



We need a buffet,
a cornucopia of delicious,
healthy choices.



April 25, 2023

HIV Prevention Plus Plus: **Developing Options that Meet the Full Range of our Sexual and Reproductive Health Needs**

Speakers include:

Ruth Akulu, ICWEA and AVAC fellow
Barbara Friedland, Population Council

Gregorio Millet, amfAR

Dr. Thesla Palanee-Phillips, Wits RHI

Danielle Resar, Clinton Health Access Initiative





HIV prevention research - a new forum
for advocacy on the latest

avac.org/choice-agenda

Next from The Choice Agenda



May 9, 2023

PrEP (In)equity: Documenting, measuring, and flipping the script towards justice

with Leisha-McKinley Beach,
Michael Chancley, and
Dr. Patrick Sullivan



Register: <https://tinyurl.com/prepinequity>

The image features a monochromatic orange color scheme. The background is a solid orange with a subtle pattern of small white stars, suggesting a night sky or a digital space. In the foreground, a white wireframe grid extends from the bottom towards the center, creating a sense of depth and perspective. On either side of the grid, there are jagged, white wireframe structures that resemble mountains or abstract terrain. The text "The Future is Multipurpose" is centered in the middle of the image in a clean, white, sans-serif font. The overall aesthetic is modern, digital, and futuristic.

The Future is
Multipurpose



What you need to know about the Dual Prevention Pill (DPP)

