver treatment are consumables and healthcare worker time. The costs of demand generation activities and/or community health workers'

[17] Additional battery may cost $45 or €190, depending on the Liger or the Wisap device

time to mobilize demand for screening or follow-up treatment are not included here as these are shared expenses across multiple government programs.

3. Consumables

Each treatment using TA requires a set of consumables, including gloves, cotton swabs, and a speculum. It is also essential to ensure sites have the proper cleaning and disinfecting solutions as the coating on the probes require special care. Without proper solutions and following the appropriate procedures, the device and/ or probes can be damaged, compromising device lifespan and functionality.

Based on the estimated lifespan of a probe and the number of treatments the device can perform over its lifetime, we also advise budgeting for an additional 2-3 probes beyond the four provided with the device to account for potential breakage.

Based on estimates for consumables from the WHO OneHealth Tool, and manufacturer prices for additional probes, the cost of consumables is estimated at ~**US$2.82** per woman treated.

4. Service delivery

With adequate training, treatment for precancerous lesions can be delivered by a range of healthcare workers, including gynecologists, medical officers, midwives and nurses. This allows for task-shifting of treatment delivery from the highest-qualified (and highest-cost) to lower cadres, who are easier to recruit and generally cost less to retain.

The cost of health worker time is estimated at **US$0.60 per woman treated**. This is calculated based on health workers' monthly salary and the time required to prepare for, conduct, and conclude the treatment procedure.

Cost comparison with cryotherapy

Based on estimates obtained from the four countries – Kenya, Senegal, Zambia, and Zimbabwe[18], it is noted that TA can be rolled out and used at one-fourth the cost of using cryotherapy. Table 1 shows a head-to-head comparison of the key cost heads.

Table 1: Comparison of cost per patient treated using TA and cryotherapy

Cost head	**Per patient cost using cryotherapy (US$)**	**Per patient cost using TA (US$)**	**% cost reduction with TA devices**
Start-up costs			
Device purchase cost including PSM charges	1.24	0.59	52%
Training and site activation costs[19]	0.12	0.07	38%

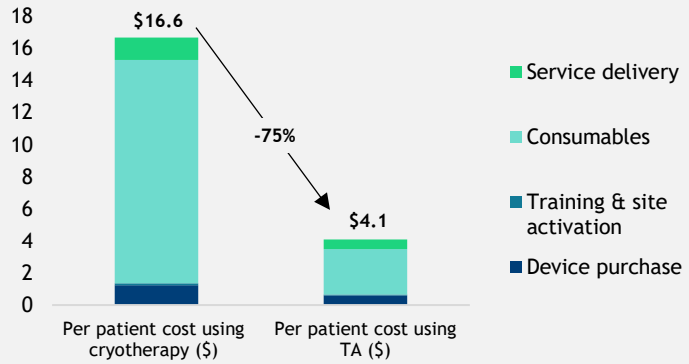
[18] These costs do not take into account routine clinical mentorship, supportive supervision costs, cost of demand generation activities or the time of community health workers to mobilize demand for screening as these are cross cutting costs spread across multiple government programs

[19] Site activation cost for cryotherapy includes the one-time cost of purchasing gas cylinder. None for TA

Cost head	Per patient cost using cryotherapy (US$)	Per patient cost using TA (US$)	% cost reduction with TA devices
Ongoing costs			
Consumables	13.91	2.82	80%
Service delivery cost	1.39	0.60	56%
Total	**16.6**	**4.1**	**75%**

While cryotherapy entails higher costs across most categories, including device and service delivery, its most significant expense is the gas required to operate the machine—a cost that is eliminated with TA treatment. The unavailability and fluctuating price of gas has been cited by countries as being the biggest barrier to providing cryotherapy treatment, alongside logistical challenges and higher overall treatment costs.

Fig 5: Cost per patient treated for pre-cancerous lesion



2.3 Enhancing TA access, procurement and budgeting for total treatment costs - Highlights

- Unitaid and CHAI negotiated global price agreements with Liger and Wisap, reducing costs for designated purchasers.
- Designated purchasers can buy TA devices directly from manufacturers, through in-country distributors where available, or via the UNICEF-SD platform.
- Use of TA device in countries may require regulatory approval or authorization, with the option to request an import duty waiver in some countries.
- Understanding the total cost of TA treatment, including initial and ongoing expenses, is essential for countries adopting or scaling up this method.
- Start-up costs include device procurement and training, while ongoing costs involve consumables and healthcare worker time. TA can be deployed at a quarter of the cost of cryotherapy, costing about US$4 per treatment.

