

The Dapivirine Ring Introduction Matrix

*Early implementation guidance for the dapivirine ring –
a case study of Zimbabwe*

December 2018





The Ring Introduction Matrix: Introduction

CONTEXT

The dapivirine ring, a new discrete and long-acting HIV-prevention product for women, marks the first biomedical prevention product with potential to be introduced since oral PrEP.

As the dapivirine ring undergoes regulatory review, global and national policymakers and implementers are asking questions about how the ring could be integrated into combination prevention, especially as many countries are currently introducing oral PrEP.

To start to answer this question, the OPTIONS Consortium selected a pilot country – Zimbabwe – and facilitated conversations with policymakers, regulators, implementing partners, and researchers to ***develop early hypotheses of how the ring could be implemented in the country.***

PURPOSE

This is an early-stage implementation tool and is intended to help policymakers and implementers consider introduction of the dapivirine ring alongside oral PrEP.

METHODS

This framework for product introduction was originally developed by OPTIONS to support rollout of oral PrEP and was adapted to the ring based on interviews with policymakers, regulators, implementing partners, and researchers in a pilot country – Zimbabwe. (*See appendix for list of interviews.*)

While this framework was adapted based on experiences and expectations in Zimbabwe, it can be easily customized to other country contexts. Inputs to develop and customize the framework include key informant interviews and secondary research.



The Ring Introduction Matrix: **Key Insights**

INSIGHTS

From interviews with key stakeholders and policymakers in Zimbabwe, several insights emerged about how the ring could be introduced alongside oral PrEP in-country:

- **(1)** There is a commonly-held expectation that the ring will be able to **integrate with oral PrEP** in many ways and will enable the ring to build on strategies, plans, processes, and infrastructure developed for oral PrEP.
- **(2)** The ring **offers new opportunities** to broaden the reach and uptake of new HIV prevention methods and enhance the impact of the HIV prevention portfolio. To leverage and understand the extent of these opportunities, they should be further researched (e.g., in demonstration projects or other research / analysis) and should be raised in early conversations with policymakers and regulators.
- **(3)** In a limited number of areas, the ring **requires considerations** distinct from oral PrEP that will need to be newly addressed by policymakers as they plan for ring introduction. These considerations should be taken into account when planning for demonstration projects / pilots or analyses to inform implementation.

To help plan for introduction of the ring alongside oral PrEP to expand prevention options for women, insights have been mapped along the product introduction matrix in the following slides. The format chosen for this tool is a matrix as it allows each step to be evaluated independently



The Ring Introduction Matrix: **Overview**

HOW TO USE THE MATRIX: The tool walks step-by-step through the process to introduce the ring. For each step, it identifies aspects of introduction that will represent:

Integration Areas: *Aspects of product introduction where the ring can integrate into oral PrEP implementation because it can build on strategies, plans, processes, and infrastructure developed for oral PrEP.*

New Opportunities: *Aspects of product introduction where the ring provides a new opportunity to grow uptake and impact of HIV prevention when added to a the HIV prevention portfolio.*

Areas Requiring Additional Consideration: *Aspects of product introduction that are new for the ring and will require additional planning, as they were not required for oral PrEP.*



The Ring Introduction Matrix

This framework includes a high-level list of the steps required to introduce the ring at the country level. This framework was originally developed by OPTIONS for oral PrEP implementation based on experiences in South Africa, Kenya, and Zimbabwe and has been adapted for the ring based on interviews in Zimbabwe.

