

OPTIONS

Dapivirine Ring Introduction: Stakeholder Consultations

December 2019





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OPTIONS interviewed key stakeholders in Zimbabwe (September 2018), Kenya, and South Africa (June 2019) to gather their insight into dapivirine ring introduction in the event of a positive opinion by the European Medicines Agency (EMA).

The stakeholders engaged for this work consisted of key **policymakers**, **implementation partners**, and **researchers** in each country.

Three key themes emerged from these discussions about perspectives on ring introduction:

- **Public Sector Considerations:** These slides share insights about public sector opportunities for the dapivirine ring specific to Kenya, South Africa, and Zimbabwe.
- **Public Sector Questions and Next Steps:** These slides outline possible scenarios for ring introduction in Kenya, South Africa and Zimbabwe and highlight what questions and opportunities remain about ring introduction.
- **Private Sector Considerations:** To what extent could private sector health care channels support access to the ring? As a complementary strategy to public sector delivery, these slides examine the opportunities for the ring in the private sector.



There is significant demand for the ring

Our stakeholder consultations confirmed there is persistent demand for the dapivirine ring:

*“We did well with family planning; women were empowered. We **really look forward to the success of the ring.***

– Senior policymaker, Zimbabwe

*“The first lesson for me is that **the ring has to be available for everyone.** We know it’s partially effective, but the women in our cities don’t have many options.”*

– Implementation partner,
South Africa

*“One thing we are seeing with oral PrEP is that some people want a product that doesn’t require daily use. **We need to give people options,** some may prefer a pill, but others a ring.”*

– Implementation partner, Zimbabwe

*“We know that oral PrEP is not for everyone; we’ve seen a lot of PrEP discontinuation. Some of the key concerns with PrEP are pill burden, the side effects, and stigma. So **if you look at those three reasons, the ring provides an opposite experience.**”*

– Implementation partner, Kenya

PUBLIC SECTOR CONSIDERATIONS



Ring introduction presents opportunities

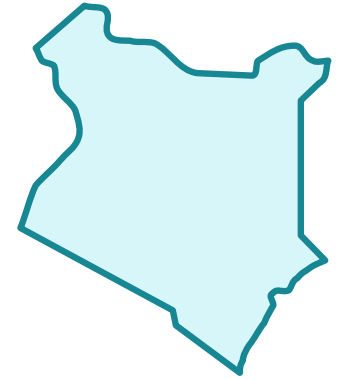
In conversations with key stakeholders in Zimbabwe in mid-2018 and in Kenya and South Africa in mid-2019, stakeholders highlighted several benefits of ring introduction.

- 1. Building on oral PrEP scale-up:** Across countries, there was consensus that introduction of the monthly ring will be able to build upon the processes, structures, and strategies in place for daily oral PrEP. This can expedite the introduction of the ring and make the process more resource efficient than the introduction of oral PrEP.
- 2. Establishing an HIV prevention portfolio:** Many policymakers and stakeholders recognize that the HIV prevention portfolio will continue to expand. The ring provides an opportunity to extend HIV prevention systems, processes and communications beyond oral PrEP to support a more comprehensive set of options. All of the policymakers and most implementers that we spoke with felt that oral PrEP and the ring should both be presented as options for all end users so women can make informed choices about their HIV prevention.
- 3. Integrating HIV prevention and family planning:** All three countries are already exploring integration of oral PrEP and family planning, which is a growing focus for many countries based on the ECHO* trial results. Policymakers see the ring as offering an even greater opportunity to spur integration of HIV prevention and family planning, specifically for adolescent girls and young women (AGYW).
- 4. De-medicalization:** Kenya and South Africa are also exploring decentralized delivery of oral PrEP, specifically in pharmacies and in community-based settings. Due to fewer testing requirements and a lower risk of building resistance relative to oral PrEP, policymakers see opportunities to introduce the ring as a product that can readily be provided by nurses or pharmacists in non-clinical settings, which could both support broader uptake and continuation and avoid additional burden on the health system, while enabling the ring to be an even stronger complement to oral PrEP.

