

Expanding access to thermal ablation to prevent cervical cancer

Experience from a multi-country
Unitaid-funded project



- 1 Overview of Unitaid supported project in secondary prevention of cervical cancer (3')
- 2 Increasing global access to thermal ablation devices (7')
- 3 Malawi's experience of rolling out TA devices (5')

Scope of intervention focuses on secondary prevention, including scale-up of HPV and/or VIA screening and linkage to appropriate treatment and care

Achieving the 90-70-90 targets by 2030 would result in **over 62 million cervical** cancer deaths averted by 2120.

90%

OF ALL

girls fully vaccinated⁷ with HPV vaccine by 15 years of age

Primary Prevention

70%

OF ALL

women screened using a high-performance test by 35 years of age and again by 45 years of age

Secondary Prevention

90%

OF ALL

women identified with cervical disease are treated

Tertiary Prevention

Vaccination & Communication



- HPV vaccination for 9–14-year-olds
- Sexuality education
- Condom promotion/provision
- Male circumcision

Screening &

Treatment of pre-cancerous lesions



- Screening with HPV and/or VIA
- On-site treatment for eligible lesions with TA or Cryotherapy
- Referral for LEEP for other precancerous lesions
- Referral for diagnosis of suspected cancer

Cancer Treatment

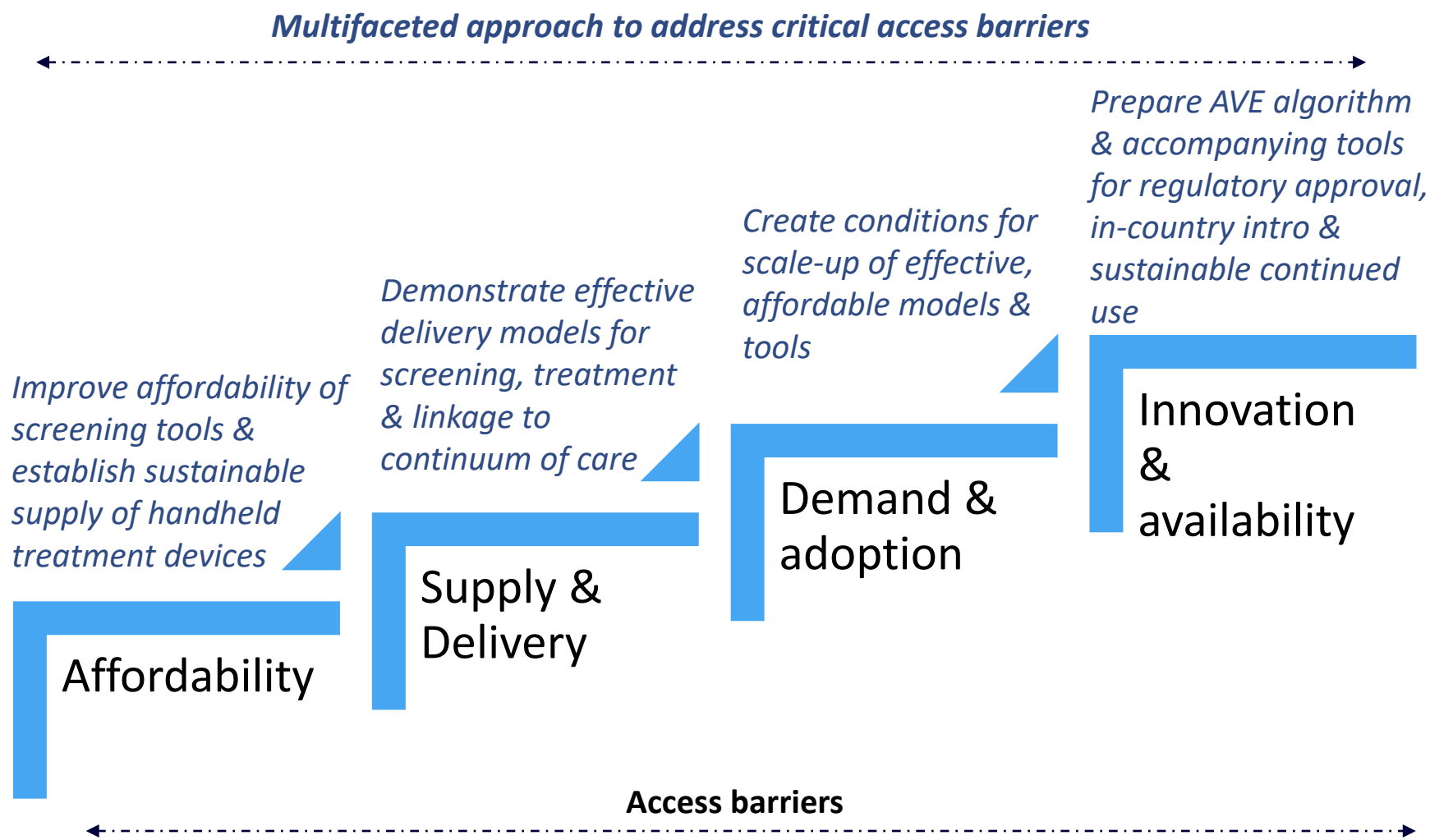


- Ablative surgery
- Radiotherapy
- Chemotherapy
- Palliative care

Focus of intervention

- 1 Demand Generation
- 2 Screening and Diagnosis
- 3 Appropriate Treatment
- 4 Patient Tracking

In response to the WHO Call to Action, Unitaid has invested almost \$70M to increase access to life-saving screening and treatment tools by addressing key access barriers, in partnership with CHAI and SUCCESS



