

Introduction of MOSAIC, PrEP choice, and new PrEP methods

AUGUST 2024

PATRICIAH JECKONIA, LVCT HEALTH





Helping adolescent girls and young women and other women prevent HIV by accelerating the introduction and scale-up of biomedical prevention products.



MOSAIC PROJECT OVERVIEW

- MOSAIC is a 7-year global project funded by PEPFAR through USAID (2021-2028)
- Focuses on introduction and access for new biomedical prevention products to prevent HIV for women in Africa
- Works across multiple countries – Botswana, Eswatini, Lesotho, Kenya, Namibia, Nigeria, South Africa, Uganda, Zambia, and Zimbabwe
- Supports a multi-product market with informed choice for HIV prevention

OUR VALUES

COUNTRY-LED

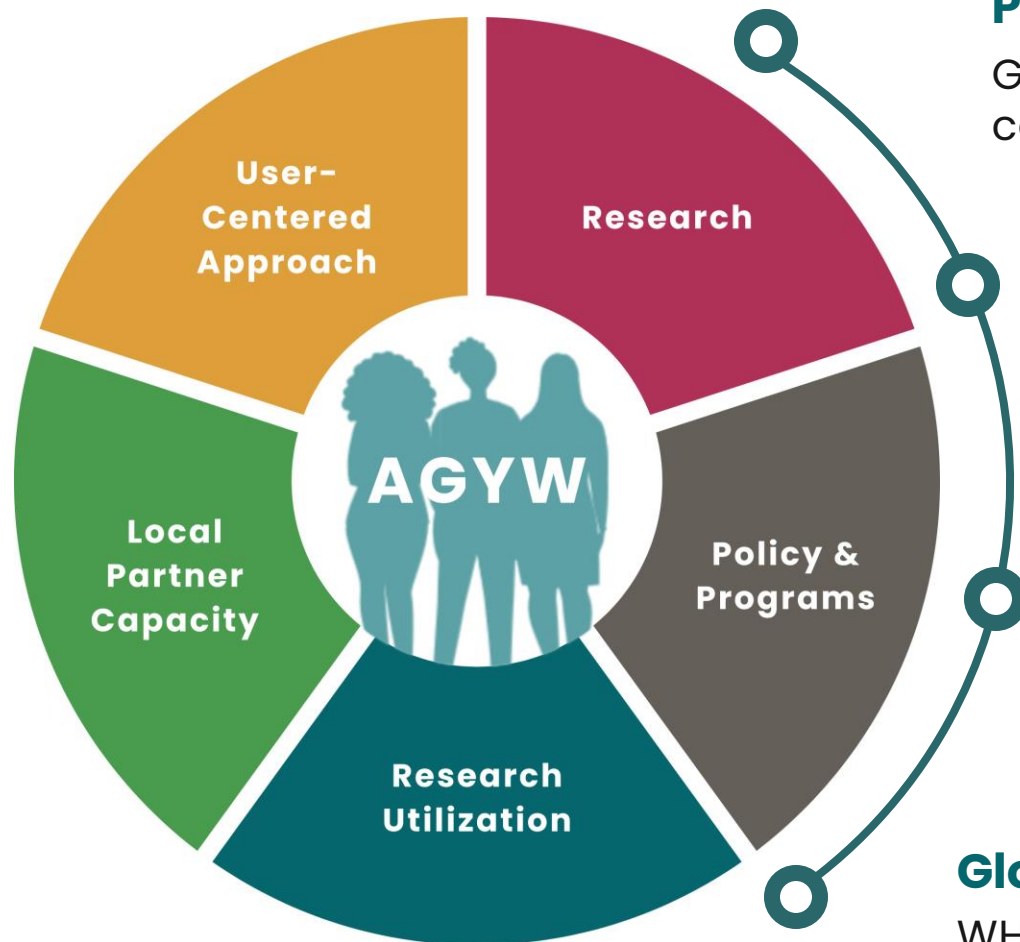
WOMEN-
FOCUSED WITH
EMPHASIS ON
AGYW

INFORMED
CHOICE

EQUITABLE CO-
LEADERSHIP

INTENTIONALITY

WE WORK IN COLLABORATION WITH STAKEHOLDERS ACROSS THE HIV PREVENTION ECOSYSTEM



PEPFAR

GHSD, USAID, CDC, DOD, PEPFAR in-country coordinators, GHSC, global and bilateral programs

MOSAIC Consortium

FHI 360, Wits RHI, Pangaea Zimbabwe, LVCT Health, Jhpiego, AVAC, 2Stories, Afton Bloom, Avenir Health, Bar Hostess Empowerment & Support Programme, Columbia University, Mann Global Health, Path Kenya, RTI, Scott Hospital, The AIDS Support Organization, University of Nairobi, University of Pittsburgh, University of Washington

National & Regional Stakeholders

Civil society organizations, national ministries of health, district and local health authorities, implementing partners, program and research projects, private sector, etc.