2.4 Post-market surveillance of TA devices

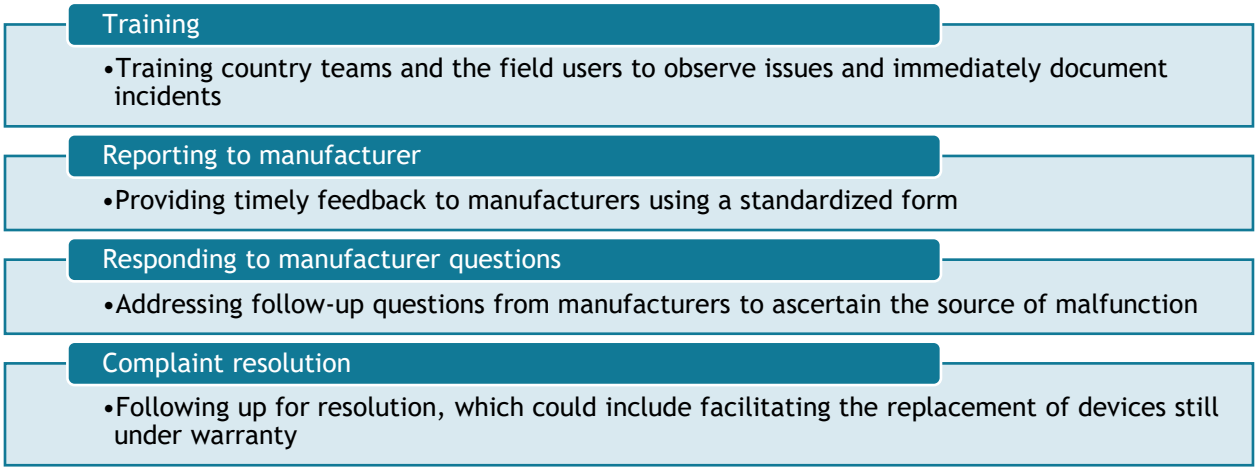
The WHO requires all medical devices manufacturers to carry out post-market surveillance (PMS) of any adverse event and product malfunction or failure. This includes end users (in this case, treatment

providers) submitting complaints directly to the manufacturer when a malfunction is detected[20]. End users play an important role in identifying issues and providing feedback to manufacturers, as well as adhering to manufacturer guidelines to ensure patients receive the highest quality of care[21]. This is essential to optimize the use of TA devices in service delivery and often provides valuable insights that help countries refine their plans for scaling treatment services.

2.4.1 PMS Process and results

Following this guidance, Unitaid-CHAI supported program countries carried out PMS of TA devices. The process for conducting this PMS includes four key steps: training, reporting to the manufacturer, responding to manufacturer questions, and complaint resolution.

Fig 6: PMS process adopted by CHAI



Between 2020 and 2022, approximately 3,000 Liger HTU-110 and Wisap C3 units deployed in public health facilities in nine countries recorded a device incident rate—defined as any malfunction of the TA device or its components—**of less than 1 percent**. No country reported adverse events with using TA devices during this period.

Among the reported device incidents, 34 percent involved battery or battery charger malfunctions, while another 34 percent were related to probes cracking or failing to heat to the appropriate temperature. Additionally, 17 percent of incidents involved the device not heating up, attributed to causes unrelated to the probes or battery. When reported to the manufacturers, these complaints were promptly addressed, often through remote video-conferencing sessions with the in-field users. In some cases, troubleshooting tips from the manufacturers resolved the issues, while in others, free-of-charge replacements were provided for devices still under warranty.

