NEXT GENERATION HIV PREVENTION:
THE DAPIVIRINE VAGINAL RING

SEPTEMBER 24, 2020

Global PrEP Learning Network
OPENING & INTRODUCTIONS

OVERVIEW OF THE DAPIVIRINE RING (DVR)

FRAMEWORK FOR DVR INTRODUCTION

ZIMBABWE REFLECTIONS ON DVR INTRODUCTION

KENYA REFLECTIONS ON DVR INTRODUCTION
Today’s Speakers

Zeda Rosenberg, The International Partnership for Microbicides (IPM)

Dr. Zeda Rosenberg is the founder and CEO of the International Partnership for Microbicides (IPM), a nonprofit dedicated to developing products that women can use to prevent HIV and protect their sexual and reproductive health on their own terms, including the dapivirine ring. A microbiologist and epidemiologist who previously served in senior leadership roles at the HIV Prevention Trials Network and the US National Institute of Allergy and Infectious Diseases at NIH, Dr. Rosenberg has been on the forefront of research on biological and behavioral factors for reducing HIV transmission for over 30 years.

Neeraja Bhavaraju, Afton Bloom

Neeraja Bhavaraju is a strategy consultant and founding partner at Afton Bloom. She has worked on the introduction of new HIV prevention options, including oral PrEP and the dapivirine ring, for the past six years as part of the OPTIONS, CHOICE and PROMISE projects.
Today’s Speakers

Taurai Bhatasara, Zimbabwe MoHCC

Taurai Bhatasara is National DREAMS and Key Populations Coordinator for the Ministry of Health and Child Care in Zimbabwe. He works with adolescent girls and young women and key populations to prevent HIV using different approaches, including pre-exposure prophylaxis. He believes we can prevent new HIV infections if we empower communities to take charge of their sexuality by introducing tailor-made interventions.

Mary Mugambi, Kenya NASCOP

Mary Mugambi is a public health and mental health specialist, and serves as the HIV testing services and pre-exposure prophylaxis (PrEP) Program Manager at the Division of National Aids and STI Control (NASCOP) program in the Ministry of Health in Kenya. Mary has more than 20 years’ experience working in the Kenyan healthcare system. She has been involved in the design, implementation, monitoring and evaluation of HIV programs in Kenya.
Reminder: Use “Chat” Function

Please feel free to ask questions and add comments to the chat box at any point during today’s presentations. At the end of the session, we will dedicate time to Q&A.

Choose “all panelists and attendees” from the drop-down menu when adding a question or comment to the chat box.
The Monthly Dapivirine Ring: Overview and Next Steps

Dr. Zeda F. Rosenberg, IPM CEO and Founder
PrEP Learning Network
September 24, 2020
Why Did IPM Develop the Dapivirine Ring?

- Available methods have not done enough to slow the epidemic among women.
- Need for discreet products that women can use on their own terms.
- No one product will solve the HIV epidemic.
- Women need multiple prevention options that make sense for their lives.
  - On-demand, daily, monthly or longer.
  - Non-systemic or systemic.
Monthly Dapivirine Ring: Overview

• Flexible silicone vaginal ring developed by IPM
• Woman-initiated
  – Self-inserted monthly
  – Discreet
  – Does not interfere with sex
• Slowly releases ARV dapivirine
  – Exclusive worldwide rights through Janssen Sciences Ireland UC
• Reduced HIV risk in Phase III trials: 35% in The Ring Study, 27% in ASPIRE
• Open-label extension studies saw increased adherence, suggested greater risk reduction
• First long-acting HIV prevention product
Dapivirine Ring Trials
Malawi, South Africa, Uganda, Zimbabwe

**Phase III**

- **ASPIRE**
  - Women did not know if they’re receiving the dapivirine ring or a placebo ring
  - 4500 participants: 2250 dapivirine, 2250 placebo

- **Risk Reduction**
  - Adherence was about 80% in Phase III trials
  - HIV risk was lower with dapivirine ring use in the Phase III trials
  - 35% ASPIRE, 27%

