

# OPTIONS

*Dapivirine Ring  
Early Introduction Considerations  
Seven Country Analysis*

*August 2018*



## **SUMMARY FINDINGS**

## **DETAILED COUNTRY FINDINGS**



# Executive summary

## THE OPPORTUNITY FOR THE RING

- Across countries, there was significant enthusiasm for the ring as a female-controlled technology that could be appropriate for adolescent girls and young women as part of a combination HIV prevention approach.
- The ring also raised questions from country stakeholders including questions on how to improve adherence among 16-24 year olds and how policies should be crafted to build the ring into a comprehensive prevention package.
- Importantly, policymakers and USAID/PEPFAR missions in most countries advised that a demonstration in each country addressing local conditions and concerns is the best way to expedite inclusion of the ring in national policies and plans. However all stakeholders emphasized the importance of linking demonstration projects to implementation – standalone demonstration projects were discouraged. This guidance is based on the experience with the introduction of oral PrEP in many countries.
- While all of the countries included in this analysis were interested in the ring, some are better positioned to be “early adopters.”
- At present, Zimbabwe and Uganda show immediate promise for a demonstration project with the ring due to national stakeholder interest and the anticipated pace of the process. South Africa and Kenya are also promising locations, though in Kenya there are still questions about how to move forward given the constraints of US funding and in South Africa stakeholders are cautious about adding new products and note that demonstrations before regulatory approval would require greater scrutiny.
- To expedite access to the ring, two steps should be pursued simultaneously over the coming year:
  1. A coordinated global effort to prepare demonstration projects in several “early adopter” countries, in close collaboration with key stakeholders and policymakers at the country level
  2. A consistent effort to communicate about the ring at the country level, especially as additional evidence is generated and the regulatory process advances

## OVERVIEW OF PROCESS

- The OPTIONS (Optimizing Prevention Technology Introduction on Schedule) Consortium is a five-year, USAID funded effort to expedite and sustain access to new ARV-based HIV prevention products in sub-Saharan Africa with a focus on women and girls.
- In May 2018, seven countries (Rwanda, Uganda, Kenya, Zimbabwe, Malawi, Tanzania, and South Africa) were prioritized for analysis due to the state of the HIV epidemic in each country and experience with ring trials.
- OPTIONS conducted secondary research and interviews with key stakeholders in these countries to understand questions about the ring that could inform demonstration and processes for introducing new biomedical HIV prevention products.
- Interviews comprised a mix of policymakers, civil society representatives, donors, implementing partners, and trial contributors.



# Key findings from country consultations

1

**Most country stakeholders are intrigued by the ring**

Country stakeholders cited female control and limited risk of creating resistance as valuable attributes of the ring. Stakeholders in Zimbabwe expressed a readiness to start a demonstration project on the ring as soon as possible. Stakeholders also had many questions about the ring (*noted on next slide*).

2

**Interest in a demonstration to inform implementation**

Most country stakeholders indicated a need for a local demonstration on the ring to inform policy-making and implementation planning, noting that evidence generated elsewhere would not provide the contextual detail required. Standalone projects not linked to implementation were strongly discouraged.

3

**Need to leverage learnings from oral PrEP and potential to integrate the ring into roll-out in several countries**

The recent experience with oral PrEP provides lessons on messaging, processes, and stakeholder engagement for the ring. Existing structures for PrEP, such as Technical Working Groups (TWGs), can also be used for the ring. The ring needs to be assessed as part of a combination prevention approach.

4

**Criticality of AGYW populations across countries, and need to better understand adherence**

Country stakeholders saw potential for the ring with AGYW populations that have been difficult to serve with other options, though they also requested additional evidence on how to support adherence amongst this population.

5

**Thoughtful, sustained engagement process needed to introduce the ring**

In many countries there is limited existing knowledge of the ring that will need to be overcome to start planning. The approval process for some countries is straightforward but each product introduction process has idiosyncrasies that need to be managed. Regular stakeholder engagement will be necessary to maintain progress.



# Questions raised by policymakers

*Across the seven countries, several key questions were regularly raised policymakers*

## ASKED BY NEARLY ALL POLICYMAKERS

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*Key policymakers from five out of six countries analyzed asked the following questions:*

- What would be the **impact** of the ring? How many infections would be averted?
- How does the ring **fit into a comprehensive package** of prevention?\*\*\*
- What is the **effectiveness of the ring in the real-world?**
- What will be the **cost of investing** in the ring?
- What are **adherence to and uptake of** the ring in the real-world?
- Which **populations** are recommended for the ring?
- What are the implications for the **health system and healthcare workers?** What additional demands will the ring place on the health system?