The next MPT on the horizon

Kate Segal, AVAC
Barbara Friedland, Population Council
Dani Resar, CHAI

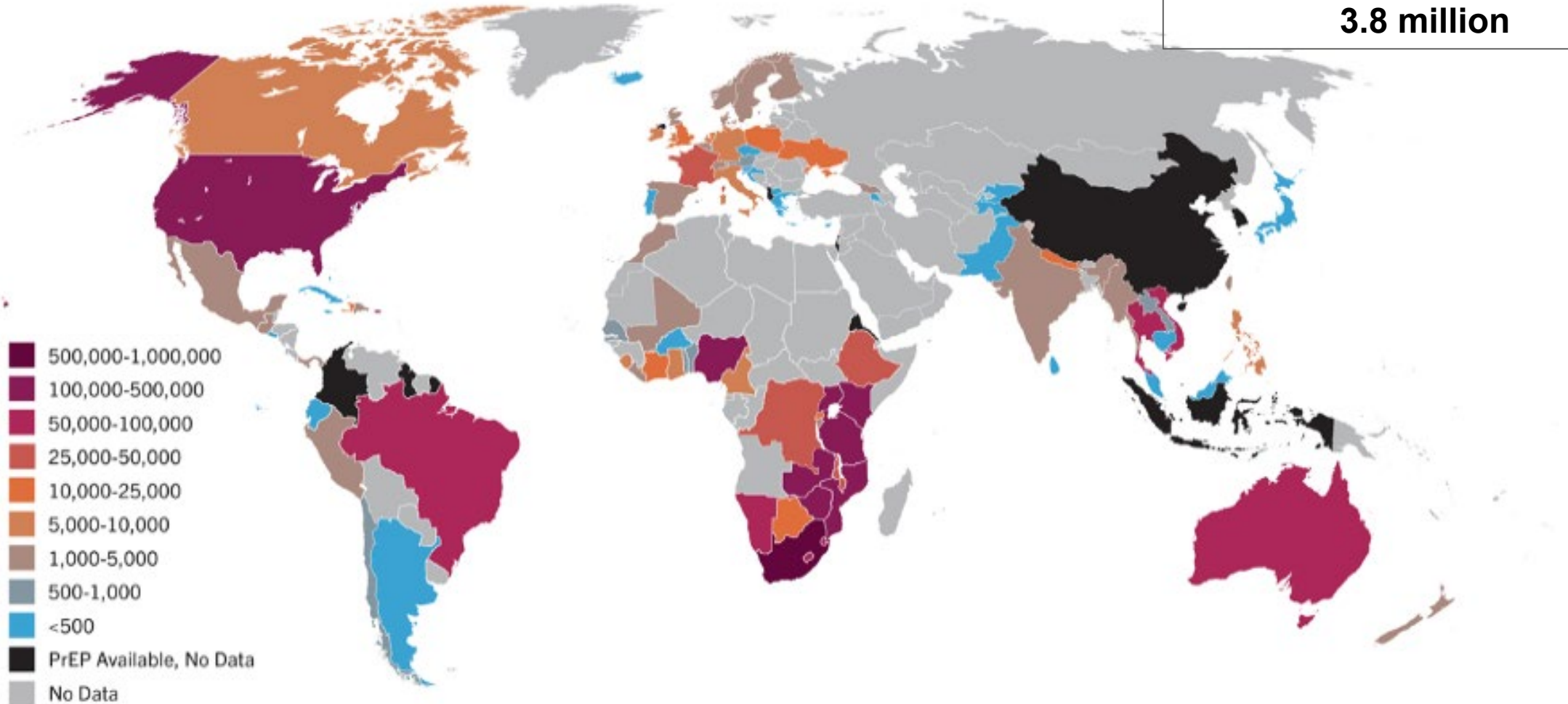


APRIL 25, 2023

Oral PrEP uptake is growing rapidly, with sub-Saharan Africa (SSA) comprising 75% of global initiations

PrEP Initiations by Country, December 2022

Cumulative global initiations:
3.8 million



Amid robust MPT and PrEP pipelines, the DPP would be the only new product on the horizon for years

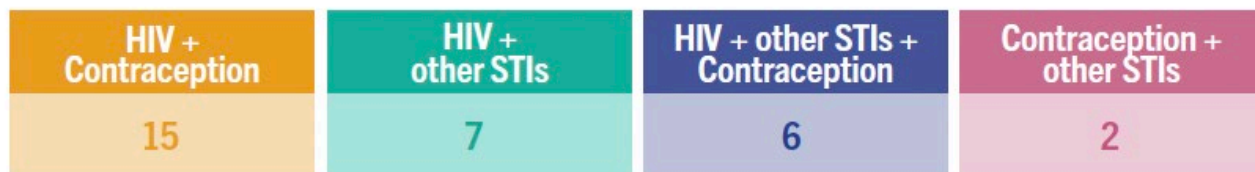
PRE-CLINICAL			PHASE I		PHASE II	PHASE III/IIIb/IV	DELIVERY SYSTEM	ACTIVE DRUG
TAF CONRAD	MAVR TNFV Nigerian Institute for Medical Research	CAB ViiV	ELVG TAF CONRAD	DS03 Pop Council		F/TAF Gilead Daily	Diaphragm	5P12 5P12-RANTES
CAB CONRAD	CAB PATH/ Queens University Belfast	MAVR ViiV/Pfizer	TNFV Johns Hopkins	DPVR Pop Council ¹ 3-monthly		LEN Gilead 6-monthly	Enema	ACZX Acyclovir-Zovirax
CAB CONRAD	DS03 Queen's University Belfast		ISL Merck ³	MK20 University of Pittsburgh		CAB ViiV-GSK ² 2-monthly	Intramuscular injection	AMPR Amphora
TNFV Gilead	BNAB Rockefeller University		TAF Oak Crest /CAPRISA	GRFS University of Pittsburgh		ISL Merck ³ 1-monthly	Implant	BNAB Broadly neutralizing antibody
F/TAF Houston Methodist	TAF RTI		OB2H Orion			DPVR Pop Council 1-monthly	Micro-array patch	CAB Cabotegravir/ GSK 744
5P12 Mintaka	DPVR University of Pittsburgh					DPVR Pop Council 1-monthly	Non-specific mucosal insert	CRGN Carrageenan
Multipurpose Prevention Technologies (MPTs)								
ETED ACZX TNFV Auritec	PC05 PATH /Pop Council /Kessel	F/TDF MAB UMass and Planet Biotechnology /Oak Crest /MassBiologics	TAF ELVG CONRAD		TNFV CONRAD	F/TAF ETED LVGR Pop Council /Medicines360 ⁴	Oral pills	5P12 5P12-RANTES
ACZX TNFV CONRAD	CAB PRGT PATH/Queens University Belfast	DPVR PRTV LVGR University of North Carolina	DPVR LVGR Pop Council		TNFV CONRAD	F/TDF ETED LVGR Viatris ⁴	Subcutaneous injection	ACZX Acyclovir-Zovirax
CAB LVGR CONRAD	ETGS GRFS ETED Pop Council	ETGS ISL ETED University of North Carolina	DPVR LVGR Pop Council				Vaginal film	AMPR Amphora
TNFV EFAV i3S/University of Porto	CRGN GRFS Pop Council /Evofem Biosciences	DPVR LVGR PRTV University of North Carolina					Vaginal gel	BNAB Broadly neutralizing antibody
PRGT ISL Magee-Women's Research Institute /University of Pittsburgh	RTI ⁵	ISL University of North Carolina					Vaginal insert	CAB Cabotegravir/ GSK 744
F/TDF MAB Oak Crest /University of North Carolina		PPCM Yaso Therapeutics					Vaginal ring	CRGN Carrageenan
								DPVR Dapivirine
								F/TAF Descovy
								DLGR Dolutegravir
								DS03 DS003 (BMS793)
								EFAV Efavirenz
								ELVG Elvitegravir
								ETED Ethinylestradiol
								ETGS Etonogestrel
								GRFS Griffithsin
								ISL Islatravir
								LEN Lenacapavir
								LVGR Levonorgestrel
								MAVR Maraviroc
								MK20 MK-2048
								MAB Monoclonal antibody
								OB2H OB-002H
								PC05 PC-1005
								PPCM PPCM polyanionic microbicide
								PRTV Pritelivir
								PRGT Progesterin
								TNFV Tenofovir
								TAF Tenofovir Alafenamide
								F/TDF Truvada