Global Stakeholders

WHO, UNAIDS, GF, Gates, CIFF, Unitaid, MedAccess, MPP, NIH, ViiV, Gilead, Population Council/IPM, Merck, IAS, MSF, MTV Shuga, etc.

MOSAIC ACCELERATES ACCESS TO A MULTI-METHOD MARKET THROUGH FIVE STRATEGIC PRIORITIES



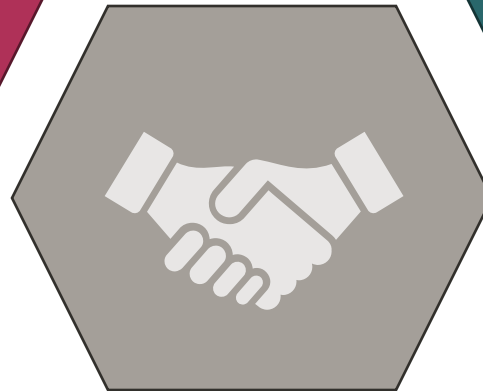
User-Centered Approach

Promote a user-centered approach.



Research

Conduct research on how to enhance product availability, acceptability, uptake, and effective use.



Policy & Programs

Coordinate and provide technical assistance on regulatory review, policy, resource mobilization, supply chain, delivery, M&E, surveillance, and demand generation.



Research Utilization

Implement research utilization activities and establish mechanisms for rapid, effective knowledge exchange.



Local Partner Capacity

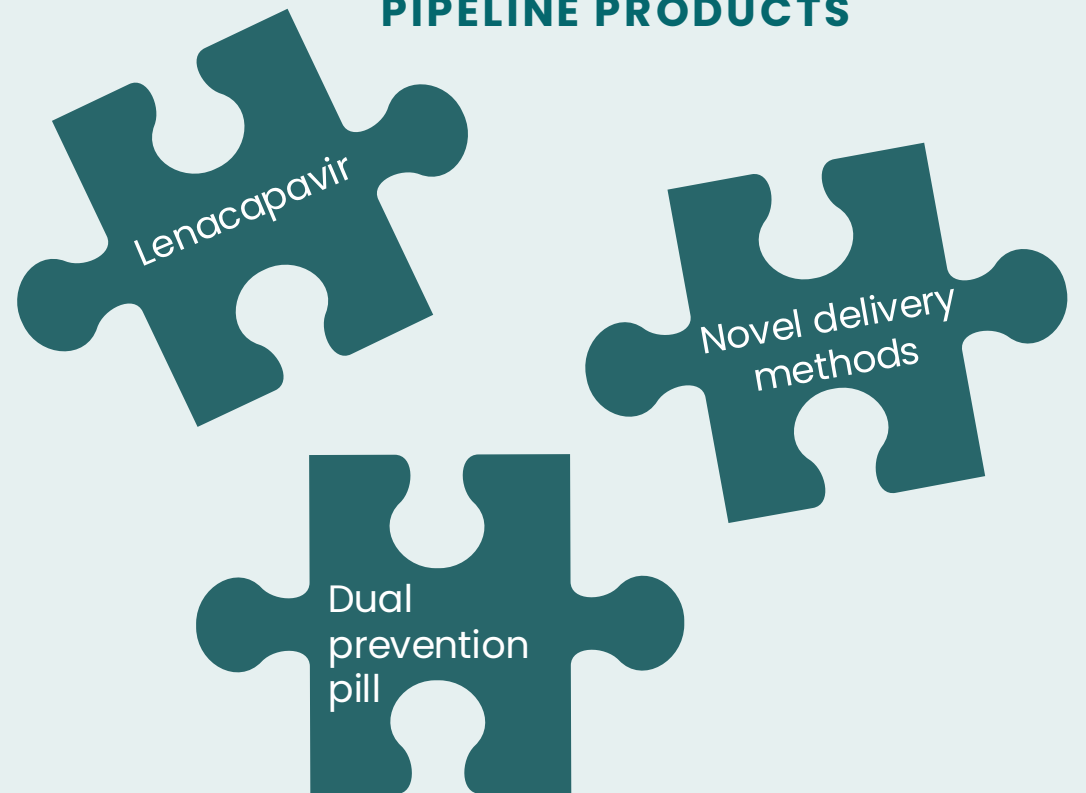
Strengthen and sustain local partner capacity to advocate for, design, and implement product introduction activities and research.

We Have Choice!