- **Safety**
  - No safety concerns were seen with use of the dapivirine ring in the Phase III trials

**Open-Label**

- **DREAM**
  - 2400 former Phase III participants
  - All women know they’re receiving the dapivirine ring (there was no placebo group)

- **Risk Reduction**
  - Adherence
  - 90%+

- **Safety**
  - The dapivirine ring’s safety profile in the open-label studies was similar to the strong profile seen in the Phase III trials

**WHAT WE KNOW**

- **01** The Phase III trials showed that HIV risk was reduced in women who used the dapivirine ring
- **02** Open-label study results suggested that the dapivirine ring reduced HIV risk by about half across both studies, an encouraging trend
- **03** Adherence was higher in the open-label studies
- **04** The dapivirine ring had a strong safety profile in all the Phase III and open-label studies, with no safety concerns
- **05** The open-label study results suggest that when women are aware that the dapivirine ring reduced HIV risk in large clinical trials, they are more likely to use the product and see greater protection
## Fills a gap in the current portfolio

<table>
<thead>
<tr>
<th>Current options</th>
<th>Innovation</th>
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<tr>
<td><strong>Condoms</strong></td>
<td><strong>TasP</strong></td>
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<tr>
<td>Frequency</td>
<td>Daily</td>
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<tr>
<td>Site of action</td>
<td>Non-systemic</td>
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<tr>
<td>Role of male partner in use</td>
<td>Male partner consent required</td>
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- **Dapivirine ring**
  - Monthly
  - Non-systemic
  - Woman-initiated
Regulatory Status
A Milestone: Positive EMA Opinion

European Medicines Agency adopted positive scientific opinion for the ring’s use by cisgender women 18 and older in developing countries to reduce HIV risk (July 2020)

• Reviewed under **EMA Article 58 procedure**
  – In cooperation with WHO to **facilitate access to essential medicines** in developing countries
  – **Same rigorous standards** as for products intended for use in the European Union

• Positive opinion **recognized by national regulators in Africa**; facilitates WHO prequalification, guidelines

• **Key step** on path to making the ring available where urgently needed
What Happens Next?

- Scientific opinion on use of a product in developing countries (via Article 58 procedure)
  - Positive opinion adopted July 2020

- WHO participates in EMA Article 58 procedure
  - Facilitates abbreviated WHO prequalification (PQ) and Collaborative Registration Procedure (CRP)

- IPM application for abbreviated WHO PQ

- IPM request to WHO, NMRAs and EMA to use SRA CRP

- Planned submissions 2020 onward

- African National Medicines Regulatory Authorities (NMRAs) approvals

- Planned submission Q4 2020

Timelines are estimates and subject to change
Planning for Access
Access Strategy

**Clinic/Public Hospital Access**
Drive ring awareness/education to encourage provider referrals to patients

**Operations & Logistics**
Deliver the ring to clinics/hospitals via approved channels and partnerships

**Government & Donor Support**
Include the ring in policy guidelines and funding decisions

**End-User Access**
Drive women’s awareness, education and use of the ring
Additional Monthly Ring Research

Phase IV post-authorization efficacy study (PAES) among cisgender women ages 18-25

- Assess efficacy in two age groups: 18-21 and >21-25
- Collect additional data on safety and potential ARV resistance
- Could also inform adherence support strategies

Additional research led by MTN in partnership with IPM:

**REACH study: Adolescent girls and young women**
- Safety and use of dapivirine ring and oral PrEP among 300 young women ages 16-21 in South Africa, Uganda, Zimbabwe; began Feb. 2019

**DELIVER study: Pregnant women**
- Safety and acceptability of ring & PrEP among 750 women in Malawi, South Africa, Uganda, Zimbabwe; began Feb. 2020

**B-PROTECTED: Breastfeeding women**
- Safety and acceptability of ring & PrEP in Africa; began Aug. 2020
Potential Public Health Impact