[20] WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer, 2020

[21] WHO Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics, 2020

Fig 7a: Device incident rate

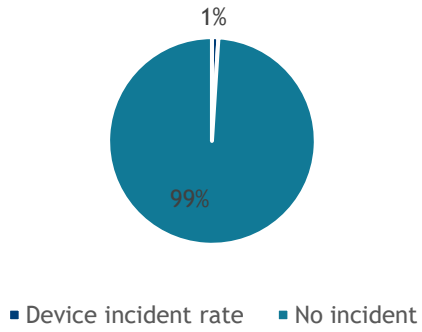


Fig 7b: Reasons for device malfunction

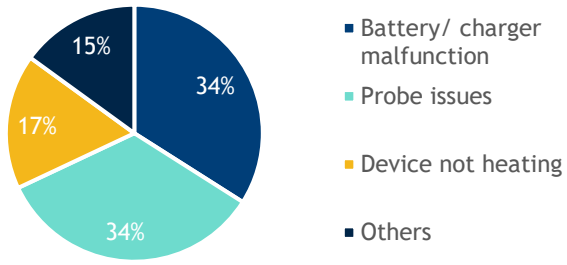


Table 2 below summarizes some common complaints observed in Unitaid-CHAI supported countries, and the troubleshooting strategies implemented.

Table 2: Common questions and complaints from users of TA devices

Common questions/ complaints	**Response/ solution explored**
The battery doesn't work even though it's a new device	In some cases, it was found that the battery had 'hibernated' because of extended disuse. It was possible to jumpstart the battery using a micro-USB charger (observed in case of Wisap devices)
How do I identify if the issue is with the battery or its charger?	To test the battery, fully charge it and use a voltmeter to measure the voltage. A fully charged battery should read approximately 12V. If the reading is below 9.5V, there may be an issue with either the battery or the charger. To confirm, try charging a second battery with the same charger. If the second battery also fails to exceed 9.5V, the problem is likely with the charger
How do I identify if the issue is in device handle or the probe?	Test the faulty probe by connecting it to a different device handle, and test the faulty handle by attaching it to working probes in order to isolate the root cause
Why does the probe on the Wisap C3 device have a 'slider' on and the Liger probe doesn't?	The Wisap probe heats up before insertion into the vaginal canal and remains hot upon removal. To prevent burns to the vaginal walls, a 'probe slider' (or sliding guard) must be manually adjusted by the provider using a plastic trigger-like ring. The guard covers the probe tip during insertion and removal and is slid off during treatment. In contrast, the Liger TA device is inserted while cool and only heats up once the probe tip is placed on the cervix. It then cools down before removal, eliminating the need for a probe slider.
Why does the probe crack? Why does it not heat to the appropriate temperature?	Probes may crack or fail to reach the appropriate temperature if improper disinfecting solutions are used or if excessive force is applied during fitting. This highlights the importance of following the manufacturer's IFUs including using the recommended disinfection solutions to ensure the probe's durability and performance.

2.4.2 Provider feedback on TA devices

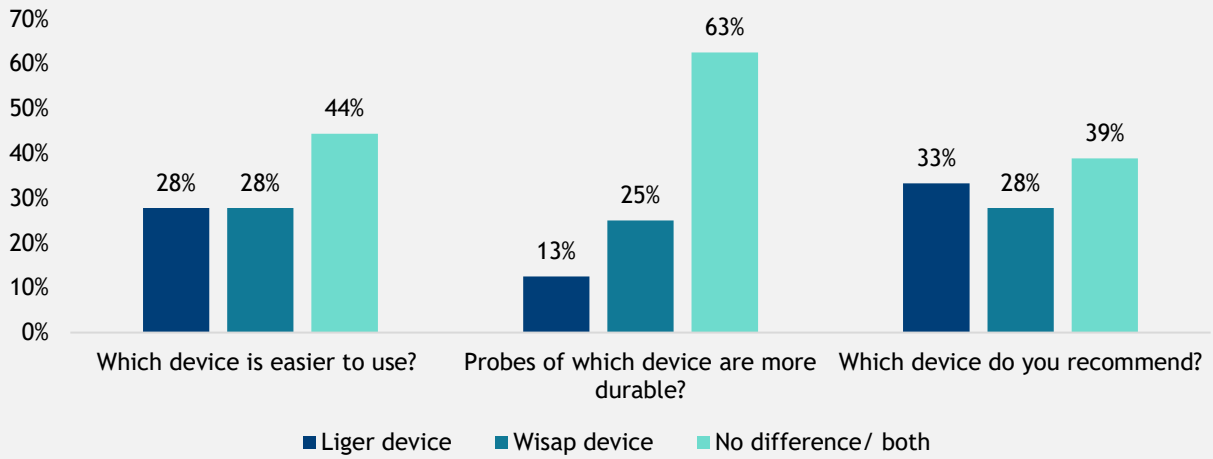
CHAI, in collaboration with the Ministries of Health, conducted a quick, anonymized survey of over 60 healthcare providers across India, Kenya, and Nigeria to gain insights into the user experience with TA devices.

