ESWATINI
PrEP Ring Consultation

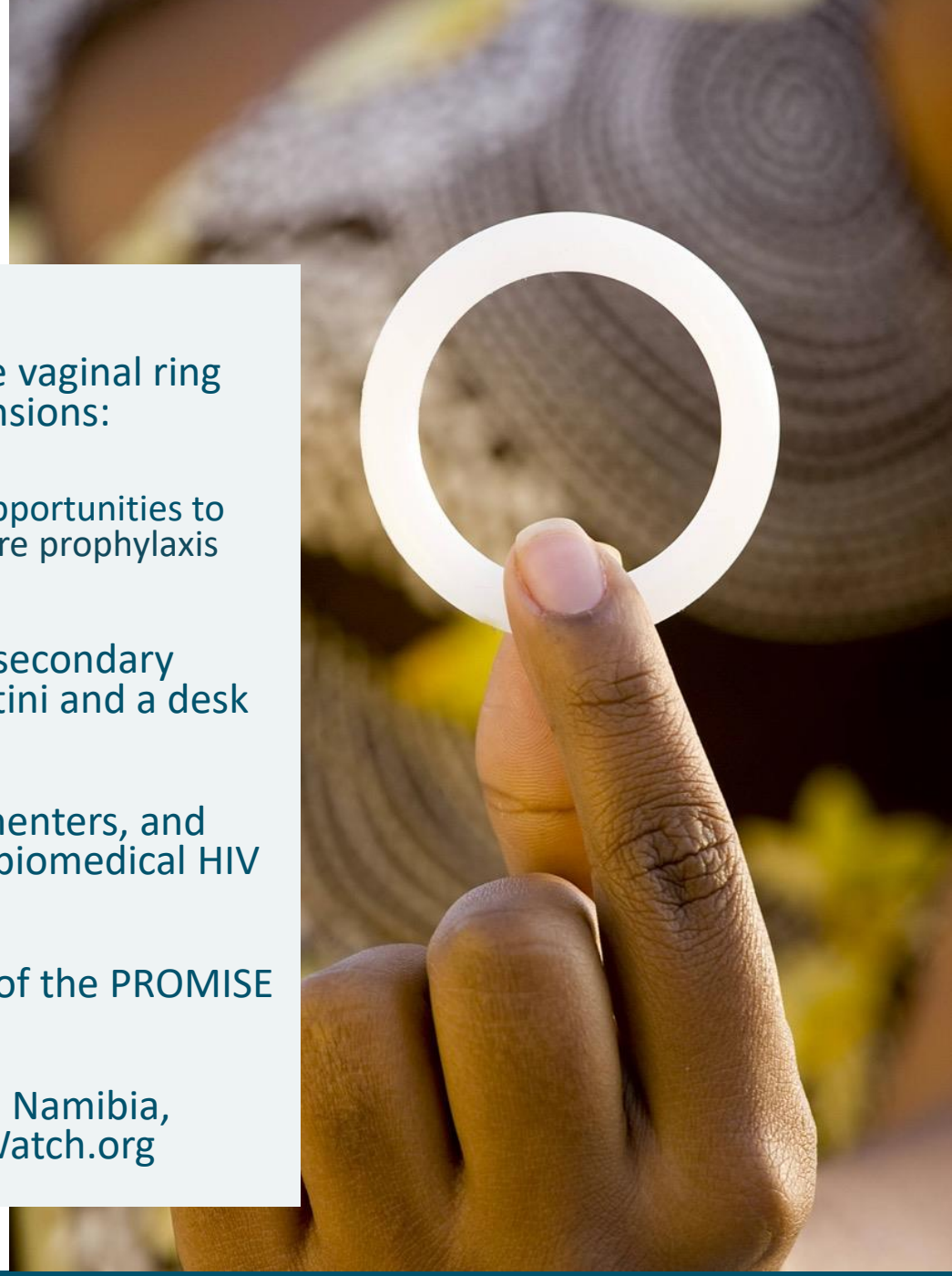
August 2021

PEPFAR

USAID
FROM THE AMERICAN PEOPLE

Introduction

- This analysis can support introduction of the dapivirine vaginal ring (the PrEP ring or the ring) in Eswatini across two dimensions:
  - Considering and prioritizing delivery channels for the ring
  - Identifying critical steps for ring introduction, including opportunities to build on the introduction and scale-up of oral pre-exposure prophylaxis (PrEP)
- This consultation is based on several inputs, including secondary research and interviews with key stakeholders in Eswatini and a desk review
- This consultation can be used by policymakers, implementers, and others planning for introduction of the ring and other biomedical HIV prevention methods in Eswatini
- This consultation was conducted in 2021 by members of the PROMISE collaboration
- Summaries of similar consultations for Kenya, Lesotho, Namibia, South Africa, and Zimbabwe will be available on PrEPWatch.org



Note on terminology

In efforts to be more precise and not contribute to the stigmatization of people living with HIV (PLHIV) or those who may benefit from HIV prevention products, we have made a few language shifts:

- **Serodifferent instead of serodiscordant**. This change reinforces that while the HIV status of people can be different, it does not put them in discord. It is completely okay for people to have different HIV serostatuses.
- **Minimizing use of the terms "risk" and "risky"**. The terms can have so many different definitions and may stigmatize certain behaviors, impose labels on clients, or stigmatize living with HIV itself.
- Using **gender neutral terms when text is not specifically about gender**. The terms are more inclusive of various gender identities.