Modeling data show that:

• A range of prevention options alongside scaled-up treatment is needed to achieve epidemic control

• Prevention methods with even modest efficacy would have a meaningful impact as part of a comprehensive strategy that could avert millions of HIV infections over time

• The ring would prevent infections among women that would otherwise not be averted by any other method

New, woman-centered options like the ring will be crucial to achieving epidemic control
Follow-on Rings
Studies led by MTN in partnership with IPM

Building on monthly ring, longer-acting rings could:
• Increase convenience to women
• Lower annual costs

3-month dapivirine ring
• Phase I results expected by early 2021

3-month dapivirine-levonorgestrel ring
• HIV prevention and contraception
• First Phase I trial results: well-tolerated, encouraging drug levels seen in blood and vaginal fluid
• Second Phase I trial results expected by early 2021
A FUTURE
WHERE
EVERY WOMAN
HAS OPTIONS
TO PROTECT
HER HEALTH

IS A FUTURE
WHERE
WOMEN
WILL THRIVE
Current IPM Donors

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OPENING & INTRODUCTIONS

OVERVIEW OF THE DAPIVIRINE RING (DVR)

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A Framework for DVR Introduction

Neeraja Bhavaraju, Afton Bloom

SEPTEMBER 2020
Introducing the dapivirine ring

This analysis was developed in 2019 as part of the OPTIONS project. It is based on the experience with oral PrEP introduction and interviews with key policymakers and other stakeholders in the three OPTIONS focus countries: Kenya, South Africa, and Zimbabwe.

Value Chain for Dapivirine Ring

PLANNING & BUDGETING
National and state plans are established to implement dapivirine ring guidelines for priority end user populations

SUPPLY CHAIN MANAGEMENT
Dapivirine ring is available and distributed in sufficient quantity to meet projected demand via priority delivery channels

RING DELIVERY PLATFORMS
Dapivirine ring is delivered by trained healthcare workers in priority delivery channels to effectively reach end users

UPTAKE & EFFECTIVE USE
End users know about and understand the ring and are able to seek out, initiate and effectively use the ring

MONITORING
The ring is effectively integrated into national, state, program, and facility level monitoring systems
# Dapivirine Ring Introduction Framework

## PLANNING & BUDGETING
- Convene new or existing technical working group/subcommittee for the ring
- Identify target populations for ring use
- Engage community stakeholders to inform planning for ring rollout
- Develop impact, cost and/or cost-effectiveness analyses to inform ring planning
- Include the ring in national HIV prevention and other relevant plans
- Adapt policies to enable ring delivery across priority channels
- Develop implementation plan and budget to guide initial ring introduction and scale-up

## SUPPLY CHAIN MANAGEMENT
- Register the ring and include the ring on the national essential medicines list
- Update supply chain guidelines and logistics systems to include the ring
- Establish monitoring, demand forecasting, and distribution systems to avoid stock-outs

## DELIVERY
- Issue standard clinical guidelines for delivery and use of the ring
- Dedicate resources to conduct regular HIV tests, initiate ring use, and support refills
- Develop trainings and materials for health care workers on the ring
- Establish referral systems to link clients from other channels to sites dispensing the ring
- Integrate support for partner communication and gender-based violence for ring users

## UPTAKE & EFFECTIVE USE
- Develop and implement demand creation strategies that include ring promotion
- Address social norms/stigma to build community and partner acceptance of ring use
- Develop information and tools for clients to guide product choice and support ring use
- Support adherence and continuation for ring users
- Develop and communicate plans for sanitary disposal of used rings

## MONITORING
- Establish monitoring tools to support data collection and analysis on ring use
- Establish systems for pharmacovigilance and to monitor drug resistance
- Conduct implementation science research to inform policy and scale-up
Key findings from initial analysis

We assessed each element to identify:

Integration Areas: Aspects of product introduction where the ring can integrate with oral PrEP implementation by building on strategies, plans, processes, and infrastructure developed for oral PrEP to create systems for a portfolio of biomedical prevention options.