*ECHO: <http://echo-consortium.com>



Kenya – Detail



Insights from June 2019 interviews:

- 1. Building on oral PrEP scale-up:** Irene Mukui, a key policymaker from Kenya, shared that PrEP implementation has been conducted with the intent of adding additional products, such as the ring: *“There is a mood of anticipation for other products. People have this feeling like we’re implementing PrEP, and yes we have issues we are working through, but we need to think broadly of other products to bring as well.”* – Dr. Mukui
- 2. Establishing an HIV prevention portfolio:** All stakeholders in Kenya expressed high interest in providing more choice, particularly given continuation challenges with oral PrEP, especially for AGYW.
- 3. Integrating HIV prevention and family planning:** In Kenya, oral PrEP was initially introduced in comprehensive care centers (CCC). As CCCs are primarily used for ARV delivery to HIV positive populations, this has limited PrEP’s reach to HIV negative populations. PrEP is currently being expanded to integrate with maternal and child health clinics, and stakeholders mentioned that this would be a good time to integrate the ring as well to build on oral PrEP scale up and ease the integration with family planning. Stakeholders in Kenya shared the desire to link all HIV prevention more closely with family planning, and felt that the ring would support that integration.
- 4. De-medicalization:** MoH policymakers and key implementation partners, such as LVCT Health and Jhpiego, were eager to explore de-medicalization opportunities in Kenya. Similar to other countries, to make de-medicalization a reality, studies demonstrating safe de-medicalized delivery would need to be conducted at a later phase of introduction.

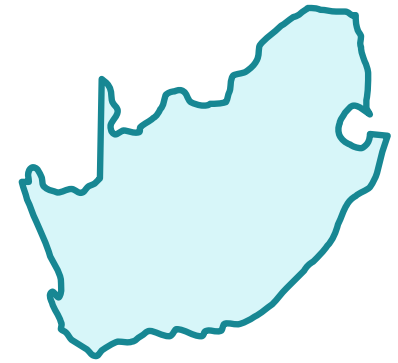
*“We’ve seen that clients want more choice. That has to feature strongly – while there is a population that will benefit from PrEP, **there are other populations that would prefer another choice.**”*
– Implementation partner

*“**Integration is the path forward.** If a client comes for family planning, they should get all services, including STI protection in the same setting. If they are getting family planning, they are sexually active.”* – Policymaker



South Africa – Detail

Insights from June 2019 interviews:



- 1. Building on oral PrEP scale-up:** In South Africa, oral PrEP is undergoing significant scale up in 2020 to 52 priority districts in 9 provinces. Stakeholders were excited about the prospect of introducing the ring simultaneously with oral PrEP in some districts so that clients could start with a choice. Hasina Subedar, a critical National Department of Health (NDoH) stakeholder, recommended piloting dual-delivery of the ring and oral PrEP in several of the expansion sites.
- 2. Establishing an HIV prevention portfolio:** Similar to other countries, all stakeholders are eager to provide choice for clients, particularly for AGYW to support improved continuation.
- 3. Integrating HIV prevention and family planning:** South Africa has made oral PrEP available as part of a comprehensive package of sexual and reproductive health (SRH) services and is investigating areas for greater integration. There was enthusiasm that the ring could provide more opportunities for integration.
- 4. De-medicalization:** Implementers and policymakers noted that a major challenge to uptake of oral PrEP is that it can only be prescribed by NIMART-trained* nurses, who are not located in many facilities. NIMART nurses dispensing PrEP may also worsen stigma for PrEP as they traditionally deliver antiretroviral therapy (ART). Given this dynamic, and recognizing the safety profile of the ring, stakeholders were hopeful that the ring could be scheduled for delivery by public health nurses. However, many technical experts and implementation partners acknowledge that more evidence is needed. To allow for this, IPM may need to develop a regulatory strategy for de-medicalization. Most stakeholders hypothesized that data on the safety of the ring and evidence of safe delivery of the ring by lay healthcare workers is needed to inform WHO guidance.