Unitaid-funded interventions supported suppliers to make devices more affordable and accessible in LMICs, and supported government partners to roll out devices in national screening programs

Market shaping and supply side work

- **Access pricing** deals with two suppliers of thermal ablation devices, Liger and Wisap
- **Supporting product development (improvement)** of thermal ablation devices
- **Business planning support** to suppliers
- **Managing procurement** of TA devices for program countries from suppliers
- Facilitated creation of long-term **sustainable procurement channels** for public sector procurers/ DPs to purchase TA devices
- Support in set up of local **distributor channels in-country**



% screen-positive women w/ lesions eligible for cryotherapy/TA/LEEP who received treatment

	2019	2020	2021
Rwanda	N/A	85%	98%
Malawi	67%	91%	96%
Nigeria	N/A	97%	94%

Select country results

Demand side work

- **Advocacy - Global and National** supporting WHO's call for elimination:
 - ✓ Global WHO guidelines
 - ✓ Inclusion National guidelines, training curriculums
 - ✓ In-country product registration, facilitating import clearances etc.
- **Mapping out appropriate delivery models** to reach women:
 - ✓ Intensive **demand generation strategy**
 - ✓ **Decentralisation** of treatment
 - ✓ **Multi-faceted training & mentorship** approach
 - ✓ Integration of care at **ART clinics**
 - ✓ **Integration of CHWs** across continuum
 - ✓ **Strong patient tracking**
- Supporting Country Governments on
 - **scale up & financing**

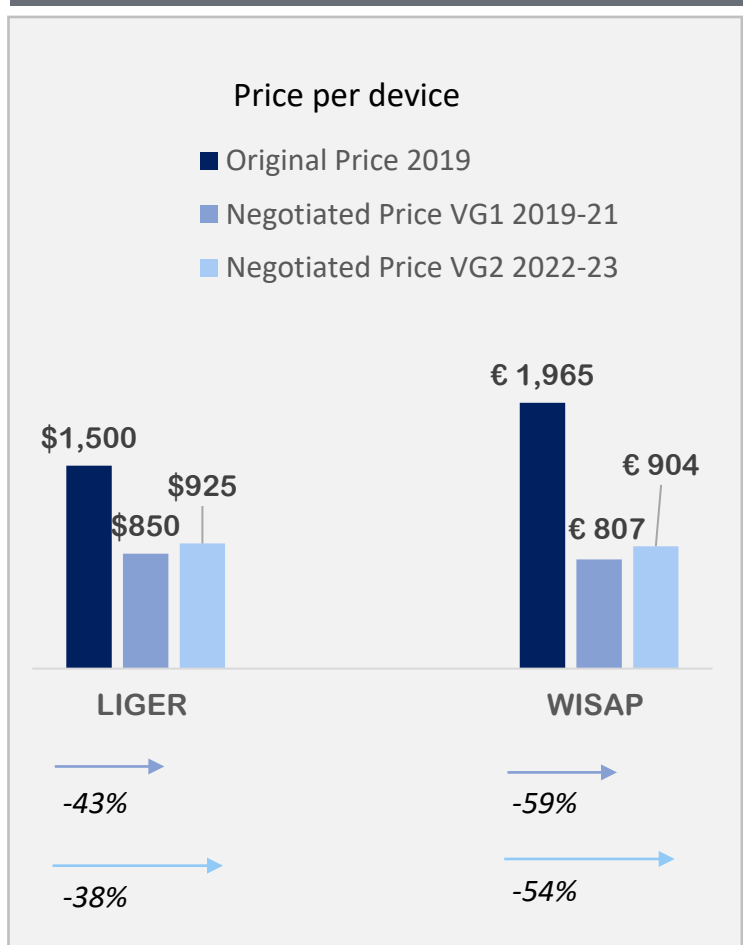
Supply side interventions led to a substantial price reductions of treatment devices enabling catalytic donations of 5,000+ TA and 500+ LEEP devices by Unitaid in 20 countries