HIV prevention context

Oral PrEP context

PrEP ring introduction planning

Desk review sources

HIV in Eswatini

Eswatini has the highest HIV prevalence in the world, although over the last decade, Eswatini's efforts have led to a stabilizing prevalence, with incidence declining over the past decade. Current data show ~226k PLHIV in Eswatini.[1]

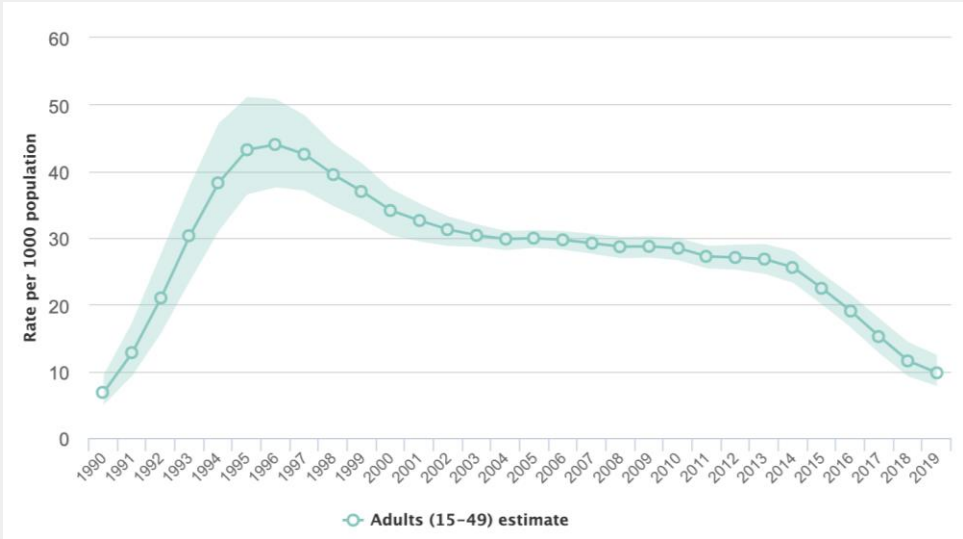
KEY STATISTICS (2020)

HIV prevalence (ages 15-49) has remained largely steady for the past several years at ~27%[2]

- 35% of females (ages 15-49) and 12.2% of young females (ages 15-24)[3]
- 18.2% of males (ages 15-49) and 4.7% of young males (ages 15-24)[3]
- Focus populations
  - 58.8% of female sex workers (FSW)[3]
  - 21% of men who have sex with men (MSM)[3]
  - 34.9% of prisoners [2]
  - Limited data available for transgender people, people who inject drugs, mobile/migrant populations, transport operators, and clients of sex workers

HIV incidence rate (ages 15-49) has been in decline over the past several years and in 2019 was 9.7 individuals per 1,000 population [7.79-12.44][2]