New Opportunities: Aspects of product introduction where the ring provides a new opportunity to grow uptake and impact of HIV prevention when added to combination prevention, and so will require additional consideration and action.

Areas Requiring Additional Consideration: Aspects of product introduction that will be new for the ring and cannot build directly on the introduction of oral PrEP.
Key findings from initial analysis

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**COLOR KEY**
- Anticipate easy integration with PrEP
- Presents new opportunity to broaden HIV prevention, but requires new effort
- Will require additional consideration beyond oral PrEP
There are a lot of opportunities for the ring to build on the introduction of oral PrEP.

This is especially true for planning and monitoring.

Many countries will be able to introduce the ring by building on existing planning process and structures, including existing technical working groups (TWGs), implementation plans, guidelines, and M&E tools and systems.
Dapivirine ring: Expanding beyond oral PrEP

- There are areas where the dapivirine ring has the potential to expand HIV prevention beyond current oral PrEP delivery.
- These areas will require additional consideration beyond PrEP alone.
- Potential opportunities include:
  - Training providers and developing materials to support a portfolio of HIV prevention options
  - Delivery outside clinical settings and/or outside HIV settings (e.g., with family planning)
Dapivirine ring: Different than oral PrEP

- Some areas will require new efforts for the ring that are different than for oral PrEP
- One area is the supply chain, where registration, logistics, and forecasting systems will be different for the ring than they were for oral PrEP
- Health care worker training and demand creation will also require new approaches as the ring will be an unfamiliar method to most people
- Disposal of the ring will be a new issue to consider
Stakeholders felt confident to introduce the ring

“There is a mood of anticipation for other products. Even at country level, people have this feeling as we implement PrEP and come across issues, and we know we should think broader and are working toward other products too. I feel like we are moving toward the family planning direction where we will have a menu of options for different audiences. We need to get to options.”

“Given that we’re several years into PrEP implementation, we have a better understanding of how to implement. That will speed up ring implementation.”

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

“We’re not starting with a blank slate. We’re going to build on experience.”
Zimbabwe national considerations for DVR

Taurai Bhatasara
National DREAMS and Key Populations Coordinator
Ministry of Health and Child Care

The adoption of PrEP is meant to address continued new HIV infections in the general population and among AGYW in particular.

PrEP Implementation Plan of 2018-2020 recognizes that PrEP will be offered in many other forms including the ring.

The country acknowledges that AGYW are disproportionately affected by HIV.

Since the inception of the PrEP programme there has been a slow uptake of PrEP among AGYW.

Some of the early lessons from PrEP among AGYW shows poor adherence and IPV due to PrEP.
Zimbabwe Road map to PrEP Implementation


Low uptake of PrEP among AGYW

- Challenges with package of the PrEP medicines, the rattling sound is not appealing.
- IPV when one finds out that she is on PrEP.
- Disclosure to partners and seeking authority to be on PrEP regardless of the partner being the risk.
- Caregiver and parent’s attitudes.
Opportunities
The Ministry of Health adopted the ART Guidelines, which include PrEP, in 2016 and acknowledges PrEP as one of the HIV prevention methods.

2016

The PrEP Implementation Plan 2018-2020 acknowledges that in the future, PrEP can be offered in different forms.

2018–2020
A total of 282 health care providers have been trained on PrEP.

PrEP is currently available in district hospitals and some primary-level facilities, including NGO-supported sites.

Capacity building of health care workers provides an opportunity for the introduction of the ring.

There is an opportunity to include the ring in the current PrEP training manual.
- Community engagement where community leaders are involved during the introduction of PrEP provides a huge opportunity for the ring and support of the programme.

- Engagement of community leaders and gatekeepers will assist in the quick uptake of the ring.

- The identification and training of the PrEP champions who also work as mobilizers for PrEP clients presents a huge opportunity.

