

September 22, 2022

RINGing the Bell for Choice Actions and Solutions on Dapivirine Ring Access



PLAYLIST DJ Manju Chatani
Ringing the Bell
mnjzzz • 11 songs, 36 min 8 sec

A dark grey rectangular box containing a playlist. On the left, there are four small album covers: the first shows a man's face, the second shows a person in a dark setting, the third shows a person in a red shirt, and the fourth shows a group of people. The text 'PLAYLIST DJ Manju Chatani Ringing the Bell' and 'mnjzzz • 11 songs, 36 min 8 sec' is on the right.

RING RING RING

- Botswana
- Brazil
- Cambodia
- Canada
- Comoros
- Côte d'Ivoire
- Denmark
- Egypt
- Eswatini
- France
- Gambia
- Germany
- India
- Italy
- Jordan
- Kenya
- Lesotho



33 countries

262 webinar registrants

- Malawi
- Morocco
- Nigeria
- Philippines
- Rwanda
- South Africa
- Sweden
- Switzerland
- Tanzania
- Thailand
- Uganda
- Ukraine
- United Kingdom
- United States
- Zambia
- Zimbabwe

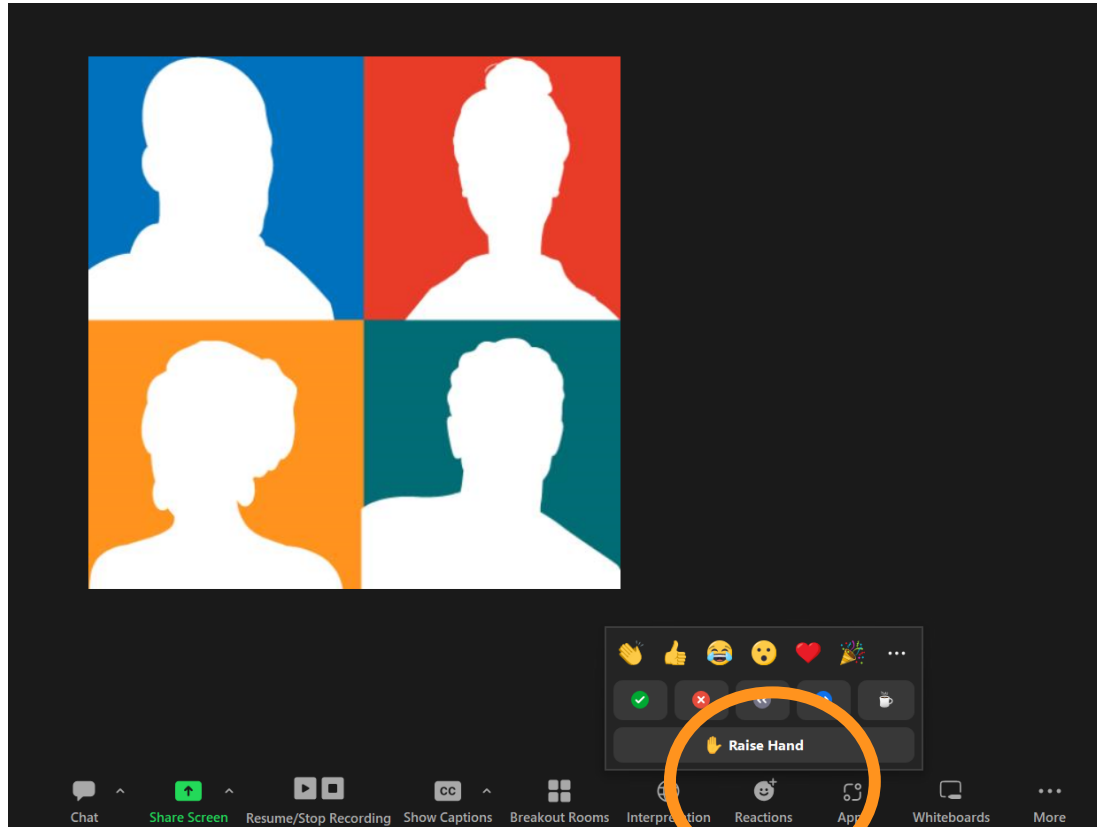


**What's next for TCA:
Friday, October 7, 2022**

Doxycycline for STI Prevention Evidence and Current Research

Register here: tinyurl.com/doxypep

Webinar Logistics



- This call is being recorded. Your presence = consent.
- We are providing closed captions.
- Please stay on mute, unless you are speaking.
- Please comment, ask questions, share info/resources in the chat.
- Thank you for all the questions that came in during registration!
- Let's hear your voice and see your face too. Raise hand to speak on camera.
- We will share links to recording and slides in follow-up email.
- Access TCA webinar resources here:
 - www.avac.org/choice-agenda

Press record!



RINGing the Bell for Choice: Actions and Solutions on Dapivirine Ring Access

Presenters

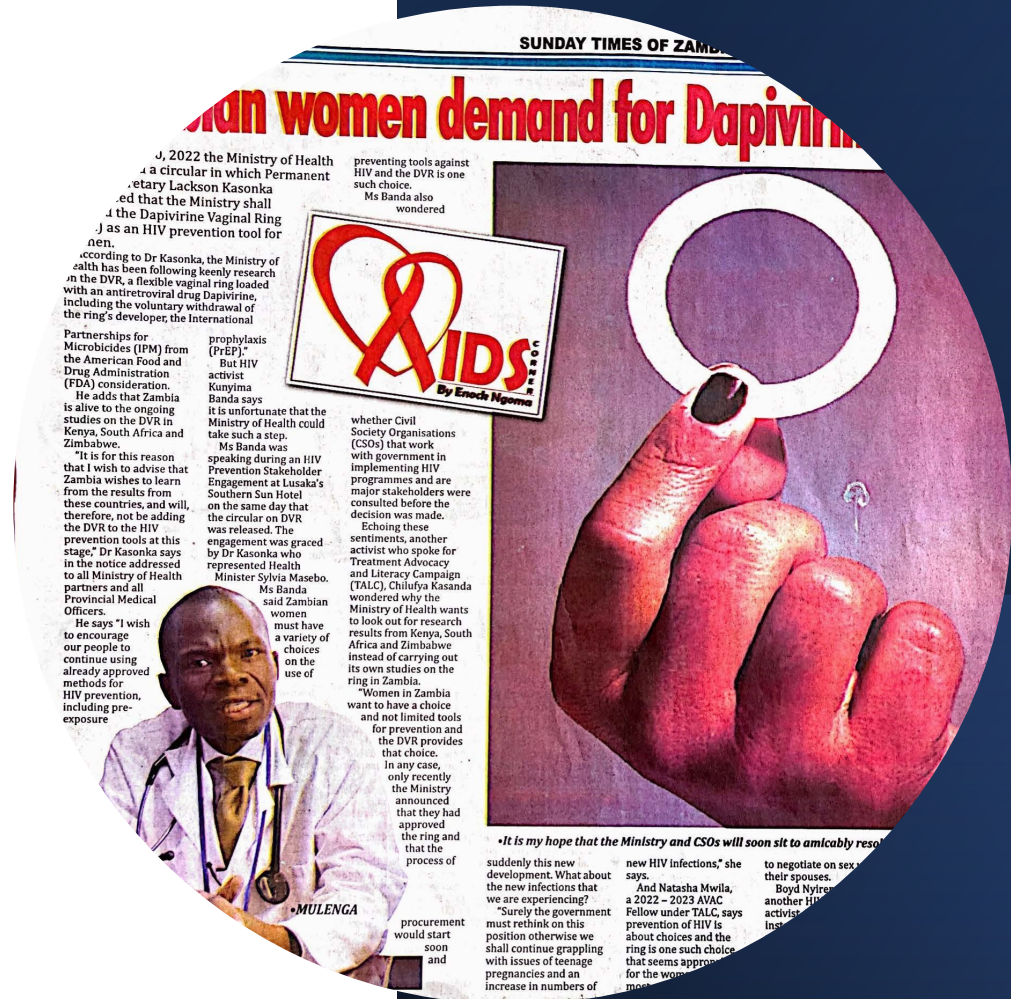
- Leonard Solai, IPM South Africa
- Yvette Raphael, APHA