IN MARKET



PIPELINE PRODUCTS



There is no perfect product



Oral PrEP

ADVANTAGES

- High efficacy
- Affordable
- Readily available

CHALLENGES

- Daily adherence
- Side effects
- Stigma



PrEP Ring

ADVANTAGES

- Monthly
- Non-systemic with minimal side effects
- Discreet

CHALLENGES

- Moderate efficacy
- Unfamiliar formulation
- Cost



Injectable PrEP

ADVANTAGES

- High efficacy
- Bi-monthly
- Discreet
- Familiar formulation

CHALLENGES

- HIV testing
- Long drug tail
- Lack of pregnancy data
- Cost



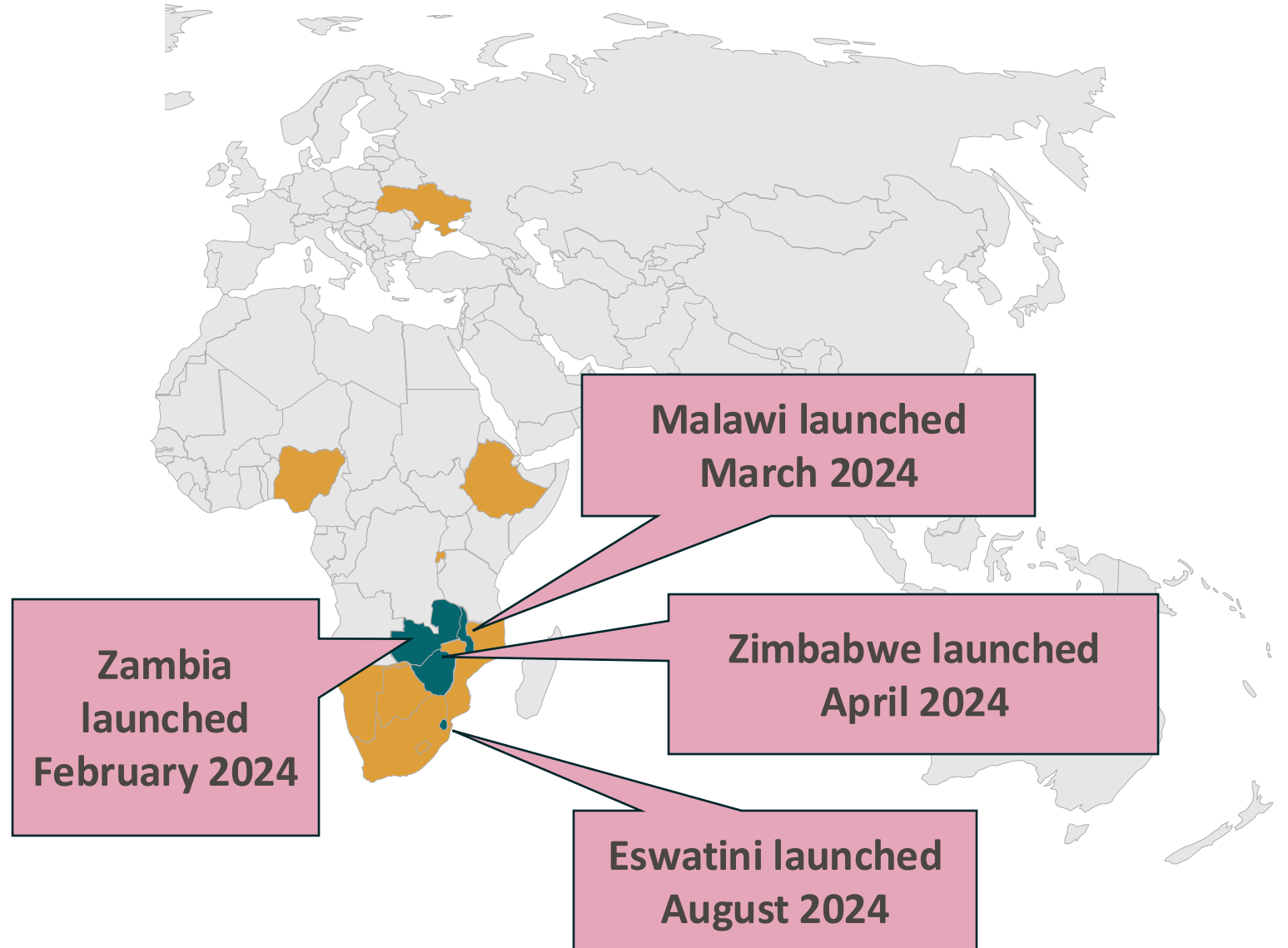
PEPFAR Programmatic Rollout (Aug 2024)

Launched

- Zambia
- Malawi
- Zimbabwe
- Eswatini

Pending

- Botswana
- Ethiopia
- Lesotho
- Mozambique
- Namibia
- Nigeria
- Rwanda
- South Africa
- Ukraine



Global Fund Programmatic Rollout (Aug 2024)