2 **Manufacturers** Liger & Wisap actively supplying portable TA devices in LMICs that are compliant w/ technical specifications laid out by WHO

~40% **Average price reduction** (across Liger and Wisap) vs. original price when products were launched in 2019

20 **Countries*** where CHAI has been able to help introduce TA devices with UNITAID's support

Ceiling Price per portable treatment device
(direct to supplier route)



Liger prices in USD \$, Wisap prices in Euro €
Wisap prices in the chart are for Option A device. Option B is currently priced at €938

Rapid pace of procurement & rollout
5,000+ **TA devices** procured to date
500+ **LEEP devices** procured to date

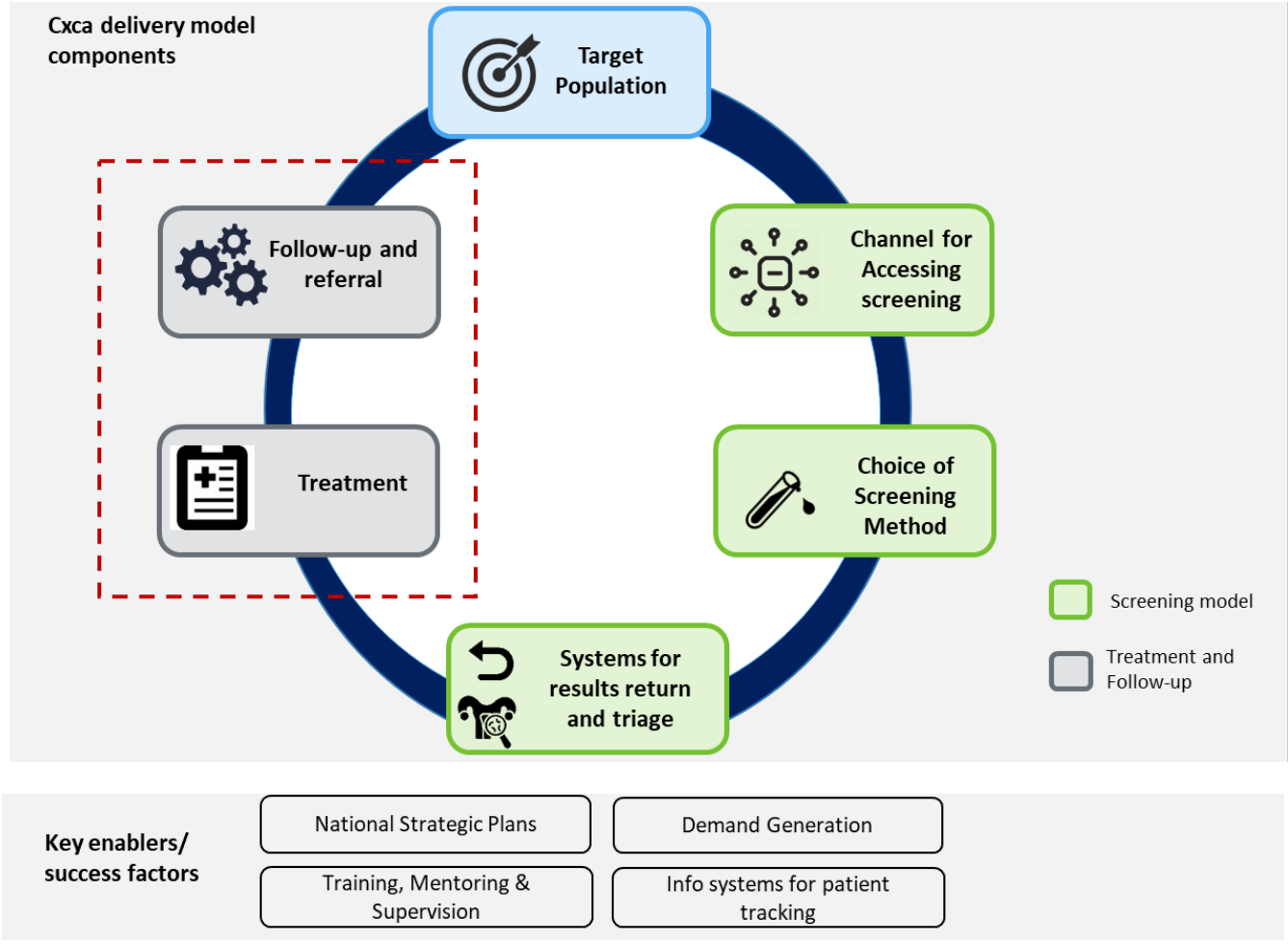
Market for TA devices expanding
1,000+ **Devices** purchased by other DPs 2019-present