Advocacy discussion

- Shakirah Namwanje, UNASO
- Natasha Mwila, Network of
Zambian People Living with HIV,
AVAC '22 Advocacy Fellow

Remarks

- Chris Obermeyer, Global Fund
- Erica Gollub, Pace University





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Dapivirine Vaginal Ring Update -

The Choice Agenda
September, 2022



Monthly Dapivirine Vaginal Ring (DVR)



- **Flexible silicone vaginal ring developed by IPM**
- **Woman-initiated and first long-acting HIV prevention product**
- **Slowly releases ARV dapivirine**
 - Exclusive worldwide rights through Janssen Sciences Ireland Unlimited Company
- **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
- **Positive Scientific Opinion from EMA in July 2020**
- **WHO recommendation and guidelines 2021 and Prequalification**
- **To date 6 approvals in Africa through the WHO Collaborative Registration Procedure**

Monthly DVR – Regulatory Updates

Country	IPM Submission Date	Status
South Africa	First electronic submission 24-Nov-2020 Final Submission via USB 26-Mar-2021	Product Registration 08-March-2022
Zimbabwe	03-February-2021	Product Registration 06-July-2021
Rwanda	11-February-2021	Under review
Uganda	17-February-2021	Product Registration 05-October-2021
Malawi	22-February-2021	
Tanzania	11-March-2021	IPM was notified on 12-April-2022 that TMDA has rejected the registration of DapiRing. IPM submitted an appeal.
Zambia	05-March-2021	Product Registration 10-May-2021
Kenya	23-March-2021	Product Registration 16-July-2021
Namibia	01-September-2021	Under review
Botswana	08-September-2021	Under review
Mozambique	TBD	
Ethiopia	TBD	
Nigeria	TBD	

MOSAIC Project Overview

- 5-year global project funded by PEPFAR through USAID (2021-2026)
- Focuses on introduction and access for new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Works across multiple countries to support evidence-informed and user-centered product introduction, research, research utilization, and capacity strengthening
- Supports a multi-product market with informed choice for HIV prevention as new products enter the market
- Collaborates closely with ministries of health (MOHs), missions, implementing partners (IPs), civil society, end users, providers, other local and global stakeholders, and product developers

VALUES

Country-led

Women-focused with emphasis on AGYW

Informed choice

Equitable co-leadership

Intentionality

Most countries have taken steps toward introduction of the monthly DVR

Zambia:

MOH indicated that it would await further research/data from other countries implementing pilot studies to inform policy and final resolution on the ring

Ethiopia:

Pilot Study under iRB will be initiated. PSI

Uganda:

On April 26, 2022, the national prevention committee endorsed the adoption of the ring . CATALYST

Kenya:

The ring is included in Kenya's HIV guidelines. CATALYST

Eswatini:

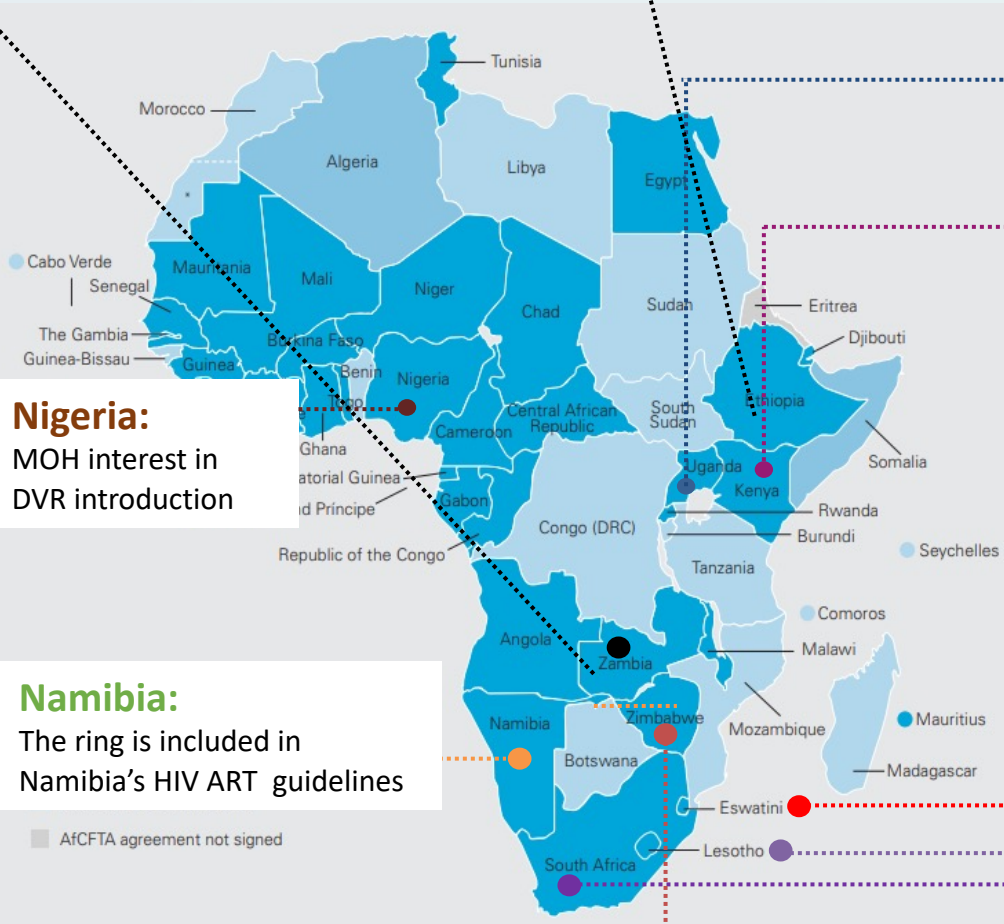
As of February 28, the MOH decided to introduce the ring and put in place an import waiver for the product. Pilot and MSF

Lesotho:

The ring is included in Lesotho's HIV guidelines and Essential Medicines List. CATALYST

South Africa:

On March 11, 2022, SAHPRA has approved the ring. The DOH, through technical working groups is planning for ring implementation.



Zimbabwe:

The ring is approved in Zimbabwe and plans are underway for an implementation study – CATALYST. PSI has commenced a pilot

Additional Monthly Ring Research

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
 - Results on next slide
- **DELIVER study: Pregnant women**
 - Safety and acceptability of ring & PrEP among 750 women in Malawi, South Africa, Uganda, Zimbabwe
 - Interim results: No safety concerns seen during late pregnancy
- **B-PROTECTED: Breastfeeding women**
 - Safety and acceptability of ring & PrEP in Africa
 - Favorable safety profile



Findings from additional research



The REACH study findings showed promising results toward consistent HIV prevention product use in AGYW:

- **Choice:** 67% of participants chose to use the ring and 31% oral PrEP
- **Safety:** No safety concerns were noted for either the ring or oral PrEP
- **Acceptability:** high for both products – the ring (88.5%) and oral PrEP (64%)
- **Adherence:** The vast majority (97%) of study participants used the ring/oral PrEP some or all of the time. Adherence was higher for both products than had been observed in previous studies



The DELIVER study, reported in interim findings:



No safety concerns were found in Cohort 1 = 36+ weeks (8-9 months) pregnant

No safety concerns were noted in Cohort 2 = 30-35+ weeks (7-8 months) pregnant

Cohort 3 is underway

- Results likely to be available in mid 2024



WHO Dapivirine Ring Stakeholder Consultations

Objective of this stakeholder engagement

Understand perspectives of national ministries of health (MOHs), civil society, ring users, donors, implementing partners, and other key stakeholders in sub-Saharan Africa on moving forward with ring rollout following IPM's withdrawal of their NDA to the US FDA