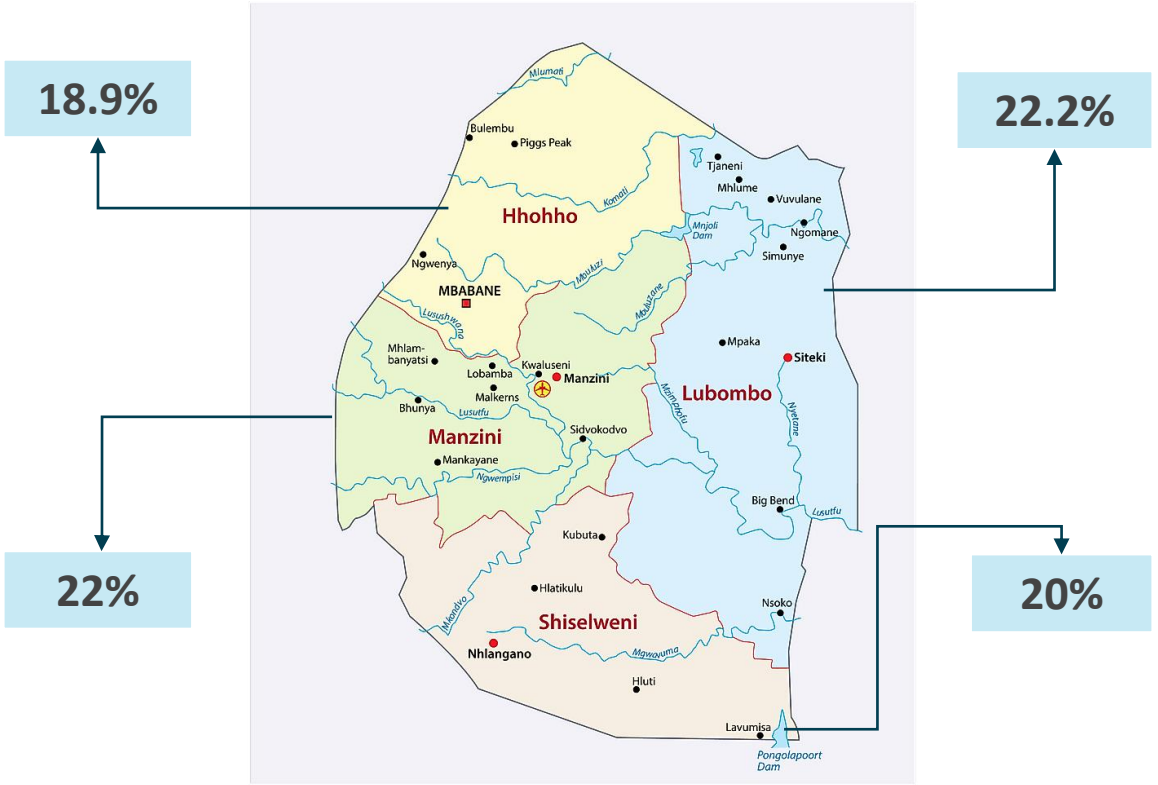
HIV incidence per 1,000 population (ages 15-49)[2]



Sources: (1) amfAR 2021; (2) UNAIDS 2020a; (3) IBBSS 2021

HIV in Eswatini by geography

In 2021, there were an estimated 226,920 PLHIV in Eswatini. The image[4] below maps the estimated HIV prevalence by region.[1,5]



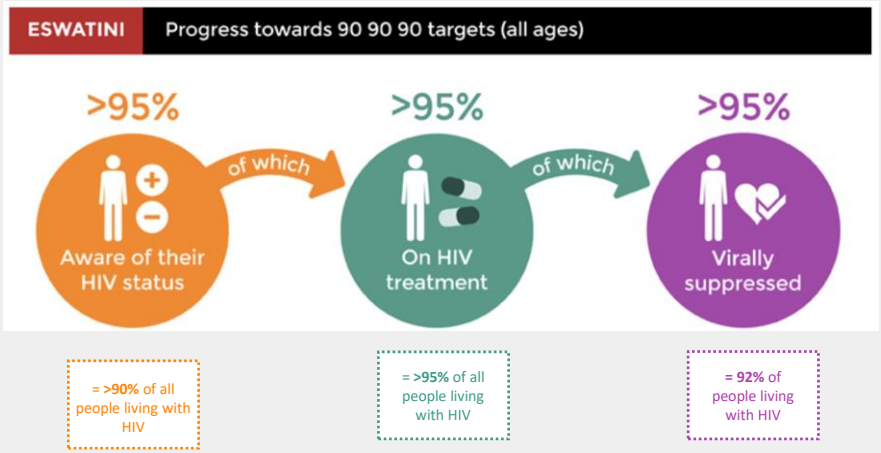
Region	PLHIV[1]
Hhohho	60,478
Manzini	78,175
Lubombo	47,303
Shiselweni	40,964
TOTAL	**226,920**

HIV Prevention in Eswatini

Eswatini's HIV policy framework prioritizes HIV prevention strategies, scaling treatment and care services, and strengthening the enabling environment; it includes oral PrEP with a focus on sub-population groups such as adolescent girls and young women (AGYW), pregnant and breastfeeding persons, serodifferent couples, FSW, clients with sexually transmitted infections, males aged 30-34 years, transgender people, and MSM with a higher likelihood of HIV acquisition.[6]

KEY STATISTICS (2020)

Eswatini is committed to achieving the 95-95-95 goals and has been making impressive progress, exceeding 95% for some targets[7]



National plans highlight several key challenges

- Low condom use in groups with higher likelihood of HIV acquisition; negative perceptions of "free to use" condoms among younger groups; outlets that are either non-youth friendly or staffed by young people and older men have difficulty[6]
- Limited access to and continuation of oral PrEP by key populations (KPs), men, adolescents, young people; low initiation rates at clinic[6,8]
- While scale-up of HIV testing has shown success, testing uptake is lower among adolescents (ages 15-24), males, couples, and children ages 0-15[6]
- Economic migration and population movement overall contribute to challenges in ongoing service delivery and progress measurement[8]
- Stigma and discrimination hinder access to services; the proportion of people expressing accepting attitudes towards PLHIV decreased by ~10% in both males and females from 2010 to 2014[6]