*“There is an eagerness to provide women with **as many options as possible**. We want services to be better for AGYW, and part of that is giving them choice.”*
– Policymaker

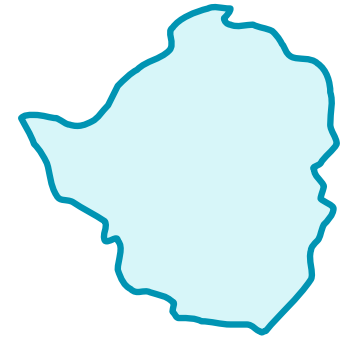
“Does it need prescription? Could it be delivered off the counter? How is that going to happen? That makes a big difference for how we roll out. A stumbling block with oral PrEP is that we rely on prescription, and because of the schedule, it can’t be prescribed by someone who can’t prescribe ART.”
– Policymaker

*NIMART: Nurse Initiated Management of Antiretroviral Therapy



Zimbabwe – Detail

Insights from 2018 interviews:



- 1. Building on oral PrEP scale-up:** In oral PrEP implementation, policymakers developed provisions for building on oral PrEP with complementary products. Policymakers mentioned that there are provisions to have the ring imported under section 75 (provisions for importing non-registered drugs and devices) in cases where there may be delays in registration with MCAZ (Medicines Control Authority of Zimbabwe).
- 2. Establishing an HIV prevention portfolio:** Stakeholders in Zimbabwe were eager to build on the HIV prevention portfolio, particularly to provide an option for women who find daily dosing challenging. Policymakers and other key stakeholders expressed significant demand and urgency to build the portfolio of options available to women seeking prevention, and noted that they would prioritize quick implementation to make this a reality.

When asked about the partial efficacy of the ring, a key policymaker from Zimbabwe MoHCC* responded: *“One HIV infection is one too many.”*

*Ministry of Health and Child Care

PUBLIC SECTOR QUESTIONS AND NEXT STEPS



Stakeholders also highlighted needs

Stakeholders in Zimbabwe, Kenya, and South Africa highlighted important considerations to support accelerated ring introduction.

- 1. Timely regulatory decisions and guidance:** In all countries, policymakers noted WHO Prequalification (PQ), normative guidance, and national regulatory authority approval as necessary pre-conditions for ring introduction. Most policymakers, however, felt that following WHO PQ, national regulatory approval could be relatively quick (e.g., several months) following submission.
- 2. Resources:** While many stakeholders noted the need for resources for ring introduction, several noted that existing resources for oral PrEP could also support ring introduction and that ongoing efforts (e.g., Jilinde in Kenya, oral PrEP scale-up in South Africa, Project STAR supporting HIV self-testing in Kenya and South Africa) could be leveraged for ring introduction as well. An estimate of the cost of the ring, especially relative to the cost of oral PrEP, will help policymakers make budgeting decisions. However, Hasina Subedar at the South Africa NDoH noted that the ring has a price comparable to oral PrEP, which would make introduction easier.
- 3. Advocacy:** Most stakeholders noted the importance of extensive education, awareness building and advocacy around the ring to ensure that it is prioritized for introduction.
- 4. Training and messaging:** With an eye to implementation, stakeholders noted that the characteristics of the ring – specifically that it is a vaginally-inserted and partially-efficacious product – will require new trainings for healthcare workers and careful messaging for end users. Stakeholders noted that new healthcare worker trainings and end user materials will also need to support women and girls to make informed choices between different HIV prevention options.



The ring could be introduced in several ways

ULTIMATE GOAL

The primary aim of IPM is to make the ring available as soon as possible to **women and girls who need additional HIV prevention options**. With this goal in mind, two possible introduction scenarios are under consideration.



PILOT IMPLEMENTATION

In June 2019, OPTIONS consultations with policymakers in South Africa and Kenya suggested that the right path forward would be to pursue a pilot rollout with evaluation benchmarks, which would allow for a close connection to national policy and rapid learning and improvement.

In this scenario, WHO prequalification and national regulatory authority would need to be secured for the dapivirine ring before introduction.



DEMONSTRATION PROJECTS

Should the timelines for WHO prequalification and national regulatory approval be prolonged, a demonstration project would be supported as an alternate path.

If demonstration projects are pursued, it would be important to design them to respond to national policy needs and to support ongoing data-sharing so that projects can inform government plans for introduction and scale-up in parallel, unlike the experience with oral PrEP demonstration projects.