## ASKED BY HALF OF POLICYMAKERS

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*Key policymakers from three out of six countries analyzed asked the following questions:*

- Will the ring be **affordable** for end users?
- Has the ring been proved to be **safe?**\*
- To what extent does the **effectiveness of the ring differ** among various populations? Is the ring **effective among AGYW?**\*\*\*
- What does behavioral data demonstrate about the impact of the ring on **condom use and other reproductive health practices?**

\* Questions that have been adequately demonstrated through past clinical trials







\*\*\* Questions that are partially studied in the upcoming REACH study

Note: Policymakers in Kenya were not surveyed due to US government restrictions



# Country readiness assessment framework

*A preliminary assessment for each country is included based on six dimensions. More dimensions may be added (e.g., availability of implementing partners) as discussions progress*

High-level assessment for the ring	
 <b>HIV epidemic characteristics</b>	<ul style="list-style-type: none"><li>Assesses the level of need in the country based on HIV prevalence and incidence</li><li>Specifically notes the HIV burden faced by women and girls</li></ul>
 <b>HIV prevention program</b>	<ul style="list-style-type: none"><li>Assesses the national HIV prevention program for comprehensiveness, inclusion of biomedical prevention, and dedicated prevention funds</li></ul>
 <b>Oral PrEP experience</b>	<ul style="list-style-type: none"><li>Assesses speed and ease of previous oral PrEP research, demonstration, and implementation, including inclusion in national guidelines and strategic plans</li></ul>
 <b>Ring trial experience to-date</b>	<ul style="list-style-type: none"><li>Highlights in-country dapivirine ring trials that could be leveraged for awareness-building and ring introduction</li></ul>
 <b>Stakeholder reactions to the ring</b>	<ul style="list-style-type: none"><li>Assesses knowledge, interest, and enthusiasm about the ring from a range of stakeholders including government, civil society, and academia</li></ul>
 <b>Product introduction process</b>	<ul style="list-style-type: none"><li>Assesses clarity and speed of typical product introduction process</li></ul>



# Cross-country assessment for ring potential

	ZIMBABWE	UGANDA	SOUTH AFRICA	KENYA	MALAWI	TANZANIA	RWANDA
<b>HIV epidemic characteristics</b>	SIGNIFICANT NEED	SIGNIFICANT NEED	SIGNIFICANT NEED	SIGNIFICANT NEED	SIGNIFICANT NEED	SIGNIFICANT NEED	MODERATE NEED
Prevalence rate	13.5%	6.5%	18.8%	4.8%	9.2%	4.7%	3.1%
New infections annually	40,000	52,000	270,000	53,000	36,000	55,000	7,500
Incidence rate	3.03	1.50	5.46	1.21	2.29	1.19	0.70
<b>HIV prevention program</b>	STRONG OPPORTUNITY	STRONG OPPORTUNITY	STRONG OPPORTUNITY	STRONG OPPORTUNITY	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY
<b>Oral PrEP experience</b>	STRONG OPPORTUNITY	MODERATE OPPORTUNITY	STRONG OPPORTUNITY	STRONG OPPORTUNITY	POTENTIAL LIMITATION	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY
<b>Ring trial experience to-date</b>	STRONG OPPORTUNITY	STRONG OPPORTUNITY	STRONG OPPORTUNITY	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY	POTENTIAL LIMITATION	POTENTIAL LIMITATION
<b>Stakeholder reactions to the ring</b>	STRONG OPPORTUNITY	STRONG OPPORTUNITY	MODERATE OPPORTUNITY	STRONG OPPORTUNITY	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY
<b>Product introduction process</b>	STRONG OPPORTUNITY	STRONG OPPORTUNITY	MODERATE OPPORTUNITY	MODERATE OPPORTUNITY <i>Due to USG ban</i>	MODERATE OPPORTUNITY	POTENTIAL LIMITATION	STRONG OPPORTUNITY



# Implications of findings for ring planning



## GLOBAL STAKEHOLDERS

- Country stakeholder interest and questions about the ring should **be shared with global stakeholders to inform planning and prioritization.**
- Feedback from country stakeholders underscores **the need for demonstration projects** as part of the global rollout and **the importance of coordinated demonstration planning** amongst global actors.
- Supporting awareness-building about the ring and its potential within **USAID, WHO, Global Fund and their relevant missions** is a fundamental step in the introduction process as planning, financing and approval of rollout in most countries hinges on their involvement.