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
Convening of a new or existing cross-sector technical working group (TWG)	Regulatory approval for the ring by national authorities	Issuance of standard clinical guidelines for prescription and use of the ring	Clear and informative communications on the ring for general public audiences	Plans to support effective use and regular HIV testing , that reflect the unique needs of target populations
Impact, cost and/or cost-effectiveness analyses for the ring as part of comprehensive HIV prevention	Manufacturer identification and contract negotiation to purchase the ring	Infrastructure and human resources to conduct initial HIV tests and prescribe the ring in priority channels	Development of demand generation strategies targeted to unique needs of different end user populations (including engaging partners, parents, social norms, etc. for AGYW)	Capacity to provide ongoing HIV testing for PrEP users accessible to target populations
Identification and quantification of target populations for the ring	Development of distribution plan and supply chain for the ring to reach target populations (e.g., at HIV or family planning sites)	Plan to engage and train health care workers on the ring and delivery to target populations (including mitigating stigma)	Links between HTC and ring access to enable uptake	Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates) and to monitor seroconversion
Inclusion of the ring in current or upcoming national HIV prevention plans	Effective demand forecasting, distribution and financing systems to avoid stock-outs in priority facilities	Tools to help potential clients and HCW assess risk and understand who should use the ring	Links between HIV prevention, STIs, and family planning for women and AGYW	Plans and communication for sanitary disposal of used rings
Timeline and plan for ring introduction and scale-up			Information for clients on how to effectively use the ring	
A budget for ring rollout to target populations				



The Ring Introduction Matrix: Integration Areas

In most areas, **the ring will be closely linked to oral PrEP implementation**. In these areas (in green), strategies, plans, processes, and infrastructure developed for oral PrEP can be extended to the ring.

Areas in gray will be less closely linked to oral PrEP implementation – they will be explored in the following slides.

PLANNING & BUDGETING		SUPPLY CHAIN MANAGEMENT		DELIVERY PLATFORMS		INDIVIDUAL UPTAKE		EFFECTIVE USE & MONITORING	
Convening of a new or existing cross-sector technical working group (TWG)		Regulatory approval for the ring by national authorities		Issuance of standard clinical guidelines for prescription and use of the ring		Clear and informative communications on the ring for general public audiences		Plans to support effective use and regular HIV testing , that reflect the unique needs of target populations	
Impact, cost and/or cost-effectiveness analyses for the ring as part of comprehensive HIV prevention portfolio		Manufacturer identification and contract negotiation to purchase the ring		Infrastructure and human resources to conduct initial HIV tests and prescribe the ring in priority channels		Development of demand generation strategies targeted to unique needs of different end user populations (including engaging partners, parents, social norms, etc. for AGYW)		Capacity to provide ongoing HIV testing for PrEP users accessible to target populations	
Identification and quantification of target populations for the ring		Development of distribution plan and supply chain for the ring to reach target populations (e.g., at HIV or family planning sites)		Plan to engage and train health care workers on the ring and delivery to target populations (including mitigating stigma)		Links between HTC and ring access to enable uptake		Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates) and to monitor seroconversion	
Inclusion of the ring in current or upcoming national HIV prevention plans		Effective demand forecasting, distribution and financing systems to avoid stock-outs in priority facilities		Tools to help potential clients and HCW assess risk and understand who should use the ring		Links between HIV prevention, STIs, and family planning for women and AGYW		Plans and communication for sanitary disposal of used rings	
Timeline and plan for ring introduction and scale-up							Information for clients on how to effectively use the ring		
A budget for ring rollout to target populations									



The Ring Introduction Matrix: Integration Areas (1/2)

Policymakers, implementers and researchers in Zimbabwe highlighted many areas where the ring could **integrate with oral PrEP implementation.**

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS
<p>Convening of a new or existing cross-sector technical working group (TWG)</p>	<p>Regulatory approval for the ring by national authorities</p>	<p>Issuance of standard clinical guidelines for prescription and use of the ring</p>
<p>Impact, cost and/or cost-effectiveness analyses for the ring as part of comprehensive HIV prevention portfolio</p>	<p>Manufacturer identification and contract negotiation to purchase the ring</p>	<p>Infrastructure and human resources to conduct initial HIV tests and prescribe the ring in priority channels</p>
<p>Identification and quantification of target populations for the ring</p>	<p>Development of distribution plan and supply chain for the ring to reach target populations (e.g., at HIV or family planning sites)</p>	<p>Plan to engage and train health care workers on the ring and delivery to target populations (including mitigating stigma)</p>
<p>Inclusion of the ring in current or upcoming national HIV prevention plans</p>	<p>Effective demand forecasting, distribution and financing systems to avoid stock-outs in priority facilities</p>	<p>Plans to help potential clients and HCW assess risk and understand who should use the ring</p>
<p>Timeline and plan for ring introduction and scale-up</p>		
<p>A budget for ring rollout to target populations</p>		

“There’s no need to create a new TWG, just to bring the ring in with PrEP. We can add a few individuals to the existing group.”