This survey asked providers for their overall experience in dealing with Liger and Wisap TA devices. The survey asked for healthcare provider opinion on the ease of use, safety, perception of effectiveness, and overall satisfaction with the tools. Of the survey respondents, 81 percent had used the Liger device, 48 percent the Wisap device and 30 percent had experience with both. At least 60 percent of the surveyed providers were nurses and 30 percent were doctors with an average of 10 years of experience. Key results of the user feedback survey are summarized below.

Results from providers who had experience using both Liger and Wisap devices

Providers with experience using both devices had no preference for one device over the other, as shown in Fig 8.

Fig 8: % providers with experience using both Liger & Wisap devices



44 percent users reported no difference in ease of use, and 39 percent saw no difference in their likelihood of recommending either device to other providers. For those who expressed a preference, opinions were almost evenly split between the two brands.

When asked about probe durability, 63 percent of providers reported no difference between the two brands. Among those who expressed a preference, a slightly higher number of providers selected Wisap for its durability.

Results from providers who had used either Liger or Wisap device

Perception of effectiveness and overall satisfaction: Healthcare providers who had used either the Liger or Wisap devices reported high and comparable scores on (their *perception* of) effectiveness of the device in treating precancerous lesions. However, it is important to note that assessing the effectiveness of precancerous lesion treatment requires patients to return for a follow-up screening one year after treatment per WHO guidelines, or as specified by their country's national screening guidelines.

Liger users reported a marginally higher overall satisfaction score as compared to Wisap device users.

Fig 9a: Provider opinions on perception of effectiveness & overall satisfaction
(Score out of 5, 5 being highest)

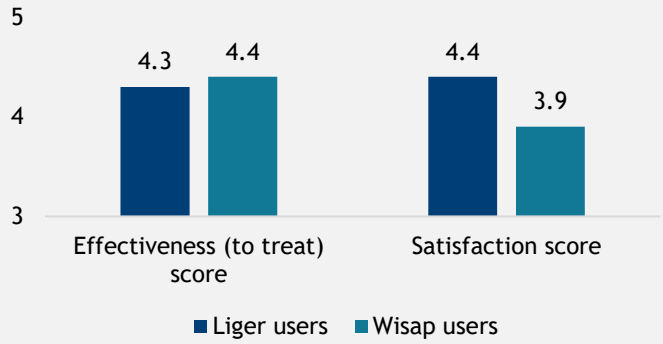
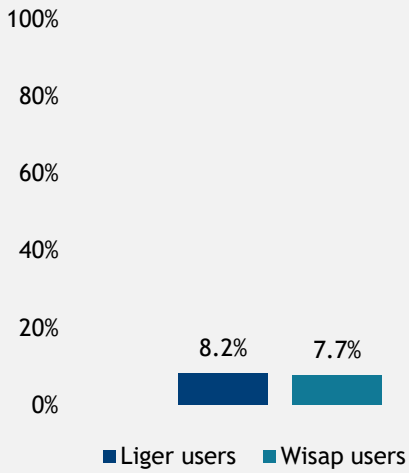


Fig 9b: % providers noting safety concern while using device



Safety concerns: A small percentage of users – 8 percent of Liger users and 7 percent of Wisap users reported safety concerns with few respondents elaborating – Liger users mentioned challenges with probe handling and difficulty finding a suitable charger, while some Wisap users expressed concern about the risk of burning a patient if the slider was forgotten.

Additionally, 8 percent of Liger users observed cases of vaginal discharge following treatment, whereas Wisap users reported no such cases.

In summary, CHAI has noted no significant differences from a providers' perspective between the two devices, affirming that either would be suitable for countries planning to introduce or scale up the use of TA devices for treating precancerous lesions.

2.4 Post-market surveillance of TA devices - Highlights

- Post-market surveillance is key for optimizing service delivery and guiding scale-up, with end users providing valuable feedback to manufacturers.
- Health workers reported low device malfunction rates, mainly linked to battery or probe issues. Following IFUs, especially for disinfection, helps extend probe lifespan.
- Providers found no significant differences between Liger and Wisap devices, confirming both are suitable for introducing or scaling up TA treatment.