## COUNTRY STAKEHOLDERS

- Introducing the ring through demonstration projects will require resources and may mean that the **first phase of rollout should take place in a subset of “early adopter” countries.**
- Identifying **strong implementing partners in each priority country** to steward the stakeholder engagement and planning process will be a critical first step.
- The limited existing knowledge of the ring, coupled with country stakeholders’ eagerness to engage on demonstration planning, suggests a need for thoughtful, **consistent communications and engagement of priority stakeholders** in country between now, the EMA opinion and thereafter.
- A **customized engagement approach for different types of stakeholder groups** in each country could support introduction. For example, civil society members across countries were supportive of the new option, though they have varying levels of influence on policy-making. They can be engaged to generate demand for the ring through formal or informal channels.



**SUMMARY FINDINGS**

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# TANZANIA





# Tanzania: Potential for the Ring

**LATE ADOPTER** due to a conservative policy environment and a slow pace of product introduction that may delay the launch of a demonstration project for the ring. However, there was interest from all stakeholders to provide another HIV prevention option.

## Opportunities

- **General interest in the ring:** Most stakeholders in Tanzania were interested to learn more about the ring and cautiously optimistic about exploring the possibility once there is greater evidence and after WHO guidelines. Stakeholders liked that the product was women-owned and only required monthly action.
- **Civil society interest:** Civil society partners are excited about another prevention option, and in bolstering the range of options available.
- **Recent movement with product introduction:** Tanzania recently introduced oral PrEP and HIV self-testing. Several stakeholders felt that these products laid groundwork that could expedite introduction of the ring. The experience of introducing these new products has clarified the overall process for introducing new HIV prevention products.
- **Strong partners:** Implementation partners have good government relationships and have been necessary champions for new prevention approaches.

## Challenges

- **Protracted process and challenging political environment:** PEPFAR and USAID representatives expressed skepticism about Tanzania's ability to move quickly on the ring based on the lengthy process to introduce oral PrEP and a new Tanzanian government with conservative SRH policies.
- **No fixed process for product introduction:** Personal relationships, implementation partner champions, and persistence from PEPFAR were the driving factors behind oral PrEP introduction, resulting in a long and often unclear process.
- **Minimal role for civil society:** Civil society plays a limited role in influencing policymakers. The government recently limited the ability for CSOs to serve key populations.
- **Limited NACP capacity:** Tanzania recently introduced oral PrEP and HIV self-testing, which require significant time and capacity from the National AIDS Control Programme (NACP) in the MoH.



# Tanzania: Assessment overview

## High-level assessment for the ring



### HIV epidemic characteristics

**SIGNIFICANT NEED:** Estimates of incidence show 55,000 new infections annually, and women face greater risk of contracting HIV.



### HIV prevention program

**MODERATE OPPORTUNITY:** Tanzania implemented VMMC effectively, but tends to be a slow adopter of new products. The current conservative administration may oppose the ring on political grounds.



### Oral PrEP experience

**MODERATE OPPORTUNITY:** Tanzania recently began a phased introduction of oral PrEP. Stakeholders thought this recent movement could either create momentum for the ring or diminish capacity to introduce a new product.



### Ring trial experience to-date

**POTENTIAL LIMITATION:** While some stakeholders were familiar with the ring, Tanzania has not been involved in any phase III or OLEs for the ring.



### Stakeholder reactions to the ring

**MODERATE OPPORTUNITY:** Stakeholders seemed interested in the ring. The MoH saw benefits of adding an additional option, and civil society advocates are eager for a women-owned product.



### Product introduction process

**POTENTIAL LIMITATION:** Tanzania has a protracted process to product introduction, with few clear steps and which can be challenging to navigate. Champions with close government relationships are critical to making progress.

*Additional details on following slides*



# Tanzania: HIV context

Tanzania has an estimated

## 1.4 million

people living with HIV, which accounts for

## 4.7% of the adult population

and

## 55,000 new infections

occur annually <sup>1</sup>

**Women are disproportionately affected** <sup>2</sup>

**Gender inequities contribute to a greater HIV burden** <sup>3</sup>

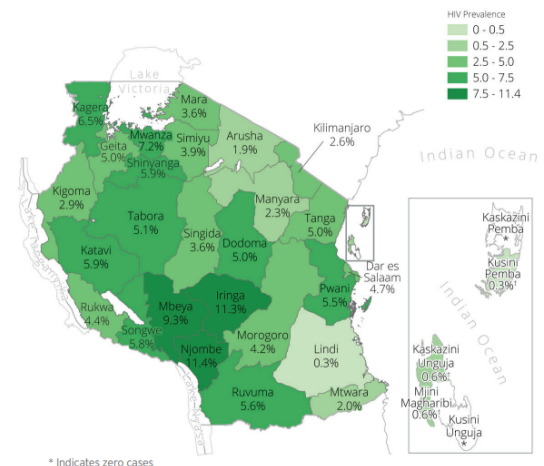
**Prevalence among young women is more than double men** <sup>2</sup>

**Prevalence varies regionally, and is highest in the regions near the Southern Highlands**

HIV prevalence for all **women is 6.4%**, compared to 3.1% for men.