Introduction pathways: additional detail

PILOT IMPLEMENTATION

Most stakeholders we spoke to volunteered their support for this approach, including **policymakers** and most **implementation partners**

“Since it was entirely new, demonstrations were helpful for PrEP, but the problem was that demonstrations happened before countries discussed PrEP. The systems were so rigid that countries changed guidelines, but donors failed to realize that they were operating in a different environment and **should operate in the national context**. The project objectives were no longer relevant in the new context. With the ring, you should talk to countries that are thinking of doing it and **just focus on answering their questions.**”

– Policymaker, Kenya

“I think there will be **less reliance on demo projects for the ring**. We will look at the lessons learned, but not over-reliance on the demonstration. Given that we’ve had three years of PrEP implementation, **we have a better understanding of how to implement**. That will speed up the implementation of the program.”

– Policymaker, South Africa

“With oral PrEP, we saw very little assistance from the demo projects to actually influence rollout. Many demo projects were holding on to their data and didn’t want to speak too soon, so **I don’t know if a demo project will be seen as a favorable output**. If they were able to do **real world implementation science project** reaching many AGYW, that would be of more value – but that would require approval from SAHPRA*.”

– Implementation partner, South Africa

DEMONSTRATION PROJECTS

Several stakeholders recommended pursuing demonstration projects. Most agreed that demonstration made sense as a back-up if NRA timelines are prolonged, but **researchers** recommended demonstration projects as their preferred option

“We need a demonstration to better understand the **feasibility and avenues of delivery**. We need a niche to start as an entry point. Maternal and child health clinics have all women clinics, and we need for girls to own it and push it.”

– Researcher, Kenya

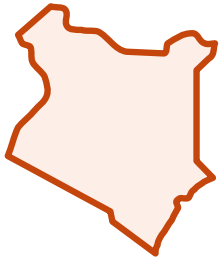
“I would want to have a **pilot intro study while waiting for WHO PQ** and NRA, perhaps using PrEP / UNITAID sites, so you can see what happens with those two options. I would add to PrEP sites and look at ECHO sites where they have contraception – so that you tip it in both directions (toward PrEP and family planning). This could demonstrate safety, efficacy, and adherence.”

– Researcher, South Africa

*South African Health Products Regulatory Authority

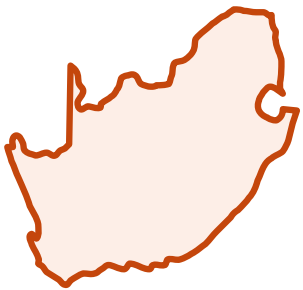


Immediate Ring Opportunities



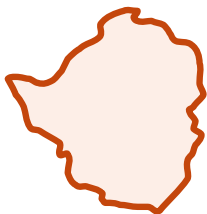
Kenya: Many of the PrEP projects that integrate best with national priorities are closing in 2020-21. If it is possible to integrate the ring into these projects while they are ongoing, stakeholders feel the ring will stand a better chance to integrate with oral PrEP and demonstrate relevance in the Kenyan context.

*“Most of the funding for PrEP projects is coming from the Gates Foundation and the projects end next year. We need to layer the ring in these existing platforms – we can’t let the ring fizzle. **So we need to layer in now into the existing PrEP platforms.**”*
– Implementation partner



South Africa: A senior policymaker noted that given study fatigue and the wide array of lessons learned with oral PrEP delivery, they would prefer to introduce the ring into existing delivery systems, alongside oral PrEP as part of the planned PrEP scale-up in 2020. If the ring could be introduced in 2020, it would provide an opportunity to allow first-time PrEP users a choice between both oral PrEP and the ring, which would be a good test of demand for the ring and its relevance in South Africa.

“We could link the ring immediately with an existing study, but I do not see a need for a new study in whatever form. I think it would be better for us to roll something into existing delivery systems. We are looking at a massive scale-up in priority districts. We can see what is happening and the implications for the ring.”
– Policymaker



Zimbabwe: Policymakers in Zimbabwe expressed urgency and readiness for the ring. Stakeholders noted their eagerness to start implementation science projects quickly to answer remaining questions for the ring.

*“Start preparing programs that show that it makes sense and is worth investing. Once the guidance comes out, we can do this **within 12-18 months.**”* – Policymaker



Questions for Early Implementation

- Over the course of 2018 and 2019, OPTIONS has **interviewed more than 200 stakeholders** from the seven African countries involved in ring trials to date (Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, and Zimbabwe). Interviewees have included a range of national policymakers, key implementing partners, researchers, donors and civil society leaders.
- The next slide highlights **key questions raised in these interviews that will inform implementation decision making**. The table on the next slide indicates whether each question has been answered, and if not, the recommended setting and timeframe to address that question.
- Our aim is to lay the foundation for effective **pilot projects** for the ring in the coming years.