3. Optimizing TA service delivery and health systems to increase treatment rates

Several Unitaid-CHAI supported program countries have achieved high treatment completion rates among screen-positive women eligible for precancer treatment. Notably, four countries—Malawi, Nigeria, Rwanda, and Senegal—had exceeded the WHO's 90 percent precancer treatment target at project sites as of mid-2023. The following sections outline the four key factors that contributed to their success.

1. Strategic placement of TA devices to decentralize treatment access, combined with decentralized clinical mentorship and continuous supportive supervision (refer to sections 2.1.3 and 2.2.2)
2. Community sensitization and engagement with women
3. Patient tracking systems to minimize women lost to follow-up
4. Ongoing training, troubleshooting, and support for device users

While success factors mentioned in point 1 have been addressed in earlier sections, the following section focuses on the remaining points 2, 3 and 4.

3.1 Community sensitization and engagement to increase treatment uptake

Community engagement has proven essential in ensuring that women who screen positive for precancerous lesions return for treatment in all program countries where TA devices have been introduced and scaled up for cervical lesion treatment. This includes continuous sensitization of community members—including local and religious leaders, family members (especially male partners), and community health workers—along with thoughtful engagement with the women. For instance, in a province in Zimbabwe, engaging male religious leaders to host and participate in health discussions at church shifted the narrative from cervical cancer being seen as a ‘woman's issue’ to a broader community health concern. This has encouraged many more women to come forward for screening.

Men play a vital role in supporting their partners and families by influencing health-seeking behaviors that promote cervical cancer screening and timely treatment. Further, community health workers (also known as community health promoters or community health extension workers depending on the country context) are often the most accessible and trusted point of contact for women, providing a safe space where they can share private concerns they might not feel comfortable discussing even with their partners. Empowering community health workers to educate and reach women about the importance of regular screening and timely treatment for precancer is vital to preventing cervical cancer, which remains a leading cause of death in many LMICs.

Across Unitaid-CHAI program countries implementing TA for precancer treatment, healthcare workers identified various reasons why women hesitated or declined treatment, even when TA devices and healthcare workers were available on-site. Table 3 below summarizes some of these reasons and the

solutions explored, many of which emphasize the importance of increased community involvement and sensitization.

Table 3: Reasons for patients declining or not receiving precancer treatment

Reason for not receiving precancer treatment	Solution explored
Women unable or afraid to adhere to the post-treatment abstinence period due to potential repercussions from their husbands and/ or co-wives	• Engaging partners early on demand generation effort, which helped secure buy-in if treatment was needed after screening • Counseling women and partners prior to and upon completion of treatment • Working with religious leaders, such as imams and traditional healers and health champions, such as cancer survivors for effective communication of key messages • Providing alternatives for harm reduction if the full six-week abstinence period was not possible, such as use of condoms
Refusal by sex workers due to loss of wages during abstinence post-treatment	• Linking sex workers to local associations that could provide compensation for wages lost due to post-treatment abstinence
Asymptomatic women unwilling to undergo treatment	• Engaging community health workers to counsel these patients on the benefits of receiving precancer treatment and the risk if the lesions progressed to cancer
Women providing incorrect contact information to avoid follow-up calls for treatment	• Incentivizing community healthcare workers to track and follow-up clients, coupled with counseling for the client and their partners. Additionally, encouraging a trusted member of the community (religious leader/ cervical cancer survivor) to follow up with the identified client
Women not having the resources to return to the facility for treatment (if asked to come back on a different date), or travel to another facility (if TA not available at screening site)	• Offering same-day screening and treatment where feasible • Placing TA devices at screening sites • Reimbursing women their transportation cost to encourage them to return to the facility for treatment

Other systemic challenges contributing to poor treatment linkage have included health workers' inability to track and follow up with women for appropriate care and a lack of clarity on referral options when treatment was unavailable at the screening site. The following section addresses this challenge.

3.1 Community engagement to increase treatment uptake – Highlights

- Community involvement boosts return for treatment: Ongoing engagement with community leaders, male partners, and health workers helps increase treatment uptake after screening.
- Men/ partners significantly influence women's health-seeking behavior; early involvement improves acceptance of screening and treatment, especially in culturally sensitive contexts.
- Trusted, accessible and empowered community health workers play a key role in counseling, follow-up, and education to encourage timely treatment.
- Addressing barriers with tailored solutions: Program experience showed tackling treatment refusal or drop-off by community-led follow-up, offering same-day treatment options, transport support etc.