- The ring provides an opportunity for empowering women to take charge of their sexuality—therefore addressing sexuality and gender dynamics in communities.

- PrEP will empower AGYW to take charge of their sexuality and result in the reduction of IPV.
• Zimbabwe is moving towards full programme integration and HIV combination prevention.
• There are opportunities with family planning and PrEP in health facilities as some family planning-dedicated sites are currently providing PrEP.
• The integration of PrEP and family planning will reduce the burden on health care workers and the time women spend frequenting health facilities.
• The country already has a PrEP TWG and the ring could be added to the existing platforms that are available.
• Zimbabwe conducted a KAP survey at the introduction of PrEP which helped understand the readiness of the country to accept PrEP.

• Communities and health facilities were ready and supported the idea of PrEP; hence, the introduction of ring will not be any different than for oral PrEP.

• The country also conducted research on the integration of FP and PrEP, and results showed that women were happy to have PrEP and family planning integrated.
The country developed a comprehensive communication strategy wherein PrEP is included as one of the HIV prevention interventions.

The strategy used human-centred design through journey mapping which provides insights on what women want as far as PrEP is concerned.

Currently, we have been developing IEC materials that include videos and radio programmes to create demand for PrEP—so the ring is coming at an opportune time.

The V-Campaign, which the country is currently working on, is meant to address the challenges with acceptability of packaging of the commodity in order to appeal to AGYW.
Doing: Unprotected sex with older boyfriend and discussing the risks with peers.

Thinking: “If PrEP is good for me, why didn’t the health care worker talk to me about it!”

They generally search for more information about PrEP on the internet, since awareness is yet to be intensive in the mass media.

Feeling: They generally feel curious and pensive about PrEP.

Key insight: Confidentiality and stigma are critical issues for her. She is terrified that she might be seen collecting ARVs from the clinic and that word might go round in the community.

What they need:

- Peer support
- Privacy and confidentiality at the health facility
- Adolescent-friendly services
- Enhanced adherence counseling
- Adequate knowledge on the benefits of PrEP through appropriate channels

Source: Comprehensive HIV National Communications Strategy: 2019 – 2025
The Ministry of Health and Child Care has developed M and E tools that are currently being used for the PrEP programme.

Using the experience and lessons learnt, the introduction of the ring will not create problems as the M and E tools are already in place.
What will the ring provide?

- It will address the challenges of packaging of oral PrEP, as AGYW were complaining about the rattling sound of the PrEP bottle.
- It will empower women to take charge of their sexuality as the ring is discreet.
- The ring will add to a wide array of HIV prevention interventions that are currently available.
Challenges
**M and E:** The programme will require financial resources to revise and print new tools including for the sensitization of facilities.

**Capacity building:** There will be a need for financial resources for refresher training for the already-trained cadres.

**Procurement:** Just like any other programme, financial resources are required to procure the DVR for use.

**Demand generation:** There will be a need for financial resources to support the development of new IEC materials to include the ring.

**COVID-19** presents challenges in reaching out to communities with programmes.
Conclusion

- The country has systems and policies in place that can provide opportunities for the introduction of the ring.
- Communities are ready for the ring as they were looking forward to an Intervention that is tailormade to their needs.
- There has been enough research, programme implementation, and experience to lead to quick uptake and utilization of the ring.
- The current demand generation and community mobilization activities that are going on present a huge opportunity for the ring.
- Once the WHO releases the guidelines on the ring, the country is ready to move forward.
Thank You
Considerations for the Introduction of the Dapivirine Vaginal Ring in Kenya

MARY MUGAMBI
PROGRAM MANAGER HTS/PrEP, NATIONAL AIDS & STIs CONTROL PROGRAMME (NASCOP)
PrEP Journey
National Roll Out

- Release of Test & Treat & PrEP guidelines: July 2016
- Demo projects learning workshop: Nov 2016
- Prep TWG and Subcommittee meetings: Nov ‘16 – April ‘17
- Approval of generic TDF/FTC: 2016
- Launch of National PrEP framework: May 2017