“We developed a costing and targeting framework for oral PrEP that have been shared with MOHCC, it can be adapted for the ring.”

“We do not need to reinvent the wheel. We have done similar analyses for oral PrEP. We will need to adapt the frameworks and assumptions, but I think this will be easier since we have done something similar with oral PrEP.”

“I think introducing the ring will be faster than for oral PrEP. We’ve learned a lot, we know what works and what doesn’t work.”

“We have PrEP guidelines, and we can adapt them to be HIV prevention clinical guidelines to incorporate the ring.”

“For training, I don’t see the ring as much of a challenge, it can be integrated into PrEP. The trainings that are already happening, and we know how to do them.”

“Now that we’ve done oral PrEP, we (our facility) can quickly adjust to the ring. There shouldn’t be any problems.”

“HCW have already been trained on HIV. [Training for the ring] would be easier than with PrEP, where we had to train on everything.”



The Ring Introduction Matrix: **Integration Areas (2/2)**

Policymakers, implementers and researchers in Zimbabwe highlighted many areas where the ring could **integrate with oral PrEP implementation.**

INDIVIDUAL UPTAKE

Clear and informative **communications** on the ring for general public audiences

Development of **demand generation strategies** targeted to unique needs of different end user populations (including engaging partners, parents, social norms, etc. for AGYW)

Links between HTC and ring access to enable uptake

Links between HIV prevention, STIs, and **family planning** for women and AGYW

Information for clients on how to effectively use the ring

“From a communications standpoint, the ring studies have been the most acceptable of any studies that we’ve done at this site – it’s been relatively simple and straightforward. It has been easier to talk about the ring than to talk about a vaccine or pill.”

“Based on experiences with the trials, I think that once people understand how the ring works and the safety, this will be an easier road than oral PrEP. I think that demand will be good.”

“We have a lot of family planning options, and we have health workers that are well capacitated to do counseling on family planning options. Since the ring is targeted to women, there is an opportunity to put the ring in that context.”

EFFECTIVE USE & MONITORING

Plans to support **effective use and regular HIV testing**, that reflect the unique needs of target populations

Capacity to provide ongoing HIV testing for PrEP users accessible to target populations

Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates) and to monitor seroconversion

Plans and communication for **sanitary disposal** of used rings

“The messages delivered for continued use between oral PrEP and the ring are similar. In the open label extension (OLE), we’re giving women all of the options, and now it’s their choice. I think we can put the information out there and have counselling on the options. We know it’s not for everyone, but the right sort of women will come for each option.”

“The ring would require less capacity from health facilities for continued use, since we don’t have to do creatinine testing.”

“For monitoring at the facility level, I think it would require something very similar to oral PrEP. We can adjust the tools we have to make it for the ring. It could even be integrated into the same form.”

“For oral PrEP, we have registers and client intake forms that could be used for the ring as well.”



The Ring Introduction Matrix: New Opportunities

Stakeholders in Zimbabwe highlighted several aspects of product introduction where the ring could **create new opportunities** to expand reach and uptake of HIV prevention and **amplify the impact** of the overall HIV prevention portfolio.