¹ This is a Bioequivalency trial with the monthly DVR.
² Dec. 2021 Approved by the FDA; Aug. 2022 Approved by the Australian regulatory agency
³ Discontinued in Sept. 2022
⁴ These two dual pill products are undergoing bioequivalency trials. The drug components are approved, but not in their combination. Therefore, it does not follow the traditional R&D pathway.
⁵ Non-specific to any drug; for development of a long-acting biodegradable implant suitable for an MPT use to protect against pregnancy and HIV. See SCHIELD Implant for more information.

Advocates' Guide to Multipurpose Prevention Technologies (MPTs)

AT A GLANCE: THE MPT R&D PIPELINE

Status of products in development



Adapted from: *The Initiative for MPTs (IMPT) Product Development Database; Treatment Action Group (TAG) 2022 Pipeline Report.*

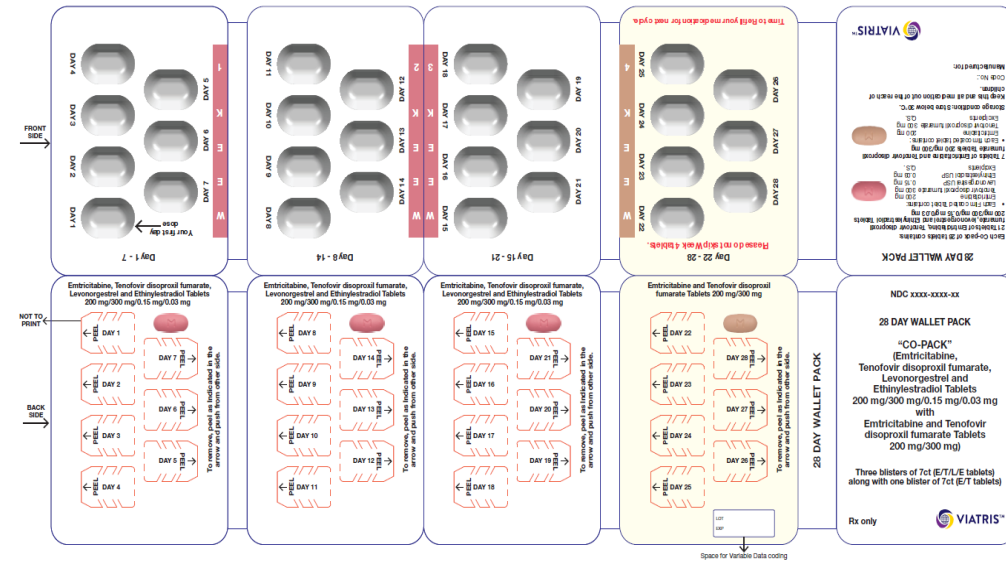
So what is the DPP?