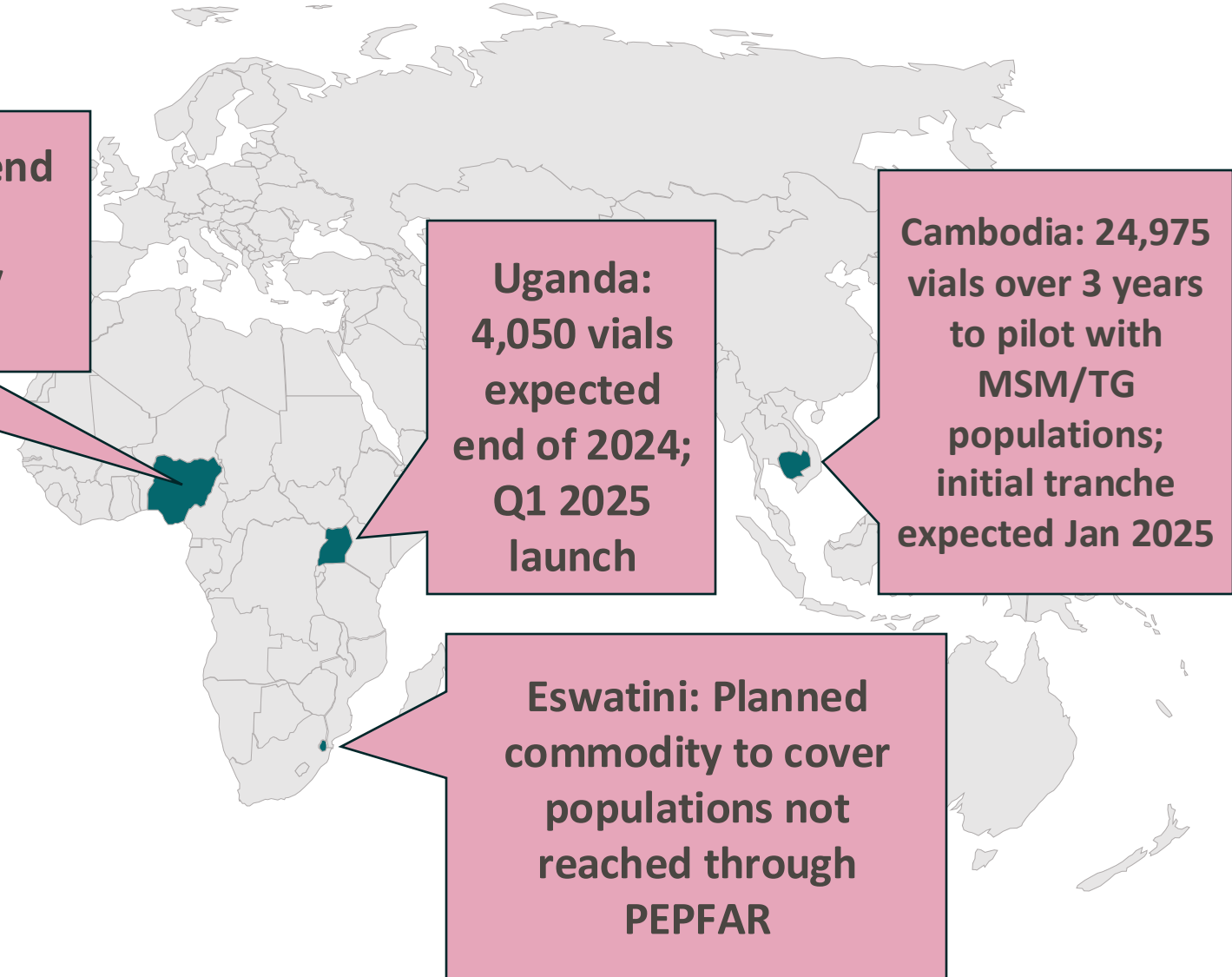
Nigeria: 5,400 vials expected end of 2024; to be layered into introduction research study starting with PEPFAR CAB

Uganda: 4,050 vials expected end of 2024; Q1 2025 launch

Cambodia: 24,975 vials over 3 years to pilot with MSM/TG populations; initial tranche expected Jan 2025

Eswatini: Planned commodity to cover populations not reached through PEPFAR

- Cambodia
- Eswatini
- Nigeria
- Uganda



CHOICE PRINCIPLES IN HIV PREVENTION

Non-discrimination	Allow individual choice of whether to use any method and what prevention option to use at a given time in a manner that it is voluntary
Availability	The widest potential array of viable HIV prevention options, supplies and equipment are in stock for users in a specific market
Accessibility	HIV prevention markets support individual choice without physical, cost-based, interpersonal or informational barrier
Acceptability	HIV prevention markets are gender-sensitive and person-first, based on medically accurate comprehensive information & responsive to demand
Quality	Include options and services that are of the highest possible quality and products are quality assured
Privacy & confidentiality	Protect and uphold the privacy of individuals including the confidentiality of medical and personal information
Participation	Meaningful & inclusive engagement of communities in all aspects of HIV prevention research, programmes, policy design, implementation & monitoring
Accountability	Put in place accountability mechanisms to respond to community and client feedback at all levels of the market

2

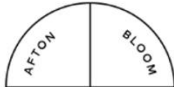
THE FOCUS THIS WEEK!