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
<p><i>"It is a big question to ask ourselves: does the ring need a prescription? Could we distribute it more like the condom to make it more available? This has been one of the biggest challenges with oral PrEP."</i></p> <p><i>"Some of the would-be beneficiaries of the ring (e.g., young women) have trouble accessing PrEP – can we think about de-medicalization of the ring? A lot of the barriers to uptake of PrEP today stem from the medicalization of the product."</i></p> <p>Timeline and plan for ring introduction and scale-up</p> <p>A budget for ring rollout to target populations</p>	<p>Regulatory approval for the ring by national authorities</p> <p>Manufacturer identification and contract negotiation to purchase the ring</p> <p>Development of distribution plan and supply chain for the ring to reach target populations (e.g., at HIV or family planning sites)</p> <p>Effective demand forecasting, distribution and financing systems to avoid stock-outs in priority facilities</p>	<p>Issuance of standard clinical guidelines for prescription and use of the ring</p> <p>Infrastructure and human resources to conduct initial HIV tests and prescribe the ring in priority channels</p> <p>Plan to engage and train health care workers on the ring and delivery to</p> <p><i>"If we were able to distribute the ring like any other family planning commodity, many more people would be able dispense it, so we could have much broader reach."</i></p> <p>understand who should use the ring</p>	<p>Clear and informative communications on the ring for general public audiences</p> <p>Development of demand generation</p> <p><i>"I think it's easier to distribute the ring through family planning, I think it would be more acceptable. ARTs are a challenge from a communications and stigma perspective, as people associate it with HIV."</i></p> <p>enable uptake</p> <p>Links between HIV prevention, STIs, and family planning for women and AGYW</p> <p>Information for clients on how to effectively use the ring</p>	<p>Plans to support effective use and regular HIV testing.</p> <p><i>"As we think about communications – HPV is a useful analogue. In South Africa, when the HPV vaccine was introduced it and was de-linked from sexual activity, and marketed as a means to prevent cancer. I think we need something similar for the ring – who is our target audience and what will make that product attractive?"</i></p> <p>visit, non-HIV STI rates) and to monitor seroconversion</p> <p>Plans and communication for sanitary disposal of used rings</p>