2 **Procurement channels created** - Direct to supplier & UNICEF-SD**

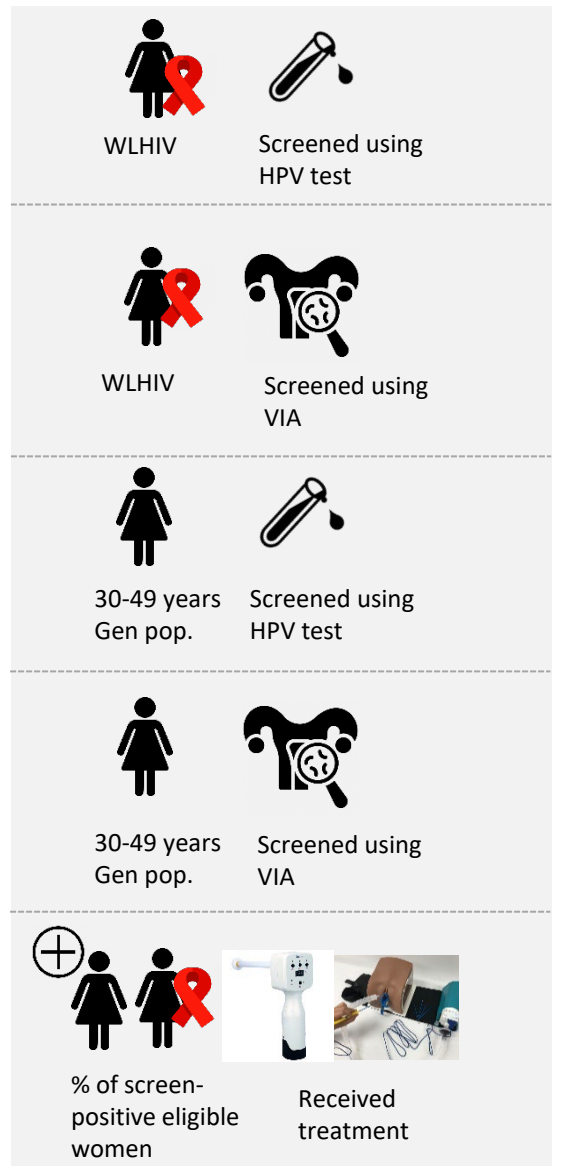
Refer to Appendix for:

* List of countries where TA products have been made available with CHAIs support/ Unitaid funding
** Full list of Terms & conditions under two procurement channels- Direct to Supplier and Via Unicef-SD

At the country level, the project worked closely with national and state government partners to map out appropriate delivery models to reach women