Sources: (6) Eswatini National Strategic Framework 2018-2023; (7) UNAIDS 2020b; (8) PEPFAR Eswatini Strategic Direction Summary 2020

HIV prevention context

Oral PrEP context

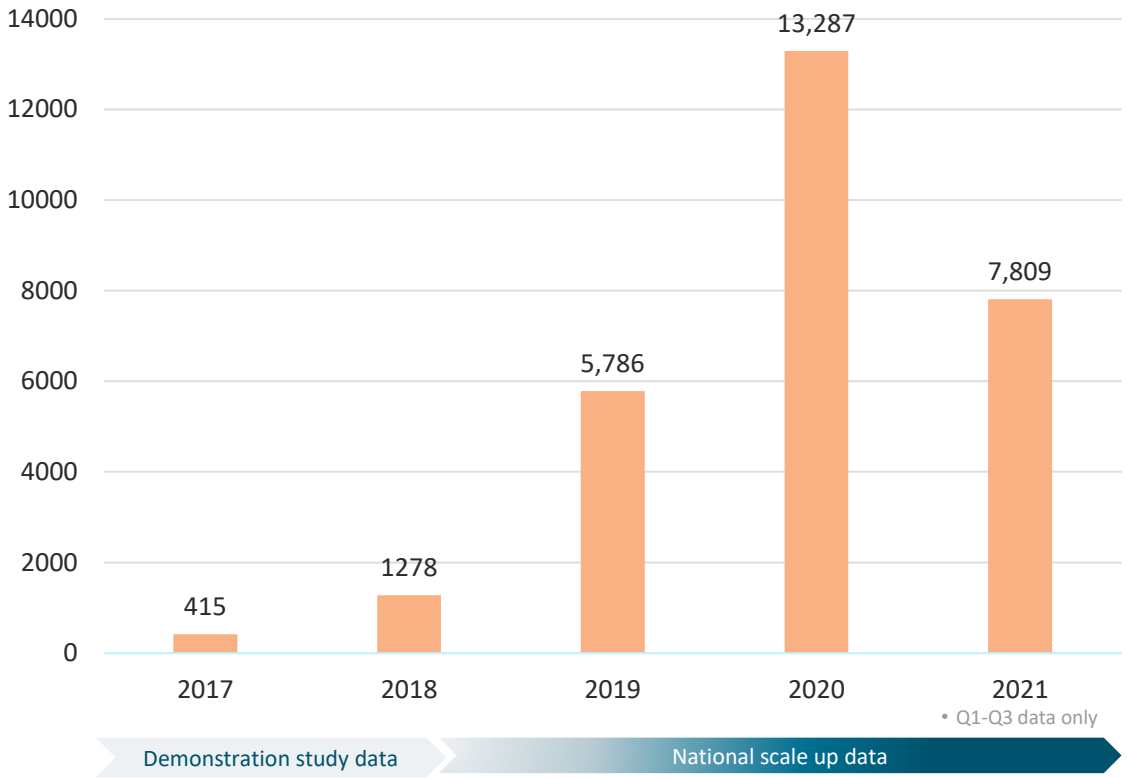
PrEP ring introduction planning

Desk review sources

Oral PrEP rollout in Eswatini

Eswatini introduced oral PrEP in 2017 and uptake has been increasing with scale-up efforts. Between 2017 and 2021 (YTD), 28,575 people have been newly enrolled on oral PrEP.

Number of new PrEP users across all regions, 2017 – 2021[1]



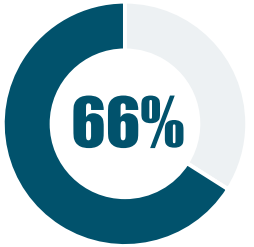
- Oral PrEP was introduced as a demonstration project in 2017 at targeted entry points for populations with an increased likelihood of HIV acquisition; those entry points included family planning (FP), antenatal care, outpatient, and HIV testing services sites[8]
- 33% of individuals medically eligible and likely to benefit from oral PrEP have agreed to initiate oral PrEP; 75% of these were women (potentially due to the selected entry points and trend of male individuals visiting clinics less frequently)[8]
- In 2020, ~13,287 individuals were newly enrolled as oral PrEP users