The Ring Introduction Matrix: New Opportunities

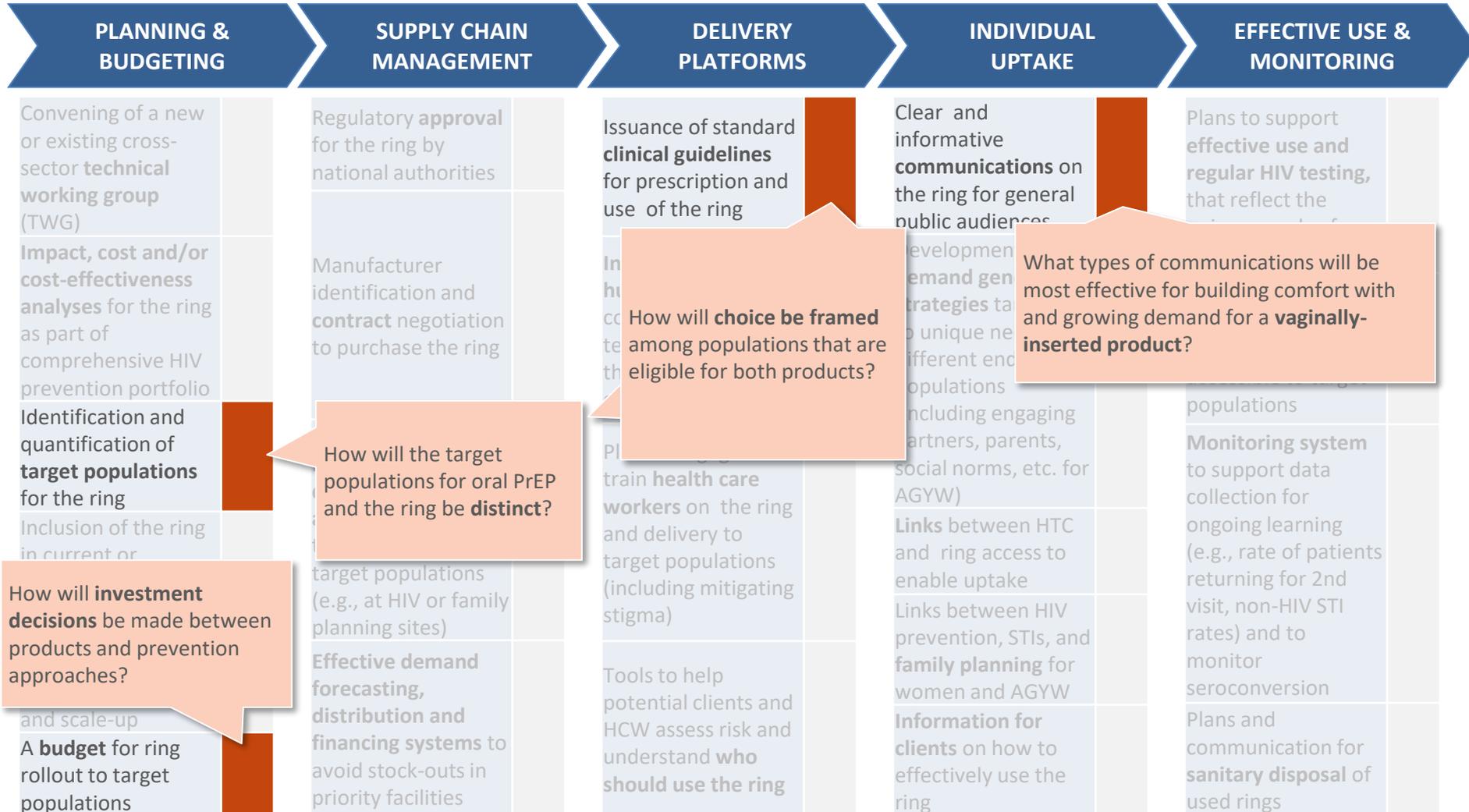
Stakeholders in Zimbabwe highlighted several aspects of product introduction where the ring could **create new opportunities** to expand reach and uptake of HIV prevention and **amplify the impact** of the overall HIV prevention portfolio – and raised **questions** about how to realize these new opportunities.

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
<p>Convening of a new or existing cross-sector technical working group (TWG)</p> <p>Impact, cost and/or cost-effectiveness analyses for the ring as part of comprehensive HIV prevention portfolio</p> <p>Identification and quantification of target populations for the ring</p> <p>Inclusion of the ring in current or upcoming national HIV prevention plans</p> <p>Timeline and plan for ring introduction and scale-up</p> <p>A budget for ring rollout to target populations</p>	<p>Regulatory approval for the ring by national authorities</p> <p>Contract negotiation to purchase the ring</p> <p>Development of distribution plan and supply chain for the ring to reach target populations (e.g., at HIV or family planning sites)</p> <p>Effective demand forecasting, distribution and financing systems to avoid stock-outs in priority facilities</p>	<p>Issuance of standard clinical guidelines for prescription and use of the ring</p> <p>Infrastructure and human resources to conduct initial HIV tests and prescribe the ring in priority channels</p> <p>Plan to engage and train health care</p>	<p>Clear and informative communications on the ring for general public audiences</p> <p>Development of demand generation strategies targeted to unique needs of different end user populations (including engaging partners, parents, social norms, etc. for AGYW)</p> <p>Links between HTC and ring access to enable uptake</p> <p>Links between HIV prevention, STIs, and family planning for women and AGYW</p> <p>Information for clients on how to effectively use the ring</p>	<p>Plans to support</p> <p>The ring presents an opportunity for a new communications and demand generation approach – how can communications promote choice and mitigate stigma around HIV prevention?</p> <p>accessible to target populations</p> <p>Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates) and to monitor seroconversion</p> <p>Plans and communication for sanitary disposal of used rings</p>
	<p>Can the ring be approved for provision without a prescription (i.e., de-medicalized)?</p>	<ul style="list-style-type: none"> Will the ring be procured with HIV prevention or family planning products? How can the ring be more closely integrated with SRH and family planning services? To what extent is there an opportunity for the ring to be sold in the private sector? 		