- Daily pill for HIV and pregnancy prevention
- Viartis developing **co-formulated tablet** with TDF/FTC (oral PrEP) + LNG/EE (combined oral contraception, COC)
- **28-day regimen with different colored pills** for 21 vs. 7 days
- **Packaging will be wallet pack** to more closely resemble OC packs, with tear-off weekly sheets with instructions
- **Branding/secondary packaging** will have women's lifestyle feel
- Population Council/Medicines360 also **developing F/TAF-based DPP**, which could be 1/3 smaller than the DPP with TDF/FTC

Figure 1: Proposed DPP tablet colors



Figure 2: Illustrative mock-up of DPP packaging by Viartis



Viartis plans to file for regulatory approval with US FDA in 2024

The DPP offers both a product that can fill critical gaps in women's health and a platform to spur integration and generate lessons for future MPTs

THE LANDSCAPE

THE OPPORTUNITY

The Product



- ✓ Oral contraception (OC) is a substantial, consistent market share in high-burden HIV settings
- ✓ Persistent unmet need for FP
- ✓ Many women at risk of HIV face challenges using oral PrEP and prefer dual-indication products

The MPT Platform



- ✓ Growing interest in MPTs with developers, researchers, governments, end users
- ✓ Accelerated pathway to market entry via bioequivalence studies (no clinical trial)
- ✓ First MPT to reach markets since condoms and first with PrEP

End Users



User-controlled, co-formulated pill supports convenience and may motivate increased knowledge, use and adherence compared to oral PrEP

Health Systems



Building off expanding PrEP delivery channels, the DPP will **foster HIV/SRH integration and prompt adaptations** that will benefit future MPTs (regulatory, delivery, financing, and more)

What progress has been made?

End Users: We developed a creative route for the DPP with end users, male partners and providers that responds to their values, beliefs & identities

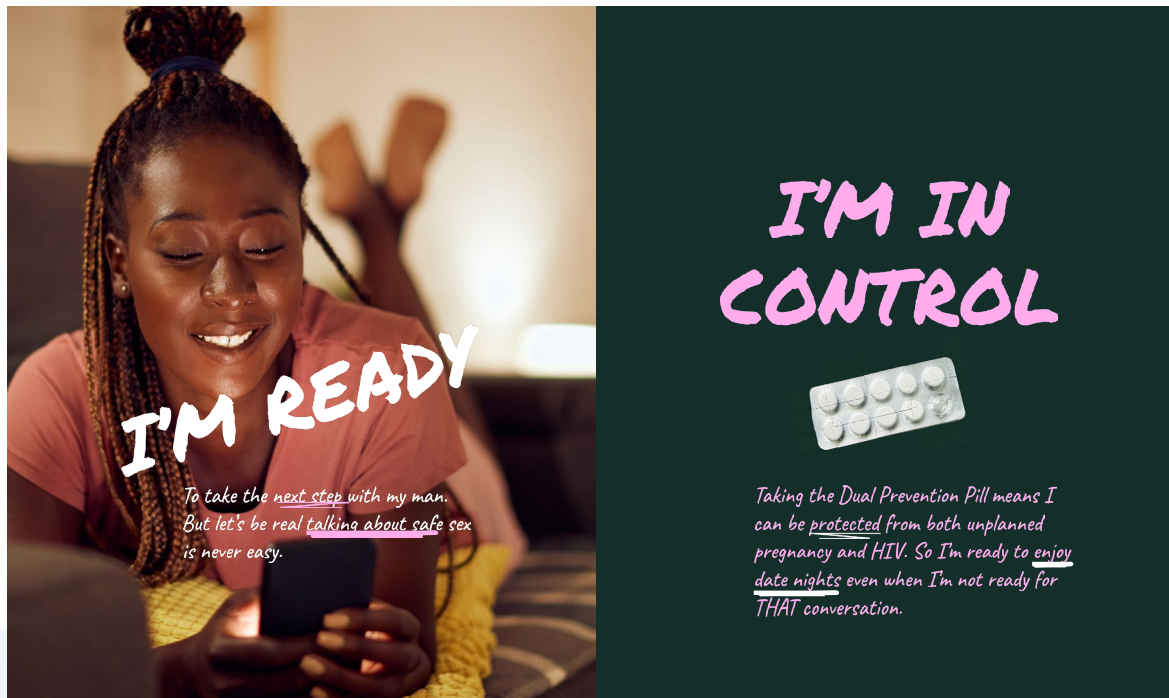


What we've learned

Women juggle competing values: self-focused, relationship and community values shape women's identities, requiring balancing sociocultural expectations with personal desires/motivations.