Financial Year 2020 National Targets vs results

National target: **17,363**

Reach: **11,460**

Gap: **5,903**



Only 66% of the National target was reached

Source: (1) amfAR 2021; (8) PEPFAR Eswatini Strategic Direction Summary 2020

Key oral PrEP implementation stakeholders interviewed

Organization	Role in oral PrEP
Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)	Clinical partner for 2 of 4 regions
Eswatini National AIDS Program (ENAP)	Ministry of Health (MoH) national program to coordinate HIV prevention, care and treatment, research, and cross-cutting interventions
FHI 360	Community clinical partner with a national focus targeting KPs
Family Life Association (FLAS)	International Planned Parenthood Foundation (IPPF) affiliate focused on integrated provision of sexual and reproductive health and HIV services
Georgetown University	Clinical partner for 2 of 4 regions
The Luke Commission	Community clinical partner with a national focus including specific programming that targets adolescent girls
Médecins Sans Frontières (MSF)	Clinical partner in targeted zones in 1 of 4 regions
National Emergency Response Council on HIV and AIDS (NERCHA)	Government parastatal coordinating the multisectoral response to HIV and AIDS
Pact	Implementing partner for DREAMS programming, focused on AGYW
PEPFAR Agencies (USAID)	Provide funding for current oral PrEP implementation programs for all priority populations as identified by the MoH
Sexual and Reproductive Health Unit, MoH	Provides coordination for FP and FP-HIV integration efforts across Eswatini
UNAIDS	Provides technical assistance in the area of PrEP implementation in conjunction with the MoH
UNICEF	Provides technical assistance in the area of PrEP implementation in conjunction with the MoH
World Health Organization (WHO)	Provides technical assistance in the area of PrEP implementation in conjunction with the MoH

Oral PrEP rollout – lessons learned from stakeholder interviews

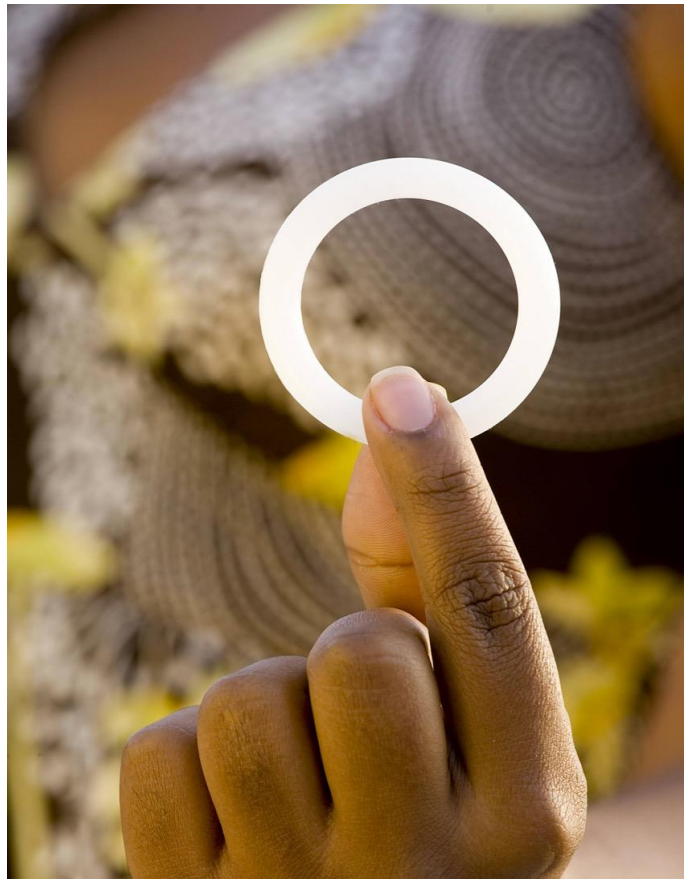
What worked well

- The MoH was very supportive of product introduction and led coordination of rollout and scale-up
    - This included a phased approach with demonstration projects in public facilities
    - The demonstration projects engaged multiple departments within the MoH
- There is a strong, existing system for high stakeholder engagement, supported by the technical working groups (TWG) and smaller core teams
- During rollout, there was successful, rapid training of healthcare providers using an established implementation framework
- Roles and responsibilities for planning, implementation, and funding were clearly defined by the MoH, with specific units responsible for planning
- The HIV guidelines were revised by the MoH prior to implementation, a process that encourages more immediate buy-in from some providers

What was challenging

- Broadly, many users are concerned about the stigma surrounding oral PrEP, including concerns that others might think they are HIV positive and taking antiretrovirals, and limitations to privacy when accessing oral PrEP
- There are misconceptions by providers and buy-in was sometimes challenging based on negative attitudes towards oral PrEP or different levels of comfortability initiating users, especially serodifferent couples
- Integration of services was challenging, as many providers do not view provision of oral PrEP as their primary role, leading to referrals within facilities and long wait times, with many users leaving instead of waiting for initiation
- More rural communities were missed by conducting information, education or communication (IEC) campaigns or through social media channels; generally, there is unmet need in rural areas that is acknowledged but not fully reached
- There are issues with both user adherence and the measurement of adherence and follow-up for oral PrEP users
- Depending on the implementing partner presence, different regions used different approaches to implementation