Questions for Early Implementation

Questions raised by national policymakers and other key stakeholders

Method and next steps

Safety and efficacy: Is the ring safe? In what scenarios is the ring most efficacious?

Complete: Answered via clinical trials

Target populations: For which populations is this product appropriate? How are these populations different from the target populations for oral PrEP?

In process: Answered via market research, will revisit post implementation research

Impact of a long-acting product on adherence and continuation: How does a long-acting product impact uptake, adherence, and continuation? In what ways will a long-acting product improve adherence and continuation for populations that have difficulty using oral PrEP consistently (e.g., AGYW)?

In process: REACH study examining choice and adherence with ring and oral PrEP among AGYW

Health system implications: What are the implications of adding the ring to HIV prevention services for the health system and health care workers? What guidelines, training, and resources are needed to support healthcare worker and end user decision-making between HIV prevention choices?

In process: IPM and partners leading the creation of provider materials.

Demand generation & acceptability: How can acceptability of the ring be increased among different age groups? What are effective demand generation messages and strategies for the ring? What messaging is appropriate for a partially efficacious product? How can messaging support informed end user choice?

In process: IPM and partners leading messaging and positioning for ring. Further market research is underway.

Delivery channels: Which channels are effective for delivery of the ring? How can delivery of the ring be integrated with family planning? How can the ring be effectively delivered in non-clinical settings? What healthcare worker cadres will be able to deliver the ring (e.g., nurse, pharmacist, community health worker)?

Immediate need: Implementation research will inform

Impact and cost-effectiveness: What is the impact of adding the ring to a comprehensive HIV prevention portfolio (e.g., alongside oral PrEP and condoms)? How many infections could be averted? How cost-effective is the ring, relative to other prevention options? What is the cost of introducing the ring alongside oral PrEP?

Immediate consideration: Implementation research and modeling will inform

Introduction of a new product: How will investment decisions be made between HIV prevention products and approaches across end user groups? What is the incremental budget required to add the ring to a comprehensive HIV prevention portfolio?

Immediate consideration: Implementation research and modeling will inform

PRIVATE SECTOR CONSIDERATIONS



Private Sector Opportunities

While the primary goal through initial ring introduction is to provide wide public sector access, the private sector offers opportunities to extend the ring's impact and complement the public sector. In early discussions, the following insights emerged about the ring's potential in the private sector:

- Use of **private sector health care** is growing in South Africa, Kenya and Zimbabwe, including both commercial / for-profit health care and NGO-run social franchises
- A **growing number of people** are willing to pay some amount out-of-pocket to avoid the long wait times and lack of discretion that are challenges in public sector healthcare
- As a result, across all three countries, there are **pilot projects to introduce oral PrEP and HIV self-testing in private sector channels**. In South Africa, the focus is on pharmacies; in Kenya and Zimbabwe the focus is on clinical settings (e.g., NGO-run franchises, private practices)
- Across settings, stakeholders noted the importance of effective **training** for providers and demand generation activities to ensure there is **sufficient demand** for the introduction of a new product to make business sense for commercial providers
- While more will be learned from these initial pilots, there is enough activity to make the private sector meaningful for introduction of the **dapivirine ring**, especially in South Africa