Women struggle with: the unpredictability of life; uptake of OC/PrEP has often been triggered by the negative actions of their partners.

Women want: Help to make it easier for them to use the DPP.



How it matters for the DPP and MPTs

DPP motivates 'her' to embrace the woman she is: Users felt motivated when their individuality as women was celebrated, whether through a goal-oriented, enjoyment or self-care lens.

Moments not demographics: Use everyday "moments" in women's lives where the DPP carries relevance as entry points. The DPP can help users navigate "moments" when they need to take control of their sexual health (e.g. unfaithful partner, want to enjoy sex outside of marriage, when not sure of partner's HIV status).

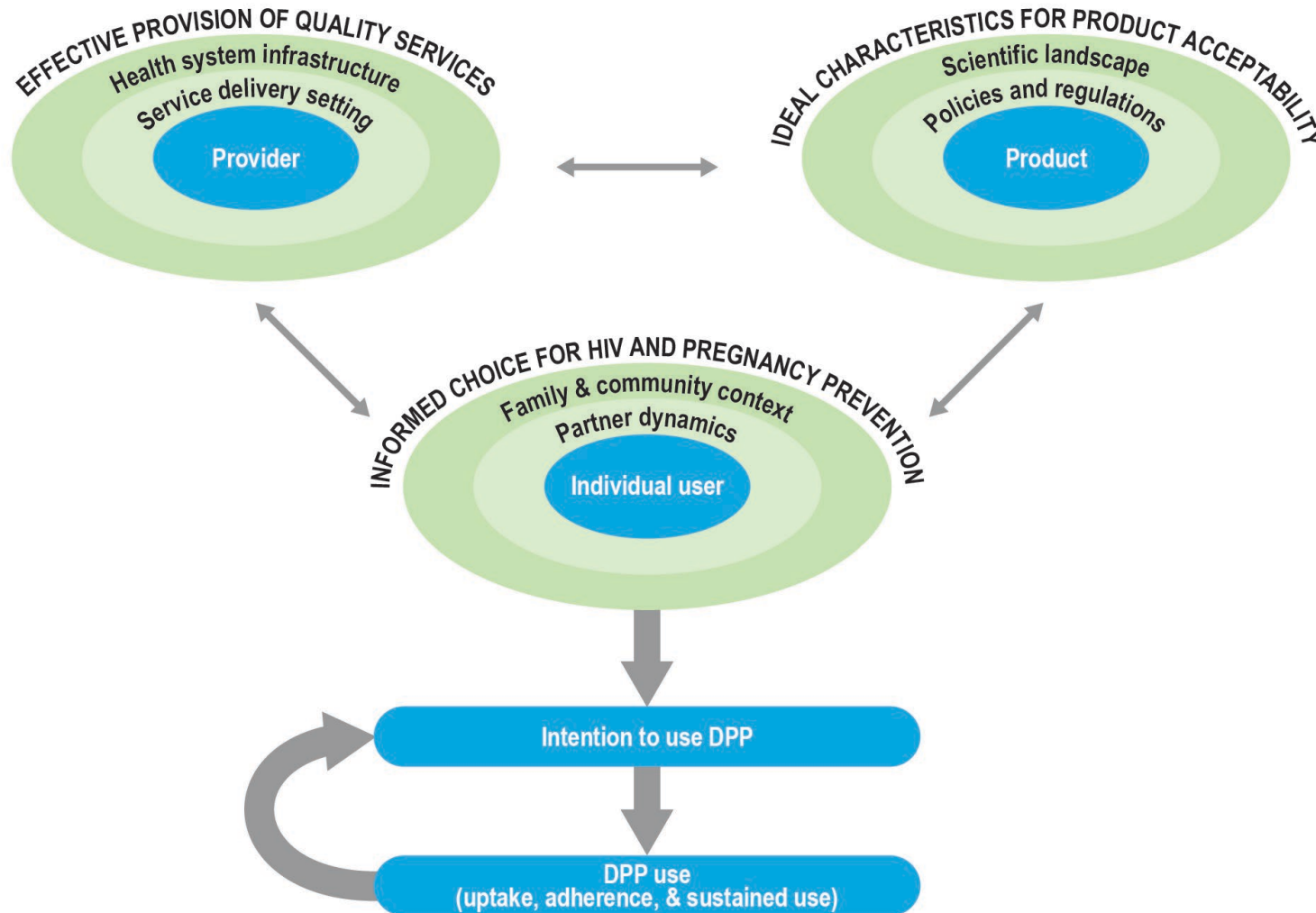
Opportunity to: position men as 'protectors' of women in their lives to engage them on support for DPP.