The PrEP ring will be an important new HIV prevention method



Key findings from stakeholder consultations

- As a user-controlled and long-acting HIV prevention option, the ring is an important complement to other HIV prevention methods in Eswatini.
- The ring may be particularly appropriate for cisgender* women, specifically cisgender AGYW and KPs, specifically SWs and transgender persons assigned female sex at birth who are at substantial likelihood for HIV acquisition through receptive vaginal sex, and often have challenges advocating for condom use, prefer not to take a daily pill, are seeking a more discreet HIV prevention option, and/or want to avoid oral PrEP side effects.
- There is a notable difference in experience between facility- and community-based referrals, initiation, demand creation, and adherence. With the potential for the ring to be available at the community level, there is opportunity to strengthen these areas.
- There is significant opportunity to build from the experience with oral PrEP to introduce the ring – for example, implementation frameworks, monitoring systems, and guidelines have been developed for oral PrEP that could accommodate the ring, and an HIV prevention TWG with a PrEP core team already exists to guide ring introduction.
- The ring also presents new opportunities, specifically integration with FP services, distribution in non-clinical settings, and the opportunity to reposition PrEP in a more appealing, less stigmatized way (e.g., as a healthy lifestyle choice, rather than HIV prevention).

*Cisgender is a term used to describe a person whose sense of personal identity and gender corresponds with their sex assigned at birth. E.g., Cisgender women were assigned female sex at birth and identify as women.

HIV prevention context

Oral PrEP context

PrEP ring introduction planning

Desk review sources

PrEP ring introduction framework

This value chain framework has been used across countries to support planning for oral PrEP introduction. It has been adapted for the ring to identify necessary steps for ring introduction and scale-up across five major categories and across priority delivery channels. It can also be used to track progress towards ring introduction by different partners.

Value Chain for PrEP Ring

PLANNING & BUDGETING

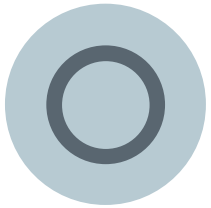
National and county plans are established to implement ring guidelines for priority end user populations

SUPPLY CHAIN MANAGEMENT

Ring is available and distributed in sufficient quantity to meet projected demand via priority delivery channels

PrEP RING DELIVERY PLATFORMS

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, initiate, and effectively use the ring

MONITORING

The ring is effectively integrated into national, county, sub-county, facility, community, and program level monitoring systems

Eswatini PrEP ring introduction situation analysis

This framework highlights critical elements of ring introduction and assesses the current state across these elements in Eswatini

PLANNING & BUDGETING

- **Establish/convene subcommittee or task team** for the ring within existing HIV Prevention or PrEP TWG
- Identify **focus 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** (e.g., FP)
- 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 (EML)
- Update **supply chain guidelines and logistics systems** to include the ring
- Establish **monitoring, demand forecasting, and distribution systems** to avoid stock-outs

PREP RING DELIVERY PLATFORMS

- 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 intimate partner violence (IPV)

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

COLOR KEY

- Anticipate easy integration with oral PrEP
- Will require new effort, but no anticipated challenges
- An area that will require significant consideration

Eswatini situation analysis summary findings

Summary findings from the Eswatini situation analysis are below, with recommended next steps included on the following slides

PLANNING & BUDGETING

- An **existing HIV prevention TWG with PrEP core team** will likely guide introduction of the ring
- MoH has **already identified priority populations** for oral PrEP; the ring would focus on subpopulations as applicable
- MoH has **a strong system for stakeholder engagement** but more **community-level buy-in and sensitization are needed**
- Oral PrEP had **clear funding** which enabled better planning and costing analysis; **planning for introduction of the ring included in Country Operational Plan (COP) 21**
- Anticipated **easy integration of the ring into current national HIV prevention plans** and implementation framework

SUPPLY CHAIN MANAGEMENT

- If WHO pre-qualified, the registration process in country is relatively straightforward; **TWG will see the product through the review and endorsement process**
- **Involving the Central Medical Stores** (CMS) in processes will help avoid stock-outs
- Government of Eswatini earmarks exist for general PrEP programming, not PrEP commodities; **clear funding for ring commodities is needed**
- **MoH handles procurement** with support from PEPFAR or Global Fund, **no need to establish new distribution systems**

RING DELIVERY PLATFORMS

- Issuing standard clinical guidelines for the ring would follow the **same pathways as oral PrEP**
- Resources for ring initiation and continuation would likely come from MoH/PEPFAR/Global Fund
- Training of trainers are popular, facilitated by the MoH with support from partners; **cascade trainings recommended with consideration of barriers**
- **PrEP core team and TWG responsible for the development of materials**, tools, and trainings
- **Referral systems exist but need to be strengthened,** especially between HIV and FP, and at the community level
- **Screening for IPV is common** in facilities for oral PrEP users