Expected outputs



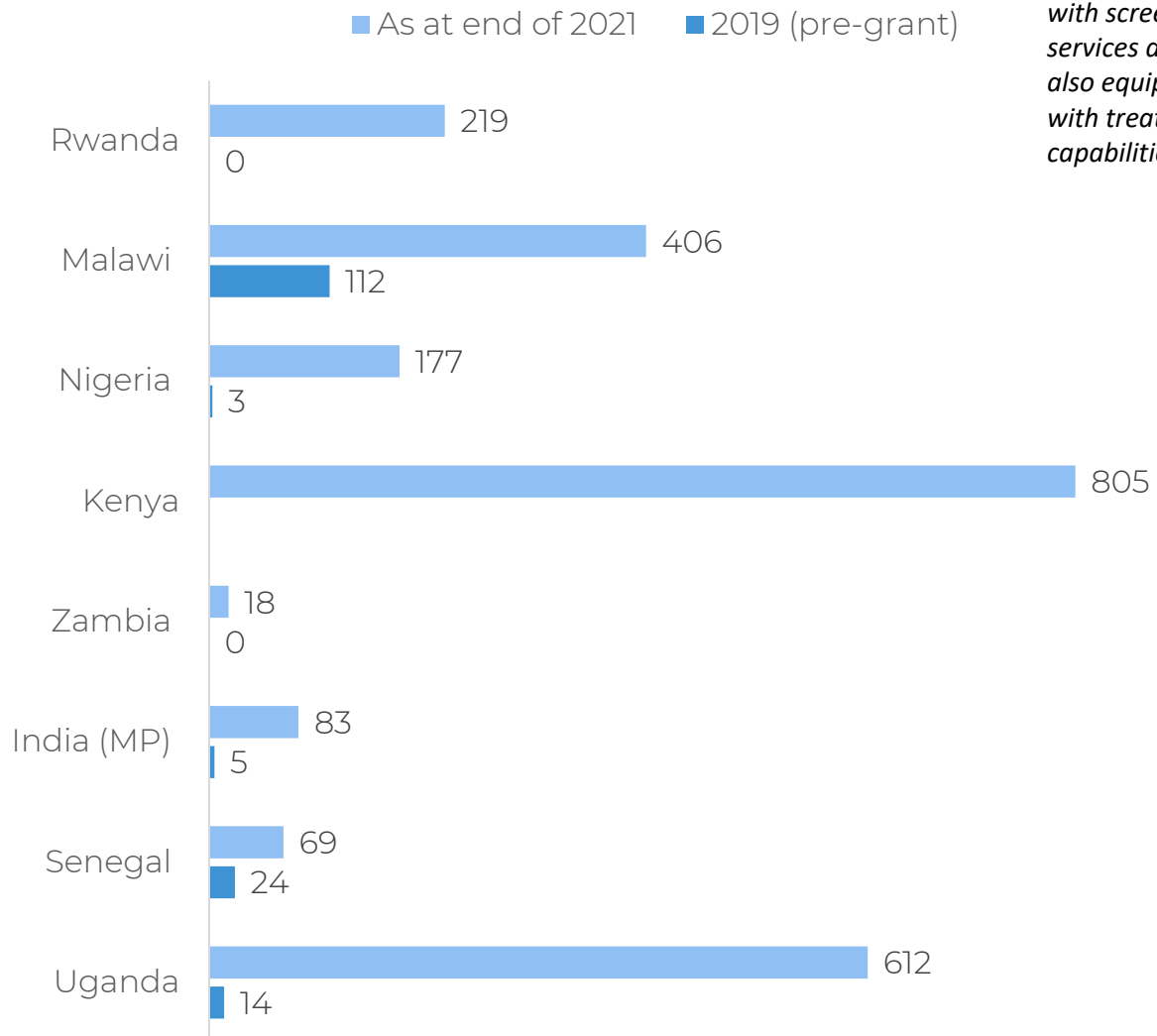
Countries have welcomed the ease of use and affordability of TA, with over 1,200 screening sites being equipped with TA, leading to true decentralization of pre-cancer treatment

9 Countries* National guidelines recommend thermal ablation

9 Countries** have authorization to use thermal ablation/ products registered in-country

>1,200 Screening sites equipped with portable treatment option & where HCWs are trained to treat