Balance the tension: between creating public awareness for social acceptability of the DPP and remaining targeted and discreet (safe/trusted channels).

Product Development and Introduction: We created a novel framework for introduction of MPTs ...



What we've proposed



How it matters for the DPP and MPTs

Successful DPP rollout requires careful consideration of user-, provider-, and product-centered factors during **product development and introduction**.

Early attention to these interrelated factors can help ensure that the DPP has the **ideal characteristics** for maximum product acceptability, that effective and **quality services** are designed and implemented, and that users can make **informed choices**, demand the product, and use it effectively.

The proposed framework outlines key considerations for the effective development and introduction of the DPP, which could also **facilitate integration models for future MPTs**.

Health Systems: We developed an innovative model to assess cost-effectiveness of the DPP, integrating HIV and FP outcomes



What we've learned

How it matters for the DPP and MPTs



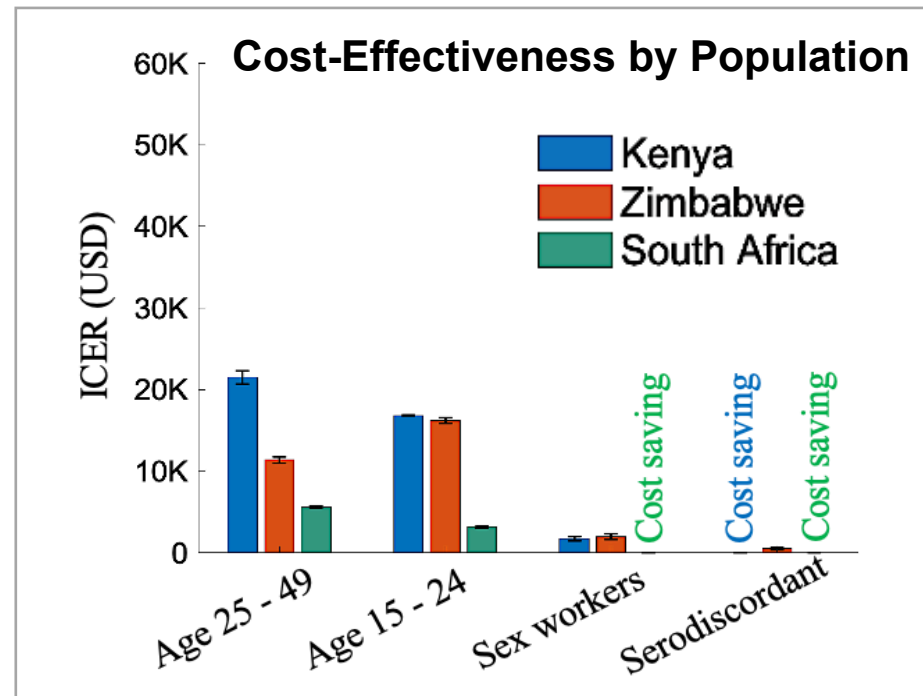
Impact of epidemic profile: The DPP is more likely to be cost-effective in settings with **high HIV incidence**.



Populations: The DPP is likely to be **cost-saving in several populations**, including SWs and SDCs.



Use Patterns: Cost-effectiveness in other groups is more likely in the context **risk-informed use and/or significantly improved adherence**.



Health Systems: With effective targeting, the DPP can generate cost savings, helping programs to do more with less.

Effective Use: DPP is cost-saving among SWs in South Africa, even with relatively low effective protection (19%), and among SDCs in Kenya and SA with moderate effective protection (>75%). The DPP is net-beneficial across most scenarios.

Need for Effective Counseling: Risk of net-harm if DPP *reduces* adherence among OCP users at lower risk of HIV. Nuanced messaging and effective counseling is needed to support informed choice and effective use.