UPTAKE & EFFECTIVE USE

- **Mass communication strategies and facility-based tools** can be used for demand creation with specific approaches considered for different groups
- **Stigma is a major barrier** to access, continuation, and adherence
- **IEC in facilities or communities could be easily adapted** for the ring
- **Peer-to-peer communication has been a successful channel** which could be used to guide choice and support ring use
- **No anticipated challenges with communicating sanitary disposal** of used rings

MONITORING

- The **ring could be easily added to existing monitoring systems**; about 60%-70% of clinics are using the standardized electronic system, Client Management Information System (CMIS)
- There **is not yet a system monitoring and reporting on for integrated services** such as the cascade of prevention services
- **All monitoring of drug resistance for oral PrEP is currently being done in the GEMS study**; would require external funding to include the ring if not included in GEMS II
- There are **pharmacovigilance systems in place** to monitor seroconversion for oral PrEP which could include the ring
- **Implementation science research** via the PrEP core team to inform ring rollout is anticipated

Recommended next steps: Planning and budgeting

PLANNING & BUDGETING

Establish/convene subcommittee or task team for the ring within existing HIV Prevention or PrEP TWG	• Continue discussions within the MoH and monitor available funding • Within the HIV prevention TWG, establish a ring task team to engage stakeholders; this ideally includes sexual and reproductive health and other HIV prevention personnel to ensure integration of services that are currently fragmented • With stakeholders, the PrEP core team to develop a road map for introduction of the ring, share with the MoH directorate, and develop other key documents • Roll out phased approach, with demonstration projects facilitated by the MoH
Identify **focus populations** for ring use	• Rollout of the ring to occur in stages based on geography and in high-volume clinics through regional and community partners • Focus populations to fall under those pre-identified for oral PrEP, with specific rollout for those populations in which it is most applicable
Engage **community** stakeholders to inform planning for ring rollout	• Include more community-level leadership in existing MoH stakeholder engagement during the demonstration and pilot projects • Ensure a variety of stakeholders are engaged over time, being mindful of constantly asking for inputs from the same individuals • Sensitize stakeholders at the programming level, across TWGs and other service providers
Develop impact, cost, and/or cost-effectiveness **analyses** to inform ring planning	• As with oral PrEP, earmark specific funding for the ring • Provide modeling and costing information to increase government buy-in
Include the ring in national HIV prevention and other relevant **plans** (e.g., FP)	• Use existing national level implementation frameworks and plans developed for oral PrEP and include adjustments for the ring • Revise implementation framework to include ring-specific information and clinical guidelines
Develop **implementation plan and budget** to guide initial ring introduction and scale-up	• Adapt/update the oral PrEP implementation plan for the ring • In consultation with stakeholders, conduct government-led development of the plan, with clear identification of which health units are responsible for which interventions and focus populations and along what timeline

Recommended next steps: Supply chain management

SUPPLY CHAIN MANAGEMENT

Register the ring and include the ring on the national essential medicines list (EML)	• The registration process in Eswatini is relatively new; WHO pre-qualification may speed up this process • Identify PrEP Task Team for the Ring committee to work with regulatory units and draft and update guidelines or classifications of the product at the clinical level • TWG to lead the coordination of procurement once registered • Motion to amend the standard treatment guidelines and EML for submission to the Deputy Director of Pharmaceutical Services office
Update **supply chain guidelines and logistics systems** to include the ring	• Complete required supply chain guideline addendum for the ring • Have product registered and procured by the government to avoid any major issues with the supply chain • Inform the CMS of intention to introduce a new product so procurements can be planned, discuss a transition plan with the CMS considering available stock
Establish **monitoring, demand forecasting, and distribution systems** to avoid stock-outs	• Establish stronger work between program and supply chain efforts to reduce the risk of stock-outs and financial mishaps (e.g., suppliers not paid on time) • Conduct procurements through the MoH, including those with Global Fund; consider use of PrEP-it to forecast • Advocate for more HIV test kits dedicated for PrEP services to be included in demand forecasting efforts • Provide target numbers of clients to be covered for quantification process