3.2 Client tracking and referral systems to minimize loss-to-follow-up

When a woman receives cervical cancer screening at a public sector facility, a healthcare worker should record her information in either a paper-based cervical cancer clinic register or an electronic system. These systems allow health providers to document screening results and follow-up with eligible patients for treatment referral for additional care. This is an important component to ensuring high linkage to care. If these systems are not in place or are inefficient, many women can be lost to follow-up.

With Unitaid's support, CHAI worked with partner governments to develop data tools and establish operational processes that ensure screen-positive women receive timely and appropriate treatment, reducing loss to follow-up. Using a combination of traditional approaches and electronic tools, partner countries successfully set up reporting systems for monitoring key cervical cancer indicators and tracking patients to ensure screen-positive women are linked to care. For example, the Rwanda government implemented an electronic medical record system in public health facilities to address the limitations of paper-based records. The digital system improved the storage and accessibility of client information for follow-up visits and clinical decision-making throughout the continuum of care. More details can be found in this article here.

In Malawi, CHAI developed paper-based facility level and referral patient tracking tools building upon existing Ministry of Health registers and reporting tools to strengthen patient tracking at focal facilities. The tools included a cervical cancer client card, tracking card, and cervical cancer control program report. In Kenya, many women were lost to follow-up after screening due to the providers' lack of awareness about facilities offering precancer treatment. To resolve this, the Ministry of Health, with CHAIs support, developed and distributed a comprehensive list of TA treatment centers to screening sites, allowing providers to refer women to the nearest treatment facility.

3.3 Ongoing troubleshooting and support for device users

CHAI-supported programs have identified that TA treatment can be implemented with fewer challenges when ongoing support is available to the program. This includes continued technical training for individuals, such as local biomedical engineers, who can help healthcare providers troubleshoot in case of device malfunction. These individuals should receive in-depth training on the devices and be able to

liaise with the manufacturers for support. In addition, creating a centralized complaint handling team and providing training on initiating devices, minimizes service interruption when TA devices need replacement.

3.2, 3.3 Strengthening follow-up and support systems – Highlights

- Effective patient tracking systems essential to minimize loss to follow-up: paper-based/ electronic tools that help record patient results, track women, and follow-up.
- Clear referral pathways improve service linkage. For example- sharing a directory of TA treatment centers with screening sites helps ensure women are referred to appropriate facilities for timely care.
- Ongoing technical support ensures smooth device use including training local biomedical engineers and creating centralized support system to reduce downtime and ensures continuity in TA service delivery.

Conclusion

TA devices have proven to be effective and affordable for delivering precancer treatment across numerous countries. When paired with decentralized services, strong patient tracking and monitoring systems, active patient and community engagement, and ongoing support for healthcare workers, TA devices enable countries to reach treat more women with precancerous cervical lesions. This approach accelerates progress toward the WHO's 90 percent precancer treatment target and plays a key role in the global effort to eliminate cervical cancer.

Annex 1: Assumptions underlying cost of TA treatment

- Device prices:
    - Dec 2024 price of Liger HTU110 thermal coagulator: US$925/ unit if purchased directly from Liger, US$948.13/ unit if purchased via UNICEF-SD, and comes with four probes.
    - Dec 2024 price of Wisap's new version of C3 thermo-coagulator titled C3 ECO4 and termed as an 'economy thermal ablation for low resource settings': €870 and comes with four probes.
- Device-related assumptions:
    - A TA device is expected to last five years and treat ~2,000 women over the device lifetime
    - A TA device may require a new probe after every ~300 treatments on average
    - Across the expected treatment lifecycle of 2,000 per device, a total of 6.67 probes would be needed. Each device comes with 4 probes, so the cost of an additional ~2.5 probes has been allocated over the lifetime of each device under consumables cost
    - A probe costs approximately ~US$60/ unit for the Liger device and ~€270/unit for the Wisap device
- PSM charges: An average of 20 percent of device cost has been assumed for freight and insurance and an additional 6 percent for in-country customs, storage and distribution.
- Replacement: It is estimated that 1 percent of devices would require replacement before end of life, with 0.40 percent devices breaking down within warranty period. Thus, the cost of device replacement (out of warranty period) has been accounted at 0.60 percent.