Approximately **35%** of both AGYW and women report **intimate partner violence** in the last 12 months.

Prevalence among women in all age groups from 15 to 39 is **more than double** that of males in the same age groups.





# Tanzania: HIV prevention context

## Context

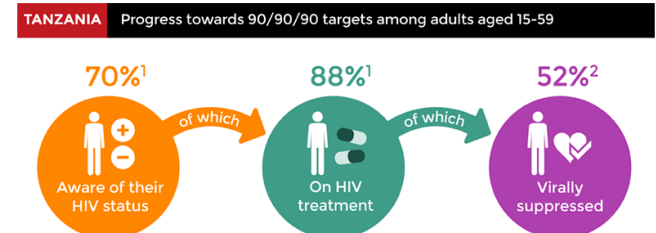
- **Political landscape:** Tanzania is known to be a **slow adopter of new technologies** and approaches. The current political administration in Tanzania is conservative and has limited key population services and civil society action.
- **Recent progress with prevention and treatment:** Tanzania has made significant progress toward the first of the two 90's, which has contributed to decreasing new infections from **82,000 in 2010 to 55,000 in 2016**.<sup>1</sup>

## National Policies and Strategies for Prevention <sup>2</sup>

- The four **strategic areas of primary investment** in the most recent NMSF from 2013 include: (1) Comprehensive sexuality, gender, and health education; (2) Condom promotion and programming; (3) HIV counselling and testing; and (4) Antiretroviral therapy.
- Additionally, the strategic areas for **secondary investment** include VMMC, provision of safe blood, treatment of STIs, and targeted behaviour change communications.
- There are two National HIV plans that are important: the **National Multi-Sectoral Framework (NMSF)**, developed by TACAIDS, which focuses on multiple sectors; and the **Health Sector HIV and AIDS Strategic Plan (HSHS)**, developed by NACP, which solely discusses the health sector. Both are developed every four years, and are currently under review for the fourth iteration, for the years 2018-2022. In between four year periods, NACP and TACAIDS create operational plans to clarify strategies to meet their goals.

## Remaining Challenges with Prevention

- **Health system infrastructure:** Weaknesses in the supply chain infrastructure has hindered the distribution of SRH products. For example, many clinics have stock outs of condoms and other products. The success of HIV interventions is contingent on the strength of the health system.
- **Services for key populations:** Adding onto existing stigmas, recent administrative policies have limited access to health services for KPs.
- **Protracted government processes:** Decision making within the Government of Tanzania is concentrated at the top, which creates protracted processes for evolving policies and requires close personal relationships.



Source: (1) UNAIDS data 2017 (2) Tanzania Ministry of Health 2017



# Tanzania: Status of oral PrEP rollout

## Oral PrEP Rollout

- Oral PrEP is currently in **very early implementation** stages. There are an estimated **500-700** current oral PrEP users in Tanzania. <sup>1</sup> Phased implementation is underway, and has started in the capital city of Dar es Salaam with plans to expand to two additional regions in the Southern Highlands soon.
- National stakeholders are utilizing a **phased implementation approach** to learn from early implementation before scaling-up oral PrEP. Key questions include feasibility, acceptability, and integration with other packages. Stakeholders **opted to skip national demonstration projects for phased implementation**.
- Advocacy efforts that have led to implementation in Tanzania include **strong championing from implementation partners** with good government relationships, and **pressure from PEPFAR, USAID, and Global Fund**, which at one stage involved the US ambassador to Tanzania.
- Tanzania was the site of a few clinical trials for oral PrEP. Gilead's Truvada (TDF/FTC) is currently registered and approved for prevention, and generic versions are pending registration.
- Tanzania has **adapted WHO guidelines** to better match the capacity of their health system, and minimize the burden on providers. These guidelines have been shared in regions where oral PrEP is available.
- Oral PrEP introduction in Tanzania was **slower relative to other countries in the region**. The main drivers for the protracted process include a lack of a clear process for product introduction, concerns about encouraging promiscuity, and regulatory challenges with the Tanzania Food and Drugs Authority, which is the regulatory body associated with the Ministry of Health.