These learnings are the tip of the iceberg...

- ✓ DPP creative route
- ✓ Product introduction framework
- ✓ DPP cost-effectiveness modeling

RESEARCH

Formative research
Acceptability studies
HPTN 104 study

SERVICE DELIVERY

Provider counseling
recommendations
Private sector delivery
strategy

HEALTH SYSTEMS

Analyses of M&E
systems, global
procurement
landscape, policies to
support choice

STAKEHOLDER ENGAGEMENT

DPP Advisory Board
DPP Civil Society Advisory
Group

AND MORE!

Visit [PrEPWatch](#) for more information on the DPP

Thank you!



**What you need to
know about the DPP**

Overview of upstream Multi-purpose Prevention Technology Products in MATRIX

A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women

The Choice Agenda

HIV Prevention Plus Plus : Developing Options that Meet the Full Range of our Sexual and Reproductive Health Needs

Thesla Palanee-Phillips on behalf of the MATRIX team
Wits RHI, Johannesburg, South Africa
25th April 2023



Overview

- What is MATRIX
- What are we trying to do?
- What are the products we are trying to develop
- What gaps do they fill in the HIV prevention landscape?

Microbicide R&D to **A**dvance HIV Prevention **T**echnologies through **R**esponsive **I**nnovation and **eX**cellence