MEETING OBJECTIVES

- a) Provide global updates on new PrEP products, including regulatory approvals and their status in national guidelines
- b) Share learnings from ongoing implementation studies and programmatic rollout of new PrEP products
- c) Discuss strategies and key considerations for implementing PrEP choice for specific populations
- d) Strengthen partnerships and collaborations for successful PrEP programming

ACKNOWLEDGMENTS

Many MOSAIC team members contributed to the slides in this deck.



MOSAIC is made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID) cooperative agreement 7200AA21CA00011. The contents of this presentation are the responsibility of MOSAIC and do not necessarily reflect the views of PEPFAR, USAID, or the U.S. Government.

Photo Credit: MOSAIC Consortium





**The 2024 Africa Regional PrEP Workshop
September 9-12, 2024 Nairobi, Kenya
Yvette Raphael, Executive Director APHA**

The HIV Prevention Choice Manifesto For Women and Girls In Africa



Introduction

The HIV Prevention Choice Manifesto is a collection of voices of African women and girls in all their diversity, feminists and HIV prevention advocates across Southern and Eastern Africa who are united in calling for continued political and financial support for HIV prevention choice.

Biomedical HIV prevention is at a historic turning point, but only if countries and funders heed evidence-based demands that programs must emphasize choice – not individual products – and that research and development of new prevention options continues.

For the first time in the history of the HIV epidemic, it is possible to build a prevention program centered around choice – offering an array of options, including oral PrEP, the Dapivirine vaginal ring, injectable Cabotegravir and condoms, with straightforward language about risks and benefits, as well as supportive counseling in selecting options that meet an individual's needs.

People Living with HIV in 2022



Options vs. Choice



Goals

A future free of HIV for our daughters and women in Africa

Our mission is guided by an HIV prevention agenda that:

- Centers girls, women and communities and enshrines the right to choose what works for her and them.
- Prioritizes the principle of CHOICE, offering a spectrum of prevention options and adaptable programs for women and girls as they navigate through the different stages and circumstances of their lives.
- Focuses on, invests in and prioritizes adolescent girls and young women in Africa and of African descent across the world.
- Positions African women and girls at the center and forefront – not only for research, but also for access to products that are shown to be safe and effective.
- Is conceptualized by the community and is responsive to community needs and priorities.
- Follows the science and uses epidemiological evidence to provide viable options to women and girls who are vulnerable to HIV infections.
- Prioritizes meaningful and ethical engagement of women and girls in clinical research aligned with the Good Participatory Practice (GPP) Guidelines.

The HIV Prevention Choice Manifesto for women and Girls in Africa

Goal:

A future free of HIV for our daughters and women in Africa

Background

- ❑ Developed by African women in their diversity, feminists, and HIV prevention advocates across Southern and Eastern Africa who are united in calling for continued political and financial support for HIV prevention choice – which includes the introduction and roll-out of safe and effective options, including long-acting HIV prevention tools.
- ❑ Biomedical prevention is at a historic turning point, but only if countries and funders heed evidence-based demands that programs must emphasize choice – not individual products – and that research and development of new choices (both user-dependent and long-acting) must continue.