of screening sites equipped with portable thermal treatment devices/ cryotherapy

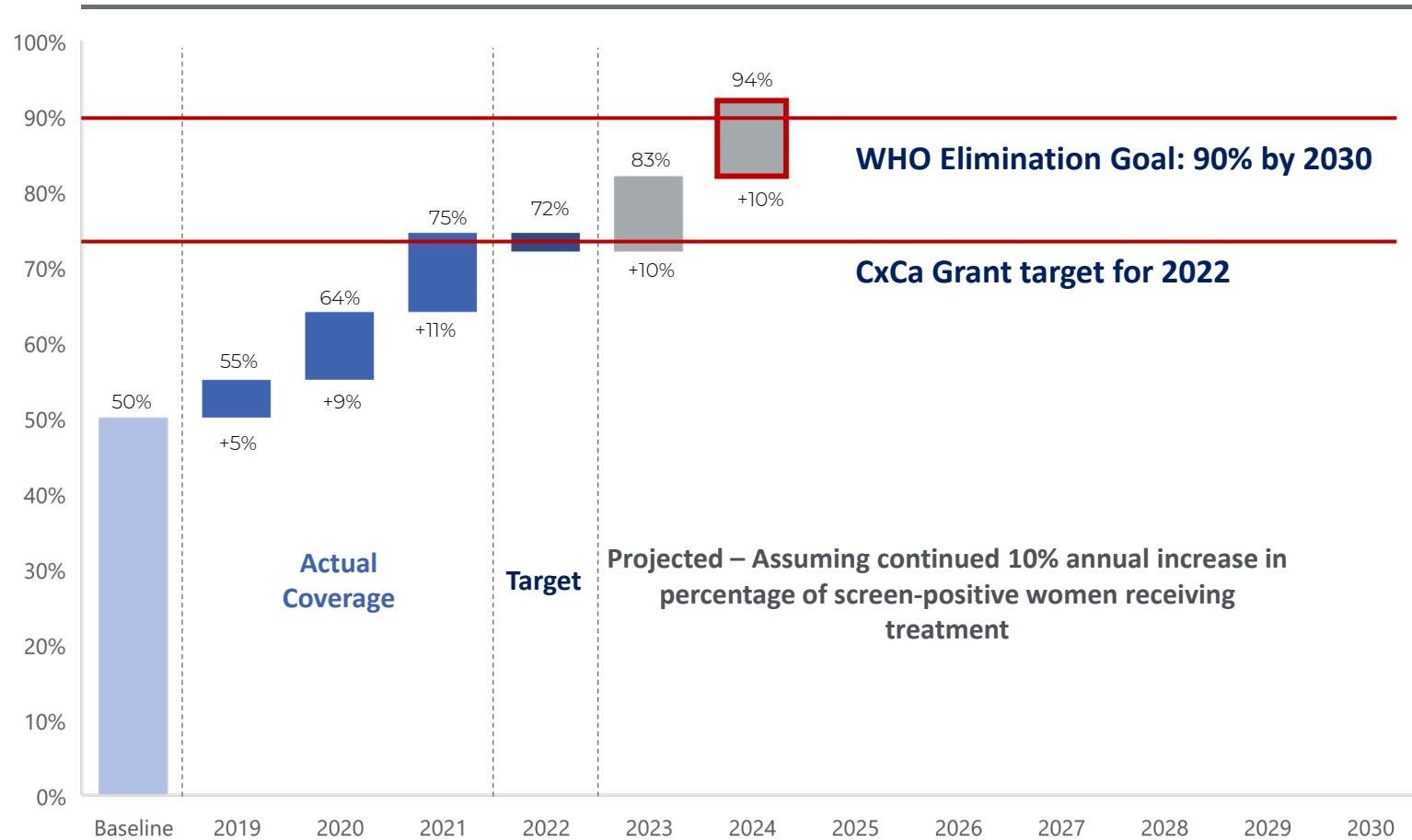


Majority of sites with screening services are now also equipped with treatment capabilities

* Countries where National guidelines recommend TA: India, Kenya, Malawi, Nigeria, Rwanda, Zambia, Senegal, Uganda, Zim
 ** Countries where TA is registered/ authorised for use: India, Kenya (not registered yet but authorised to use exists), Malawi, Nigeria, Rwanda, Zambia, Senegal (TA are being used in Senegal, no official registration requested), Uganda (explicitly registered in any national catalogue of sorts but they are approved for use in country, Zimbabwe
 For the balance countries (SA): TA is not recommended in National guidelines in SA

The Unitaid investment has already driven a substantial improvement in the rate of treatment of screen-positive women, approaching the WHO elimination target

Percentage of screen-positive women with lesions eligible for cryotherapy/thermal ablation or LEEP who received that treatment



Spotlight Malawi: Experience using TA products and key success factors enabling high treatment rate

Benefits of using TA



Ease of use: Portable, battery operated, easy operation intuitive automated timer & visual/ audio indicators



Ease of clinical rollout: Straight forward requirements for rollout, easy to use, broader range of HCWs can operate



Improved access and health equity: Enabled decentralization of treatment with portable TA devices can be placed at lower level facilities. Has helped deliver services in hard to reach/ remote/ rural areas



Ease of procurement: Single supplier from which device+ consumables are procured. Logistically easier to procure than cryotherapy that comes with the challenge & variability involved with supply of gas cylinder & its refills

Key success factors driving high treatment coverage/ rate



Community sensitization



Decentralized mentorship approach - Deployment of TA devices in all focus facilities accompanied by training and mentorship of providers