Key Themes

1	Autonomy Countries largely look to their own regulatory bodies and WHO rather than the US FDA to make decisions	7	Lack of clarity about NDA withdrawal Lack of clarity about why the NDA was withdrawn could lead to distrust of US-funded products not approved by the US FDA
2	Funding Confusion MOHs raised that an effect of the NDA withdrawal is that they need to seek funding for procurement outside of PEPFAR	8	Information for providers and clients Clear messaging on the product attributes of the ring is needed for providers and clients
3	“Real-world” Studies Needed The next step to better understand how to deliver the ring as part of HIV prevention choices for AGYW are real-world studies	9	Clear messaging to dispel myths Without clear messaging, myths and misinformation regarding the ring and its efficacy may circulate on social media and other channels
4	Choice for Women No one product works for all women; AGYW want choice in HIV prevention options	10	Trust Lack of community support for and enrollment in future US-funded trials is a potential concern
5	Choice for Impact Choice in HIV prevention products may have a greater impact on incidence, helping us to reach global and local targets	11	Ethical Considerations Ethical considerations of post-trial access need to be addressed
6	Context Framing the ring for African women only may be problematic		

Supply Chain Overview



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Monthly DVR Procurement and Distribution Update

- **First commercial DVR shipment to Zimbabwe via Chemonics (on behalf of PEPFAR)**
 - ~14,500 rings Shipped in March and April Rings will be used in a PSI-Zimbabwe implementation project
- **Launch of the DVR dedicated website (prepring.org) in March 2022, supporting the first batch of rings to Zimbabwe, and future countries when they start receiving the ring**
- **DVR is now eligible for procurement by the Global Fund. The product is in list of eligible products (updated March 2022): <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/>.**
 - IPM is awaiting guidance to set up this procurement pathway
- **MSF has started the process to procure rings from IPM to support implementation projects in Mexico and Eswatini.**
 - There is additional interest in making rings available for projects in several other African countries in the near future



Dapivirine Product
Pipeline

Three-month DVR

- Off-white flexible silicone ring containing 100mg dapivirine that is self-inserted every 3 months
- Same dimensions, formulation, and manufacturing process as DapiRing
- Sustained-release *in vivo* over three-months
- No cold chain or special storage needed
- The three-month DVR will reduce the yearly cost by 66% of the current annual cost of the monthly DVR



Bioavailability Study (IPM 054)

- Phase I crossover design to investigate bioavailability of 25 mg dapivirine ring to 100 mg dapivirine ring
- **Primary Objectives**
 - PK: determine the bioavailability of 100 mg dapivirine ring relative to 25 mg dapivirine ring
- **Secondary Objective:**
 - Safety
 - Evaluate the safety of the two dapivirine vaginal ring formulations used continuously for 90 days
 - Characterize the vaginal microenvironment over the course of 90 days of ring use

Dapivirine Contraceptive Vaginal Ring: Update

- Three-month ring containing levonorgestrel for contraception and dapivirine for HIV prevention
- Two Phase I clinical trials performed with 200 mg dapivirine and 320 mg levonorgestrel in silicone matrix
 - No major safety signals for DPV or LNG
- More rigid EVA-based formulation developed as a result of slippage and expulsions with the initial silicone rings
- GMP clinical manufacturing of EVA rings completed and shipped to one of two trial sites
- CCN019b/IPM 056 Phase I study designed to compare two ring strengths

Community Engagement and Partnerships



[AIDS-Fondet](#), Denmark



[Aidsfonds](#), The Netherlands



[AVAC](#), USA



Community Health, Empowerment, Development and Relief Agency (CHEDRA), Uganda



[The Drum Beat of Uganda](#)



[Deutsche Stiftung Weltbevölkerung \(DSW\)](#), Germany



[emthonjeni Counselling & Training](#), South Africa



[Frontline AIDS](#), UK



[Generation Alive](#), Zambia



[Global Health Technologies Coalition](#), USA



[Hope2Educate](#), South Africa



[Interagency Coalition on AIDS and Development](#)