## Tanzania: Ring trial activity

Tanzania has **not been the site for any phase III or open-label extensions for the ring**. Tanzania was only involved in **phase I/II studies** to assess the safety of the ring in 2009 (details below).

Study	Phase	Results	Partners
<b>Phase I/II</b> (ages 18-40) IPM 015	I/II	No safety concerns or clinically relevant differences were observed between the dapivirine and placebo ring groups.	<ul style="list-style-type: none"><li>Led by International Partnership for Microbicides</li></ul>

- One of the ten sites of the study was in Tanzania. The study site was the **Kilimanjaro Christian Medical Centre (KCMC)** in Moshi, Tanzania, and the site enrolled **9 of the 280 women** that participated in the study.
- IPM colleagues shared that Tanzania was **not included in the phase III studies** because the prevalence at the study site was not considered to be high enough.





# Tanzania: Impressions of the ring

## Opportunities

“Everyone is **excited about the ring**. At the MoH, we are interested to see what it can offer Tanzania. We believe it will be received well because it is non-intrusive, self-driven, and convenient.” – Policymaker

“I think given the timing of PrEP being considered for roll out and scale up, **it’s a nice time to start** thinking about how to pair the PrEP work we’ve done with the dapivirine ring.” – International donor

“The ring might take a similar process to PrEP and self-testing. If we get prepared and involve the policymakers now, it might be able to **shorten the process** after those two products.” – Implementation partner

“The ring is **easier to use and simpler than PrEP**. The government will like that, especially if it is cost effective.” – Civil society representative

## Challenges

“Tanzania has been **slow to adopt new efforts**. There is a great emphasis on showing that a product is effective in the local context. Decision makers want to see studies conducted here.” – International donor

“Unlike some other countries, the **MoH has been conservative**. Each new product comes with negotiating and discussion.” – Implementation partner

“There’s **tremendous stigma** currently among healthcare providers, and those of us who are FSWs **cannot go to access health services**. We used to have drop-in centers, which the administration recently closed. Now we cannot go anywhere.” – FSW community organizer

“The **introduction process is a hoop but not a roadblock**. The government is resistant to new things, which will be a challenge. There has been a lot of demos recently, and a lot of the international community pushing Tanzania, which has made the government uncomfortable.” – International donor



# Tanzania: Key questions about the ring

## *Strategic questions to inform introduction*

- 1 How do you **ensure adherence** among users?
- 2 How would the ring impact the **behaviors of end users**? Would the ring decrease use of condoms? Would it increase promiscuity among AGYW?
- 3 What would be the **ultimate cost** for end users? What **service delivery mechanisms** would be used? Distribution through which facilities?
- 4 What would be the implications on the **health system and health care workers**? What types of **investments and trainings** are required?

### **Basic Technical Question about the Ring**

- How long does the ring have to be inserted before sex to be effective?



# Tanzania: Interviews

## Polymakers

1. Dr. Leonard Maboko, TACAIDS, Executive Director
2. Dr. Aafke Kinemo, National AIDS Control Program, Coordinator

## Civil Society

3. Albert Komba, Jhpiego (Sauti Program), Chief of Party
4. Richard Muko, National Council for People Living with HIV and AIDS, Program Technical Manager
5. Dr. Magnus Ndolichimpa, Jhpiego, Learning Collaborative Participant
6. Kelly Curan, Jhpiego, Head of HIV Program
7. Laura Glish, PSI, Technical Advisor, Reproductive Health
8. Alex Ngaiza, PSI, Program Manager
9. Peter Masika, Tanzania Youth Alliance, Country Director
10. Jason Reed, Jhpiego, Epidemiologist and Senior Technical Advisor
11. Joan Chamungu, Tanzania Network of Women Living with HIV and AIDS positive woman
12. Lulu Nyenzi, Women with Dignity
13. Sia Edward, Connect Community with Advocacy & Empowerment Tanzania
14. Hellen Benedict, Totoz Sisters
15. Maua Abdul, Zamzam Women Development

## Researchers

16. Dr. Jessie Mbwambo, Muhimbili University of Health and Allied Sciences (MUHAS)
17. Dr. Samuel Likindikoki, MUHAS

## International Donors and Funders

18. Siobhan Malone, Bill & Melinda Gates Foundation
19. Jessi Green, PEPFAR
20. Kelly Hamblin, USAID, Senior Supply Chain Advisor