Strengthened counselling on **completing** the treatment cascade



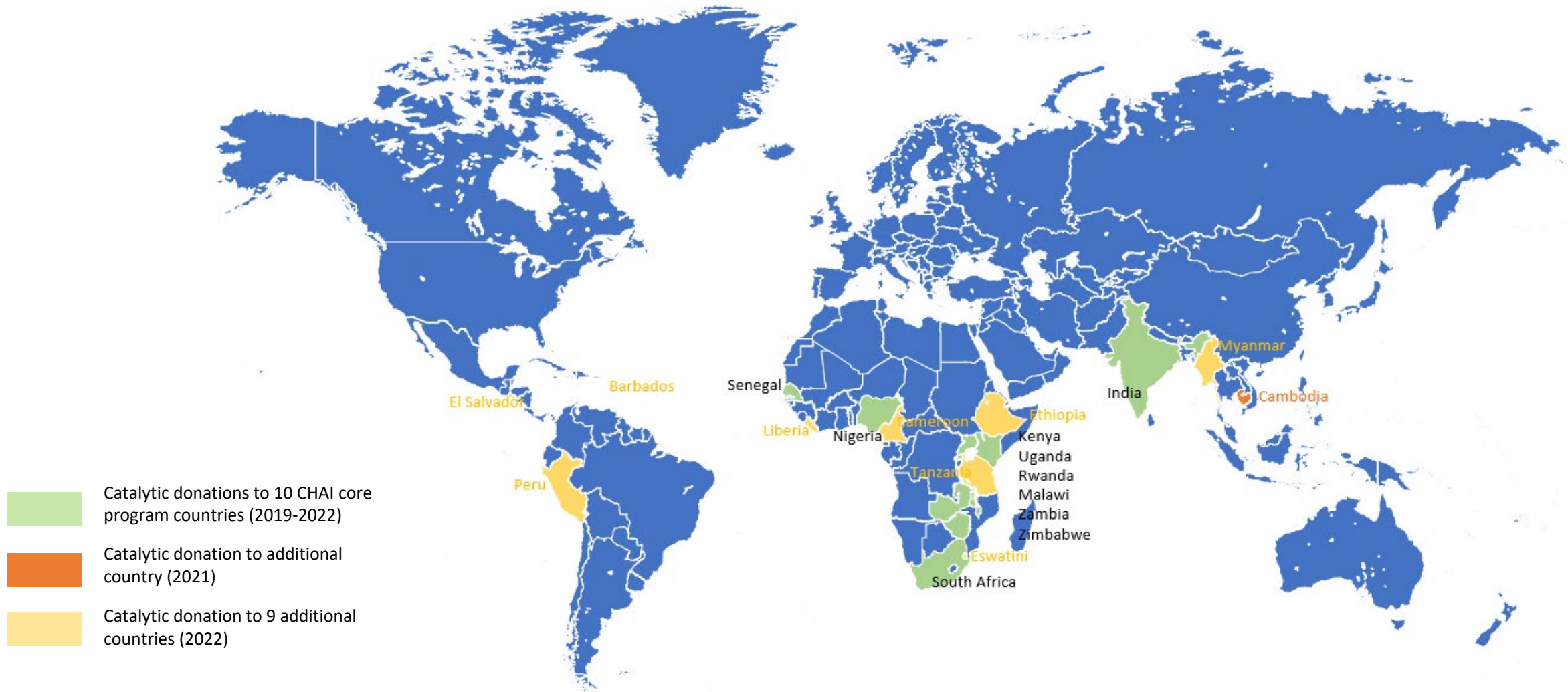
Systems for **patient tracking** – including engagement of community health workers and volunteers, follow up using phone calls to patients

A few considerations for a new country introducing TA devices for treatment of pre-cancerous cervical lesions

Consideration	Action
National guidelines	Work with Ministry of Health to endorse TA for use in its National guidelines on cervical cancer prevention and treatment
Clinical guidelines	Work with MoH to update clinical treatment guidelines and / or training curriculum with TA (who can use the device, what level facility can it be used at etc.)
Import clearances, product registration* (if needed)	Work with relevant Customs authority to include TA in the list of medical devices that can be imported, and obtain waiver of custom duty on import of devices received as donation. Some countries may these products to be registered with relevant regulatory authority.
Training and mentorship approach	Develop the approach to training and conducting ongoing mentorship; develop didactic and practical training resources (<i>in addition to use of device, procedure preparation, device cleaning/disinfection, processes for filing complaints are important topics to cover during the training</i>)
Information systems and integration with National MIS	Develop data entry tools to track treatment and follow-up care; integrate cervical cancer screen and treat data with National MIS
System for adverse event reporting, device incidents/ malfunctions **	Integrate treatment using TA in existing adverse event reporting protocols; Develop a process flow to deal with breakdown of device (or a part thereof)/ device incident reports from sites where TA is being used
Rollout of devices	Develop a strategy to prioritize sites/ regions for deployment of TA devices, identify cadre(s) of HCWs to perform treatment using TA devices
Demand generation strategy	Develop strategies to spread awareness encouraging care seeking behavior
Patient tracking and follow-up care	Set up patient tracking mechanism and tools to ensure minimal loss-to-follow up after receipt of result of a VIA/ HPV screen
Scale-up planning	Work with MoH to develop short/ medium/ long term plans for placement of thermal ablation devices modelling different scale up rates; inclusion of costed plans in annual budgeting cycle

Appendix

Countries where TA products have been made available with Unitaid funding



TA Access pricing terms and conditions under the two procurement channels

Table 1: Terms and conditions applicable under direct to supplier procurement

	Liger	WISAP
Product Name	HTU-110 Thermal Ablation	C3 THERMO-COAGULATOR Thermal Ablation
SRA Approval	FDA Cleared: Device Class 2 CE Marked, EU: Class IIa	CE Marked, EU: Class IIa
Product Kit Configuration	HTU-110 Kit [A/ B / C Variants] <ul style="list-style-type: none"> Thermocoagulator unit, Two 12-volt, 2aH Li-Ion batteries Universal charger 4 probes [selection out of 3 configurations - 16 mm flat, 19 mm flat, 19 mm nipple] Instruction For Use (IFU) Hard carrying case 	C3 Thermo-Coagulator Kit Option A <ul style="list-style-type: none"> Handle Thermos probes 2 x 20mm flat shaped Battery pack with cable Sliders 2 x 20 mm Carrying case Option B Power supply unit in addition to all the components for Option A
Price	USD 925/ unit	Option A Euro 904/unit Option B Euro 938/unit
Validity	31 st Dec 2023	14 th March 2023
Warranty	2 Years	
Incoterm	EXW	
Freight and insurance	Designated purchasers to make arrangements and cover costs	
Minimum order quantity	5	5
Eligible countries	Specified eligible LMICs	