[Journalists Association Against AIDS \(JournAIDS\)](#), Malawi



[Kenya Medical Women's Association](#)



[People Living with HIV/AIDS \(PLAS\) - Lyantonde](#), Uganda



[Rinda Ubuzima](#), Rwanda



[Sex og Politikk](#), Norway



[South African Positive Women Ambassadors](#), South Africa



[SENSOA](#), Belgium



[SRHR Africa Trust \(SAT\)](#)



[STOPAIDS](#), UK

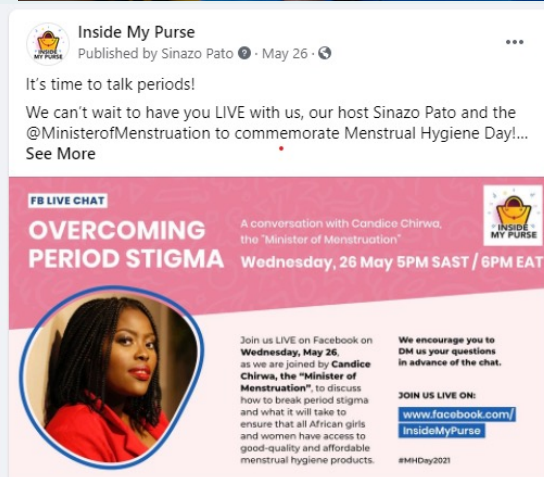
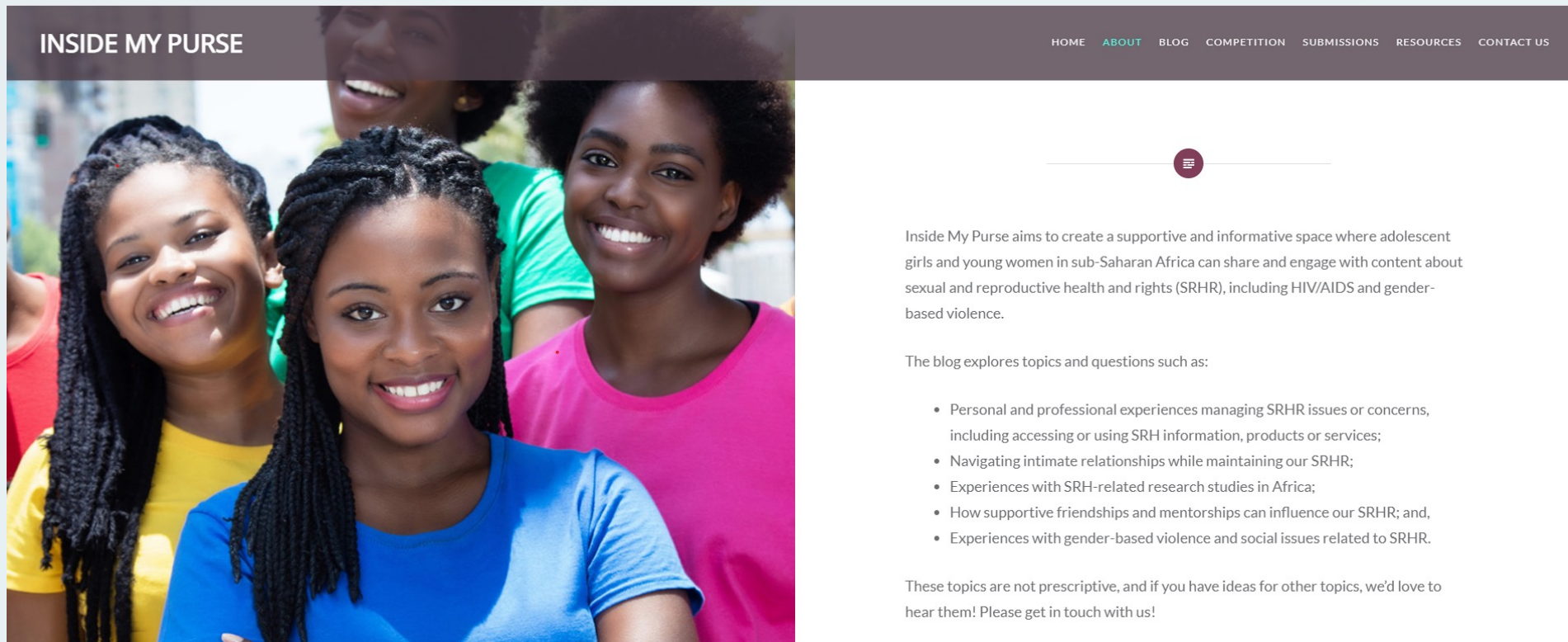