The Ring Introduction Matrix: **Additional Considerations**

Stakeholders in Zimbabwe highlighted several aspects of ring implementation that would be **distinct from the experience with oral PrEP**. The questions below should be considered when planning for demonstration projects, pilots, or analyses to inform implementation.





The Ring Introduction Matrix: **Additional Notes**

Stakeholders in Zimbabwe highlighted several aspects of ring implementation that would be **distinct from the experience with oral PrEP**. The notes below highlight ring-specific questions that emerged in Zimbabwe, which already have some answers but may require broader discussion.

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
<p>Convening of a new or existing cross-sector technical working group (TWG)</p>	<p>Regulatory approval for the ring by national authorities</p>	<p>Will regulatory approval for the ring require both approval for dapivirine (the drug) and the ring itself as a device?</p>	<p>Clear and informative communications on the ring for general public audiences</p>	<p>Plans to support effective use and regular HIV testing, that reflect the unique needs of target populations</p>
<p>Impact, cost and/or cost-effectiveness analyses for the ring as part of comprehensive HIV prevention portfolio</p>	<p>Manufacturer identification and contracting to purchase</p>	<p>Structure and resources to deliver HIV services to priority</p>	<p>Development of demand generation strategies targeted to unique needs of different end user populations (including engaging partners, parents, social norms, etc. for AGYW)</p>	<p>Capacity to provide ongoing HIV testing for PrEP users accessible to target populations</p>
<p>Identification and quantification of target populations for the ring</p>	<p>Development of distribution plan and supply chain for the ring to reach target populations (e.g., at HIV or family planning sites)</p>	<p>Train health care workers on the ring and delivery to target populations (including mitigating stigma)</p>	<p>Links between HTC and ring access to</p>	<p>Monitoring system to support data collection for ongoing learning</p>
<p>Inclusion of the ring in current or upcoming national HIV prevention plans</p>	<p>Effective demand forecasting, distribution and financing systems to avoid stock-outs in priority facilities</p>	<p>Tools to help potential clients and HCW assess risk and understand who should use the ring</p>	<p><i>Note: Prior experience has offered an option: "The disposal of a ring should be the same as a condom: it would be good to rinse it if possible, put it back in a package, and then throw it in the dustbin. Just like a sanitary pad; there's the option of putting it back in a package."</i> –HOPE site leader</p>	<p>How will ring disposal be managed (e.g., information for clients, new infrastructure or processes)?</p>
<p>Timeline and plan for ring introduction and scale-up</p>				
<p>A budget for ring rollout to target populations</p>				<p>Plans and communication for sanitary disposal of used rings</p>



The Ring Introduction Matrix: **Key Takeaways**

FOUR KEY TAKEAWAYS

1. There are many areas where **ring implementation can build on oral PrEP implementation**, such as national guideline refinement, decision making bodies like the TWG, provider training curricula, and communications. These opportunities for integration should be fully pursued to minimize duplication, maximize choice for women, and ensure integration across the HIV prevention and SRH portfolio.
2. There are new opportunities where **the ring could expand the uptake of HIV prevention**, including improving choice for women, potential for de-medicalization, greater integration with family planning and SRH, and a new product form with new communications and demand generation potential. These opportunities should be further considered in research (in demonstration projects or other research / analysis) and should be raised in early conversations with key policymakers and regulators.
3. There are several aspects of implementation for the ring that will be **distinct from oral PrEP**. Additional analyses or research to inform choices such as prevention-investment decisions, target populations, the framing of biomedical prevention options, and ways to communicate about vaginally inserted products will likely be needed. Other aspects that are distinct, such as regulatory differences and disposal needs, will not require further research.
4. Across all of these considerations, **resources remain a critical factor** to support successful implementation for the ring.



The Ring Introduction Matrix: **Appendix**

Key Stakeholders Interviewed *(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)