Clinical trails, demo projects, pilot projects: < 2016

2016

Prep TWG and Subcommittee meetings

Approval of generic TDF/FTC

Launch of National PrEP framework

May 2017
Key highlights of PrEP implementation (June 18 – May 19)

- June 18
- July '18
- Aug '18
- Sept '18
- Oct '18
- Nov '18
- Dec '18
- Jan '19
- Feb '19
- Mar '19
- Apr '19
- May '19

PrEP facility assessment data analysis and reporting

County-level data progress review and work planning

PrEP M&E tools training

Private sector PrEP assessment

Development of the National PrEP website and research repository

PrEP QI & learning forum

Costing meeting convened

Combination prevention integration

Launch of National PrEP framework

May 2017

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May 2017
What does the national Ministry of Health need to know about DVR to decide to include it in Kenya’s HIV prevention program?

• Evidence of effectiveness of the ring
• Evidence that the ring has been trialed in countries with a similar epidemiological profile to Kenya
• Potential impact on HIV prevention
• Cost of DVR
What opportunities does the DVR bring to the HIV prevention program in Kenya?

- DVR increases the number of HIV prevention methods available in Kenya, particularly for the vulnerable population that is adolescent girls and young women (AGYW).

- Those who struggle with oral PrEP, particularly AGYW, may find DVR a more acceptable and beneficial HIV prevention option thus improving adherence and helping the Ministry of Health meet its HIV prevention targets.

- DVR can be included in the ongoing initiative to integrate HIV prevention and sexual and reproductive health (SRH) services at facility level.
What would it take to add DVR to Kenya’s national HIV combination prevention policy? What would be the steps of the process of DVR introduction in Kenya once WHO pre-qualification is completed?

- Evidence on effectiveness, cost and impact
- Release of WHO guidelines
- Approval of DVR in country by the Kenya Pharmaceutical and Poisons Board
- HTS/PrEP TWG would spearhead necessary updates to existing policies and guidelines and the development of new guidelines and implementation plan as required
What challenges are anticipated in introducing the DVR into the HIV prevention program in Kenya?

• Some stakeholders may challenge the introduction of DVR on the basis of it being “too soon” since Kenya has not yet realized the full potential of oral PrEP

• How to sustain the gains of Oral PrEP as we introduce DVR

• Demand creation for a potentially de-medicalized product like DVR

• Low understanding of risk among target populations

• Resources to train providers could be limited

• Revision of existing national Monitoring & Evaluation tools to accommodate DVR or development of new Monitoring & Evaluation tools for DVR
What has been learned from experience with the introduction of other new medical products for HIV prevention or sexual and reproductive health services that could be applied to the introduction of DVR in Kenya?

• Buy-in from government is critical

• Meaningful involvement of target populations in design, implementation and monitoring and evaluation of DVR rollout

• Sustained demand creation

• Effective communication with the media and Kenyan communities to avoid assumptions, propagation of myths and negative publicity

• Demonstration studies will be beneficial particularly to demonstrate acceptability and feasibility and to highlight key considerations that arise from real-world implementation
Thank You!
DVR Introduction Sister Projects:

**OPTIONS Project: Jul 2015-Jul 2020**
Focus on global and national market development for ring

**CHOICE Collaboration: Jan 2020-Jun 2021**
Focus on market development and product introduction for ring, as well as support for IPM’s global regulatory and supply chain strategies

**PROMISE Collaboration: Mar 2020-Aug 2021**
Focus on market development and product introduction for ring in sub-Saharan Africa including analysis of service delivery channels, support for integrated demand creation strategies and tools, support for national policy and program planning, and knowledge sharing
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https://mailchi.mp/prepnetwork/ring-network
Upcoming Sessions

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PrEP for AGYW: Experiences from DREAMS programs

OCT 22

CHARISMA: Community Health Clinical Model for Agency in Relationships and Safer Microbicide Adherence

NOV 19

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Thank You!