Recommended next steps: PrEP ring delivery platform

RING DELIVERY PLATFORMS

Issue standard **clinical guidelines** for delivery and use of the ring	• Use WHO guidance as a guiding document adapted for context • PrEP core team to develop, review, and recommend an agenda for the ring, check against stakeholder perspectives, and collectively finalize guidelines for approval by MoH senior management • Leverage lessons learned from rollout of other products
Dedicate resources to conduct regular **HIV tests, initiate ring use, and support refills**	• Use available resources from MoH, PEPFAR, and Global Fund with government coverage of public facilities
Develop trainings and materials for **health care workers** in the ring	• Use popular method of training of trainers and consider the barriers with cascade approach (some providers think that without direct training, they cannot deliver the service) • Develop material on motivational counseling and peer-to-peer counseling in a way that is not stigmatizing • Trainings should occur both on- and off-site and include partners, staff, community-level stakeholders, and on-site personnel (guards, janitors, other sources of information) • Maintain MoH ownership of trainings, standard operating procedures, and other materials
Establish **referral systems** to link clients from other channels to sites dispensing the ring	• Strengthen referral systems within clinics and between community outreach and clinics; reduce client wait time, increase privacy, and improve provider attitudes to be successful • Integrate the ring across service delivery points (especially FP-HIV) to encourage cross-sectoral referrals and better use of CMIS referral system at the clinic level • If approved, provide support to private pharmacies for provision of HIV prevention products in a way that incorporates the need for regular HIV testing and other follow-up services and consider how the private sector may be reimbursed through national health systems
Integrate support for **partner communication** and intimate partner violence	• Continue to include counseling on gender-based violence, including IPV and referral to services in conversations at the clinic • Consider implications of transient populations and how to screen and capture data for routine vs. seasonal users

Recommended next steps: Uptake and effective use

UPTAKE & EFFECTIVE USE

Develop and implement **demand creation strategies** that include ring promotion	• Focus strategies for facility- and community-based demand creation efforts with intentional understanding of the cultural context • Continue demand creation efforts through peer networks, newspapers, social media, radio, and TV and build out more specific strategies for KPs • Fill the gap in non-facility-based demand creation by engaging community health workers to conduct education sessions and provide IEC
Address social norms/stigma to build **community and partner acceptance** of ring use	• Strategize around the appeal for the discreet use of the ring to combat low uptake driven by harmful gender norms and social nonacceptance of PrEP • Conduct sensitization for providers and users on provision of the ring, and consider providing PrEP at multiple points in facilities, not just in the antiretroviral (ART) group • Use hotlines and community-based outreach or peer engagement to help improve acceptance for the ring • Engage religious leaders, chiefs, youth champions, and other community-level leadership
Develop **information and tools for clients** to guide product choice and support ring use	• Mirror the existing implementation of oral PrEP ambassadors for the ring • Provide more information and tools on the ring and ring decision-making to users pre-initiation or at points before they arrive at the clinic; this can enable users to arrive with preferences, information, or questions, and allow counseling, initiation, and/or referrals to occur more effectively • Develop IEC and other decision aids with focus populations
Support **adherence and continuation** for ring users	• Strengthen follow-up strategies for community-based users and from facilities without electronic reminder capacity • Train providers on adherence support and establish follow-up via telephone, SMS, phone calls, or home-based visits • Create community-based support groups for the ring (like what exists with ART and is in process for oral PrEP clients) • Offer home-based provision and/or multi-month dispensing of the ring
Develop and communicate plans for sanitary **disposal** of used rings	• Follow similar messaging to condom disposal • Provide proper disposal information to users

Recommended next steps: Monitoring

MONITORING

Establish **monitoring tools** to support data collection and analysis on ring use	• Update the PrEP-specific register used for tracking to include the ring • PrEP core team to determine monitoring and evaluation with standardized electronic tracking • Develop a monitoring tool to show FP and HIV data together with an integrated component for cascaded prevention
Establish systems for **pharmacovigilance** and to monitor drug resistance	• Include the ring in the existing MoH pharmacovigilance system • Consider how to expand current resistance monitoring efforts to include the ring
Conduct **implementation science** research to inform policy and scale-up	• Follow the process occurring for oral PrEP with a small-scale start and then building out guiding documents • Roll out implementation science research on the ring in a few locations through the PrEP core team

HIV prevention context

Oral PrEP context

PrEP ring introduction planning

Desk review sources

Desk review sources

Sources

1) amfAR 2021 https://mer.amfar.org/location/Eswatini/PrEP_NEW

2) UNAIDS 2020a https://www.unaids.org/en/regionscountries/countries/swaziland

3) IBBSS Prevalence 2021

4) World Atlas 2021 https://www.worldatlas.com/maps/eswatini

5) UNFPA 2017 https://eswatini.unfpa.org/en/news/swaziland-releases-population-count-2017-census

6) Eswatini National Strategic Framework 2018-2023 https://hivpreventioncoalition.unaids.org/wp-content/uploads/2019/06/Eswatini_NSF-2018-2023_final.pdf

7) UNAIDS 2020b https://aidsinfo.unaids.org/

8) PEPFAR Eswatini Strategic Direction Summary 2020 https://www.state.gov/wp-content/uploads/2020/07/COP-2020-Eswatini-SDS-FINAL.pdf

9) Eswatini Ministry of Health 2021

Thank You!

For more information, please visit:

- https://www.ipmglobal.org/our-work/our-products/dapivirine-ring
- https://www.prepwatch.org/about-prep/dapivirine-ring/

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