Private Sector Country Details

	South Africa	Kenya	Zimbabwe
Use of private sector healthcare	41% of South Africans report that their last medical visit was to a private sector practitioner ¹	40% of Kenyans have recently sought some private sector healthcare ²	Private sector healthcare is growing rapidly; private sector healthcare spend is now greater than public sector spend
HIV prevention in the private sector	<ul style="list-style-type: none"> • Piloting delivery of oral PrEP in pharmacies in late 2019 • Oral PrEP delivery in pharmacies is limited to refills, as current PrEP scheduling requires NIMART trained nurses to provide an initial prescription • The STAR project is also introducing HIV self-tests in private sector pharmacies 	<ul style="list-style-type: none"> • Oral PrEP being delivered via private health care providers (commercial providers and social franchises such as PS Kenya) for free via partnership with the public sector • Goldstar Kenya, a FHI 360 franchise, is training private sector providers on HIV and oral PrEP delivery 	<ul style="list-style-type: none"> • Increasing demand for oral PrEP in the private sector, primarily among those who are willing to pay out-of-pocket and do not want to be seen at public facilities • Some private sector providers have been trained as part of the national PrEP program
Pricing considerations from similar products	<ul style="list-style-type: none"> • Truvada remains expensive (~\$15-20 USD per month) as generics are not yet available • HIV self-tests and pregnancy tests have had private sector success at a slightly higher price point (range \$5 – 15 USD) 	<ul style="list-style-type: none"> • Depo-Provera (injection that lasts for 3 months) is generally sold for 100KSH (\$1 USD) at lower-end private sector pharmacies 	<ul style="list-style-type: none"> • Depo-Provera (injection that lasts for 3 months) is priced at \$4 USD and the contraceptive pill is priced at \$1.35 USD per month in the private sector – a similar price would be appropriate for the ring • Long-acting contraceptive methods (e.g., implants, IUDs) are also priced at \$4 USD.

1: Statistics South Africa, [General Household Survey](#), 2016.

2: Gabrielle Appleford and Saumya Ramarao, [Health financing and family planning in the context of Universal Health Care: connecting the discourse in Kenya](#). Population Council, 2019.

APPENDIX: STAKEHOLDER LISTS



South Africa Stakeholders Interviewed

South Africa *(Interviews conducted June 2019)*

1. Hasina Subedar, South Africa National Department of Health (NDoH)
2. Busi Radebe, World Health Organization (WHO)
3. Elmari Briedenhann, University of the Witwatersrand Reproductive Health and HIV Institute (Wits RHI)
4. Diantha Pillay, Wits RHI
5. Lulu Nair, Desmond Tutu HIV Foundation (DTHF)
6. Thesla Palanee-Philipps, Wits RHI
7. Rutendo Bothma, Wits RHI
8. Helen Rees, Wits RHI
9. Billia Luwaca, South Africa National AIDS Council (SANAC)
10. Lifutso Motsieloa, SANAC
11. Neveline Slinders, SANAC
12. Mohammed Majam, Wits RHI
12. Francois Venter, Wits RHI
13. Karin Hatzold, Population Services International (PSI)
14. Jacqui Dallimore, DTHF
15. Keshani Naidoo, DTHF
16. Eve Mendel, DTHF
17. Jason Naidoo, DTHF



Kenya and Zimbabwe Stakeholders Interviewed

Kenya *(Interviews conducted June 2019)*

1. Dr. Irene Mukui, National AIDS & STD Control Programme (NASCOP)
2. Prof. Elizabeth Bukusi, Kenya Medical Research Institute (KEMRI)
3. Prof. Nelly Mugo, KEMRI
4. Dr. Daniel Were, Jilinde
5. Dr. Patricia Oluoch, Centers for Disease Control (CDC)
6. Dr. Joshua Kimani, Sex Workers Outreach Program - Kenya (SWOP)
7. Patriciah Jeckonia, LVCT Health
8. Lucy Maikweki, Population Services Kenya (PSK)
9. Kate Nkatha Ochieng, PSK
10. Charity Muturi, FHI 360 Gold Star Network
11. Dr. Jesse Njunguru, Triggerise

Zimbabwe *(Interviews conducted September 2018)*

1. Taurai Bhatasara, Ministry of Health and Child Care (MoHCC)
2. Dr. Abaden Svisva, CHAI
3. Dr. Emily Gwavava, Population Services International (PSI/Z)
4. Sithembile Ruzario, Medical Research Council of Zimbabwe
5. Imelda Mahaka, Pangaea Zimbabwe AIDS Trust (PZAT)
6. Definate Nhamo, Pangaea Zimbabwe AIDS Trust (PZAT)
7. Dr. Portia Hunidzarira, University of Zimbabwe College of Health Sciences Clinical Trials Research Centre (UZCHS)
8. Sister Musvosvi, Zimbabwe National Family Planning Council (ZNFPC)
9. Chamunorwa Mashoko, ACT (Civil Society Organization)



Thank you

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