Language Check

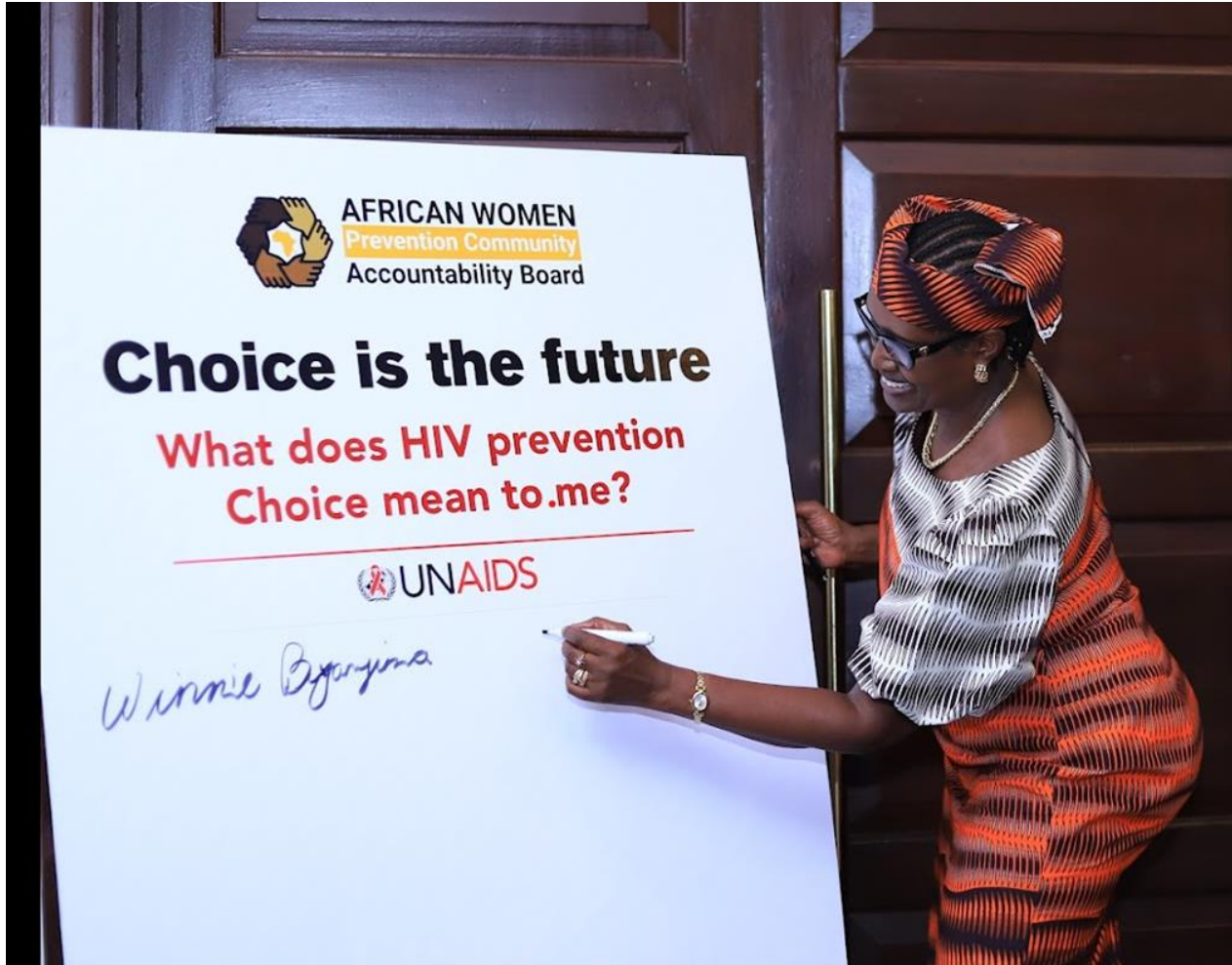
- Options
 - ❑ Biomedical methods that are safe and effective
 - ❑ Requires R&D of additional options to add to the “method mix”

- Choice
 - ❑ The ability for an individual to select from an array of options
 - ❑ Requires policy makers, donors, governments & implementers to make the “mix” available, accessible & affordable

The choice manifesto demands a HIV prevention that;

- Follows the science and uses epidemiological evidence to make options available to women and girls who are vulnerable to HIV infections.
- Includes CHOICE among both prevention options and programs for women and girls to prevent HIV as they navigate through the different stages and circumstances of their lives.
- Focuses, invests and prioritizes adolescent girls and young women in Africa and of African descent across the world.
- Puts African women and girls at the center – not only for research but also for access to products that are shown to be safe and effective.
- Is conceptualized by the community and responds to community needs.

Launched by our choice champion HE. Mama Winnie Byanyima (September 8th)



Launch moments



Sign-Ons during the launch

Name/Designation	Signature	Date
Winnie Byanyima UNAIDS Exp		8/09/23
Uthman Mwonelo NOMFUNDO ELAND MWANDA		8/09/23
SHAKIRAH NAMWANJE IOAH MUKALA		08/09/2023
Yvette Ropaul		08/09/2023
Cweyita Jansara		08/09/23
KUANYUSEMBE Piloje Dr. Lilian Benjamin Mwakyesi		08.09.23

Choice is the future

What does HIV prevention Choice mean to me?

Winnie Byanyima UNAIDS
 Yvette Ropaul APHA
 Nelson Musoke UAC
 Kennedy Otundo UNFPA
 Charles Brown PCI
 Kyomya Macklean - AWAC Uganda
 ... (and many others)

#Champions4Choice #LetWomenLead #EndNewInfections

Choice in a real-world setting



Choice in a real-world setting



Call to Action

Center People & Communities

- ❑ **Prioritize key and marginalized populations** and scale interventions Ensure that R&D and delivery are informed by communities in alignment with the [Good Participatory Practice Guidelines](#) –communities must inform the ongoing and future pipeline from the onset, design, and formulation, as well as the introduction of proven interventions.