[Tanzania Network of Women living with HIV and AIDS \(TNW+\)](#), Tanzania



[WACI Health](#), Kenya

Engaging Adolescent Girls and Young Women



- Target audience include young women age 16-28 years, and older, programme managers, advocates etc.
- Content contributed by AGYW sharing personal stories on SRH, HIV and GBV issues.

Thank You to IPM's Recent Donors



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Irish Aid

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An Roinn Gnóthaí Eachtracha

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The Global Fund Relies on Country Leadership



Countries where the Global Fund invests take the lead in determining where and how to best fight the three diseases (HIV/AIDS, tuberculosis, and malaria), and present funding applications and changes to current grants for review by different Global Fund structures.



Country ownership allows countries to tailor their own response, considering their political, cultural and epidemiological context.



Funding applications and changes to current grants are developed through Country Coordinating Mechanisms (CCMs)



The Global Fund is built on meaningful, transparent, and inclusive [country dialogues](#).

Engagement of diverse individuals, groups, and organizations in country dialogues is essential to quality and impactful programs.

CCMs are responsible for coordinating an inclusive country dialogue process and are best placed to inform stakeholders about where, when and how the country dialogue will take place

The Global Fund Supports Implementation of the PrEP Ring

- The PrEP ring is recommended by the World Health Organization (WHO) for HIV prevention.
- As a WHO recommended product, the Global Fund stands ready to support countries which wish to introduce and provide the PrEP ring if integrated into current grants (either because it is already in the grant or through reinvestments) or in new funding applications.
- Those wishing to discuss inclusion of the PrEP ring in Global Fund grants should engage with the Country Coordinating Mechanism in their country.

Engaging the Global Fund Country Coordinating Mechanism

- Those interested in being part of country dialogues should contact the [Country Coordinating Mechanisms](#) for their country by reaching out to the Administrative Focal Points found in the [Coordinating Mechanism Contacts Tool](#).
- Those providing feedback may also wish to [review the current grant](#) for their country in order to strengthen their advocacy efforts.

The screenshot displays the 'Coordinating Mechanism Contacts' tool interface. At the top, a dark blue header contains the title and subtitle: 'Coordinating Mechanism Contacts' and 'Available contacts for Coordinating Mechanisms by country.' Below this is a search filter for 'Geographic Area *' with 'Kenya' selected. A '* Required' label is present. Navigation buttons include 'GET REPORT', 'DOWNLOAD', and a set of arrows. The page is identified as 'PAGE 1 OF 1'. The main content area features the 'THE GLOBAL FUND' logo and the title 'Coordinating Mechanism Contacts'. Under the heading 'Kenya', the 'CCM Kenya' section is divided into three columns: 'Chair', 'Vice Chair', and 'Administrative Focal Points'. The 'Administrative Focal Points' column is highlighted with a red rounded rectangle and lists two individuals: Ms Margaret MUNDIA (Finance & Operations, w.mundiam@gmail.com) and Mr Samuel MUIA (Coordinator, muiasammy@yahoo.com).

Chair	Vice Chair	Administrative Focal Points
Ms Susan MOCHACHE Principal Secretary/Ministry of Health	Ms Faith Mwendu NDUNG'U Program Development & Advocacy Manager	Ms Margaret MUNDIA Finance & Operations w.mundiam@gmail.com
		Mr Samuel MUIA Coordinator muiasammy@yahoo.com

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AIDS, Tuberculosis and Malaria

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