Table 2: Terms and conditions applicable under Unicef-SD procurement:

	Liger	WISAP
Product Name	HTU-110 Thermal Ablation	C3 THERMO-COAGULATOR Thermal Ablation
SRA Approval	FDA Cleared: Device Class 2 CE Marked, EU: Class IIa	CE Marked, EU: Class IIa
Product Kit Configuration	HTU-110 Kit [A/ B / C Variants] <ul style="list-style-type: none"> Thermo-coagulator unit, Two 12-volt, 2aH Li-Ion batteries Universal charger 4 probes [selection out of 3 configurations - 16 mm flat, 19 mm flat, 19 mm nipple] Instruction For Use (IFU) Hard carrying case 	C3 Thermo-Coagulator Kit <ul style="list-style-type: none"> Handle Thermos probes 2 x 20mm flat shaped Battery pack with cable Sliders 2 x 20 mm Carrying case Power supply unit
Price	USD 948.13/unit	Euro 938/unit
Validity	April 2023	April 2023
Warranty	2 Years	
Incoterm	FCA	
Freight and insurance	UNICEF SD delivers on CIP (INCOTERMS 2020) basis. Associated freight to the nearest international airport in the receiving country, insurance and inspection costs will be included in addition to FCA price of the TA product	
Minimum order quantity	None	5 units
Eligible countries	All low- and middle-income countries (LMICs) as per the World Bank classification	

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List of countries eligible for TA Access pricing under direct-to-supplier route

Afghanistan	Croatia ¹	Korea (Democratic Peoples Republic)	Philippines ²
Albania ¹	Cuba	Kosovo ¹	Romania ²
Algeria ¹	Democratic Republic of the Congo	Kyrgyz Republic ¹	Russian Federation ¹
Angola	Djibouti	Kyrgyzstan ¹	Rwanda
Argentina	Dominican Republic	Lao (Peoples Democratic Republic)	Sao Tome and Principe
Armenia ¹	Ecuador	Lesotho ²	Senegal
Azerbaijan ¹	Egypt ¹	Liberia	Serbia ¹
Bahamas	El Salvador	Madagascar	Sierra Leone
Bangladesh ²	Equatorial Guinea	Malawi	Solomon Islands
Barbados	Eritrea	Malaysia ²	Somalia
Belarus	Estonia ¹	Maldives	South Africa
Belize	Eswatini	Mali	South Sudan
Benin	Ethiopia	Mauritania	Sri Lanka
Bhutan	Fiji ²	Mauritius	Sudan
Bolivia	Gabon	Mexico	Suriname
Bosnia And Herzegovina ¹	Gambia	Micronesia, Fed. Sts.	Syrian Arab Republic
Botswana	Georgia ¹	Moldova ¹	Tajikistan ¹
Brazil ²	Ghana	Mongolia	Tanzania
Bulgaria ¹	Guatemala	Montenegro ¹	Timor-Leste
Burkina Faso	Guinea	Morocco ¹	Togo
Burundi	Guinea-Bissau	Mozambique	Trinidad and Tobago
Cabo Verde	Guyana	Myanmar ²	Tunisia ¹
Cambodia ²	Haiti	Namibia	Turkey ¹
Cameroon	Honduras	Nepal ²	Turkmenistan ¹
Cape Verde	India	Nicaragua	Uganda
Central African Republic	Indonesia	Niger	Ukraine ¹
Chad	Iran (Islamic Republic) ¹	Nigeria	Uruguay
Chile	Iraq ¹	North Macedonia ¹	Uzbekistan ²
China ²	Jamaica	Pakistan	Vanuatu
Colombia	Jordan ¹	Palestine	Vanuatu
Comoros	Kazakhstan ²	Panama	West Bank and Gaza
Congo, Rep.	Kenya	Papua New Guinea ²	Yemen
Costa Rica	Kiribati	Paraguay	Zambia
Côte d'Ivoire		Peru ²	Zanzibar
			Zimbabwe

¹ Countries eligible only for Liger prices.

² Countries eligible only for Wisap prices.