Choice Is Key

- ❑ Ensure **massive scale-up and increased access** to all safe and effective HIV prevention methods
- ❑ Ensure women have control over their health and their bodies and access to the full range of safe and effective options so that they can choose what works best for them at different times of their lives

Call to Action

Programs That Deliver

- ❑ **Integrate HIV prevention** into existing information and service packages such as family planning, cervical cancer prevention, antenatal care, and postnatal care to ensure easy access and availability of prevention methods

Finance choice

- ❑ Strategize, staff, budget, and procure for choice-based HIV prevention

The Future

- ❑ **The current options are good, but not sufficient** – prioritise R&D of additional systemic and non-systemic options

Adopt a Human Rights based approach to choice

- ❑ Address stigma, discrimination, and criminalization



AFRICAN WOMEN

Prevention Community

Accountability Board

AWPCAB Members:

14 Women, 7 Countries



AWPCAB Structure

Secretariat : APHA (SA) & ICWEA (EA)

Communication: WACI Health

Membership

AWPCAB Members

Girls and Young Women

Key community organizations



How we are organized and What we do

Geography:

Eastern & Southern
Africa

Choice Agenda:

Introduction of options

Age:

**Intergenerational
intentional AGYW**

Focus:

Policy change
Access and roll out
Financing for choice

**Engagements: National,
Regional, and Global
Levels**



What we do

- Prioritizing Choice Advocacy in the prevention space
- Local, national, regional, and global level prevention advocacy
- Engagement with regulatory authorities
- Advocating for financing for choice
- Advocating for access to affordable, effective biomedical prevention methods
- Mentorship to young women and girls in East & Southern Africa

Engagements



REGULATORY
AUTHORITIES



POLICY
ENGANGMENT



NATIONAL
GOVERNMENTS



LOCAL
GOVERNMENTS



COMMUNITIES



Achievements

- UNAIDS: Gaining support from the UNAIDS Executive Director;
- Meeting with Amb. John Nkengsong leading to summoning his scientific Committee with clear and strong recommendations;
- Meeting with the EMA leading to their recommendation that the ring had a space within the prevention options;
- A champion for choice and manifesto.
- Advocating for funding from PEPFAR and Global Fund for DapiRing & Cab La;



Achievements

- Active involvement in the 2022/2024 AIDS Conference;
- Driving and sustaining advocacy efforts on choice for women and girls in Africa;
- Advocating for financing and inclusion of CHOICE programs and language in Global Fund applications and PEPFAR;
- Conceptualization and drafting of the HIV prevention Choice Manifesto for women and girls in Africa;
- Manifesto Readiness: Ready to launch the manifesto;
- PEPFAR's funding of the MOSAIC demonstration studies could be the nail to unlock the puzzle
- The Global Fund commitment to fund DVR is a game changer
- LAUNCH OF THE CHOICE MANIFESTO

YVETTE RAPHAEL,
CO-FOUNDER AND EXECUTIVE DIRECTOR
OF ADVOCACY FOR PREVENTION OF HIV IN
AFRICA (APHA) IN SOUTH AFRICA.

Provide women, girls with full range of HIV prevention options

Wto stand at a thrilling precipice in the fight against HIV/AIDS. For the first time in history, the end of this devastating epidemic is within our grasp. This isn't just hopeful thinking – it's a real possibility, thanks to an expanding basket of options that are revolutionising our approach to HIV prevention.

In recent years, we have seen remarkable advancements such as oral pre-exposure prophylaxis (PrEP) which has proven highly effective when taken consistently. Long-acting injectable PrEP like cabotegravir offers protection for months at a time and addresses some of the challenges that daily regimens present. Promising research is underway for PrEP implants and antibody infusions, which could provide even longer-lasting protection.

But today, I want to highlight a groundbreaking addition that is discreet and doesn't require women to ask permission from their partners to use it: The dapivirine vaginal ring. The ring symbolises a shift towards truly empowering women in HIV prevention. It is the first long-acting, non-systemic, women-controlled HIV prevention method. Women in six African countries, through 30 pilot projects, can now put into this new product.

Unfortunately, a major obstacle remains: The women and girls in the region who urgently need the products, particularly the dapivirine ring, cannot actually access them.

One young woman from Malawi who wrote to me said, "I do not have access to the ring, but it would help me have control of my health by giving me protection against HIV and it would give me peace of mind."

Another young woman wrote, "I have tried to access the ring for over a year now since I heard about it, but sadly I could not have access to it because it's not yet approved to be used in Tanzania."

Another, in Zambia, says, "I have not tried the ring. I don't have access because it is not accessible in my country. But it will help me achieve my goals."

The problem is that the only way to access this product is through one of these pilot research projects. Women hear about the ring and ask their healthcare providers about it, but then they can't obtain the product to safeguard their health.

We need to do better because HIV/AIDS is a serious problem for women in sub-Saharan Africa. According to the UN, 82 per cent of all adolescent girls and young women (ages 15-24) globally who acquired HIV in 2022 live in sub-Saharan Africa. Yet, in the high burden of HIV infections, less than half of all locations with high HIV incidence have dedicated HIV prevention programmes that serve adolescent girls and young women.

I believe the ring can be a critical component of these services. Made of flexible silicone, the ring slowly releases the antiretroviral drug dapivirine in the vagina over one



month. It was developed to provide long-acting prevention for women so that they could choose a method that best suited their lifestyle. A dapivirine ring that would work for three months is also undergoing the final stages of research.

Recent research has confirmed the importance of choice. After using both the ring and oral PrEP for six months each, 67 per cent of the participants chose the ring, 31 per cent chose oral PrEP and only 2 per cent chose to use neither. Simply put, we need to make sure women have better access to the ring.

In Eswatini, access will be scaled up once the pilot projects there have concluded and we expect that the other five countries with pilot projects – Kenya, Lesotho, South Africa, Uganda, and Zimbabwe – will do so as well.

I'm encouraged to see that Botswana, Malawi, Namibia, and Rwanda have provided regulatory approvals for the ring, or authorisation for its use, through import permits. A South African pharmaceutical company plans on manufacturing the ring

locally, which would lower the cost of the product.

It is also very exciting that, at the 25th International Aids Conference, the Children Investment Fund Foundation and the Global Fund announced an initiative of US \$2 million to purchase approximately 150,000 dapivirine vaginal rings for countries that implement the Global Fund's grants.

We need more commitments to rapid and widespread implementation of the dapivirine ring beyond the pilot projects, from policymakers, governments, and global health organisations. The success of these pilots should trigger automatic scale-up plans in each country now especially that there is available funding.

I urge health ministries to work closely with NGOs and community organisations to develop comprehensive rollout strategies that reach beyond urban centres into rural and underserved areas.

But the ring is just one piece of the puzzle. We must ensure that the full range of prevention options are made readily available to women and girls. As part of my work with Advocates for the Prevention of HIV in Africa, we launched the Choice Manifesto to challenge and hold policymakers and governments accountable.

Equity must be at the forefront of these efforts. It is unacceptable that African women and girls, who have contributed their bodies and time to research studies, often face the greatest barriers in accessing the very interventions they helped develop. Instead, they should receive preferential access and pricing.

The time for half-measures and pilot projects is over. We need bold, comprehensive action to make the full range of HIV prevention options available to every woman and girl who needs them. Their lives and futures depend on the actions we take today.

“We need more commitments to rapid and widespread implementation of the dapivirine ring beyond the pilot projects, from policymakers, governments, and global health organisations.”

African Wide Coverage of Yvette Raphael, co-founder and Executive Director of Advocacy for Prevention of HIV in Africa (APHA), July 2024

- **AllAfrica:** [The basket of HIV prevention options needs to be filled](#)
- **Capital (Ethiopia):** [The Basket of HIV prevention options needs to be filled](#)
- **Chronicle (Zimbabwe):** [The basket of HIV prevention options needs to be filled](#)
- **Citizen (Tanzania):** [The basket of HIV prevention options needs to be filled](#)
- ***Coast Media (Kenya):** [The Basket of HIV Prevention Options Needs to Be Filled](#)
- **Daily Monitor (Uganda):** [Basket of HIV prevention options needs to be filled](#)
- **Daily Nation (Kenya):** [Basket of HIV prevention options needs to be filled \(online\)](#)
- **Daily Nation (Kenya):** [Basket of HIV prevention options needs to be filled \(Print\)](#)
- **Daily News (Tanzania):** [Basket of HIV prevention options needs to be filled \(Print\)](#)
- **Modern Ghana:** [The Basket of HIV prevention options needs to be filled](#)
- **New Vision (Uganda):** [The basket of HIV prevention options needs to be filled](#)
- **Reporter (Ethiopia):** [The basket of HIV prevention tools needs more filling](#)
- **Rwanda Dispatch:** [The Basket of HIV Prevention Options Needs to Be Filled](#)
- **Shift Media (Uganda):** [RIPPLE EFFECT: The Basket of HIV Prevention Options Needs to Be Filled](#)
- ***Standard (Kenya):** [Provide women, girls with full range of HIV prevention options](#)
- **New Times (Rwanda):** [The basket of HIV prevention options needs to be filled](#)

Collaborations For product introduction

- Product developers
 - ViiV
 - Gilead
 - IPM/ Pop Council
- Policy
 - World Health Organization (WHO)
 - UNAIDS
 - National Governments (HIV prevention councils)
- Regulators
 - National regulatory authorities
- Communities and CSOs





Opportunities

- Building African women's leadership
- Intergenerational leadership building
- Setting the Agenda for HIV prevention centering on choice
- Engaging policymakers at national, global and regional level
- Achieving the AGYW Prevention Agenda
- Continual Advocacy and Mobilization
- Collaboration and Commitment for Women's Health



Challenges

- Translating Commitment into Actions
- Funding for products roll out (Ring)
- Advocacy for Product Approvals with regulatory authorities

Acknowledgements

Collaborators

- National Governments
- WHO
- USAID and PEPFAR
- CASPR Partners
- AVAC
- UNAIDS
- ViiV
- IPM/ Pop Council

Partners

AWPCAB Members

- APHA
- ICW EA
- WACI Health
- PZAT
- ACTS 101
- LVCT Health
- TALC