USAID Product Research and Development Guiding Principles Over the Last 5 Years



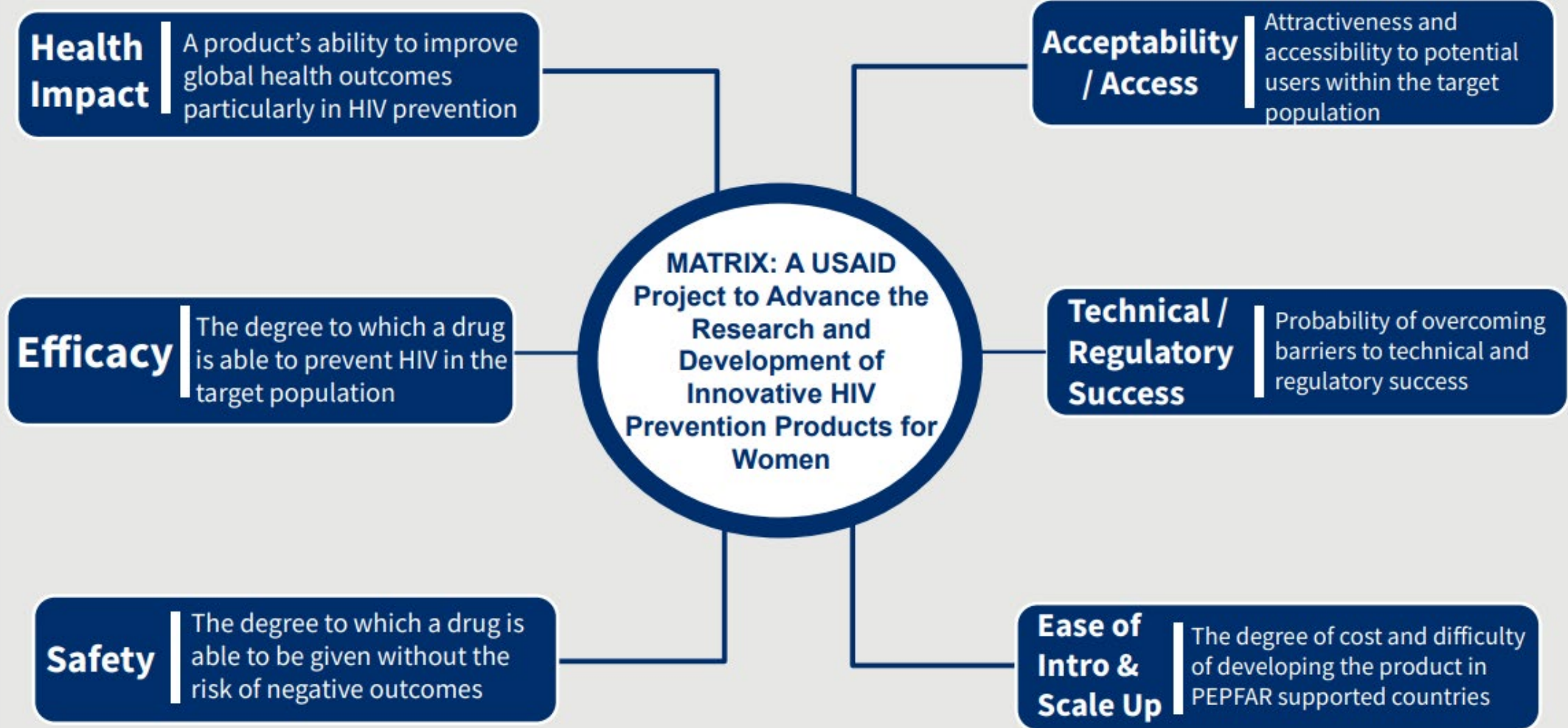
Project Overview

- 5-year, \$125 million Cooperative Agreement Funded by the USAID – initiated in 2022
- Implemented with oversight from the Magee-Womens Research Institute and Foundation, USA and Wits RHI, SA alongside 19 implementing partners in South Africa, Kenya, Zimbabwe and the USA

Project Goal: Develop a range of HIV prevention products which are **acceptable, affordable, scalable, and deliverable and meet the unmet needs of women at risk of HIV infection** through equitable **North-South partnerships** and rigorous evaluation of project R&D activities



USAID Strategic Priorities for HIV Prevention Product R&D





MATRIX Overview:



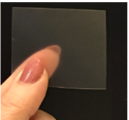



Advancing R&D of Innovative
HIV Prevention Products for Women

Six Technical Areas



Technical Area	Objective	Led by
1: Early-stage product R&D	Support research of game-changing products (within 5 years of an IND application)	MATRIX Prime and Technology Accelerator Activity Hub; Includes Product Development (PD)
2: Late-stage product R&D	Support research of later-stage products (within 5 years of regulatory approval)	no PD groups in this space currently
3: Clinical trial design for R&D	Implementation of strategies to provide evidence of product safety among US and African women	Clinical Trials Activity Hub
4: Participatory research for product R&D	Engage HIV prevention target populations/ audiences to identify product preferences, needs and priorities and inform technical decisions	Design to Delivery (D2D) Activity Hub
5: Local R&D capacity strengthening	Improve and expand equitable and productive R&D partnerships among local institutions, scientists	Capacity Strengthening, Engagement and Mentorship (CaSE) Activity Hub
6: Business case for R&D	Ensure R&D investment decisions are informed by an understanding of eventual market uptake	Business, Market Dynamics and Commercialization Hub (BACH) Activity Hub

MATRIX Product Pipeline Overview

2	Product	Developer	Product Type	Active ingredient	How used	How long protected?	MPT?	Unique features	Status
1	 TAF/EVG Fast-dissolving insert	CONRAD (USA)	Fast-dissolving insert	TAF/EVG tenofovir alafenamide & elvitegravir (NRTI & integrase inhibitor)	On-demand (at the time of sex)	Up to 3 days	HIV and HSV	Could be used vaginally or rectally - as PrEP or PEP	US/North American studies conducted first Phase 1 study in African women planned for 2023
2	 Griffithsin Fast-dissolving vaginal insert	Population Council (USA)	Fast-dissolving insert	A protein -Griffithsin Viral entry inhibitor	On-demand (at the time of sex)	4 hours	HIV and HPV HSV	Active ingredient derived from seaweed	Pre-clinical
3	 One month dapivirine vaginal film	Univ of Pittsburgh (USA)	Vaginal film	Dapivirine NNRTI	Women insert themselves	1 month		Releases drug until film completely dissolves	Placebo study being planned for 2023
4	 Non-ARV/ nonhormonal contraceptive multipurpose vaginal ring (LAMP-IVR)	Oak Crest Inst of Science (USA)	Vaginal ring	A peptide (protein fragment)- acts against HIV (& HSV/HPV) A small molecule Inhibits sperm's movement & ability to penetrate, fertilize eggs	Women insert themselves	1-3 months	HIV and HPV HSV pregnancy	Non-ARV and nonhormonal Could be used with or without contraceptive	Placebo trial being planned for 2023
5	 Cabotegravir injectable depot	CONRAD (USA)	Injectable depot (storage bubble)	Cabotegravir Integrase strand inhibitor	Injection given under the skin	4-6 months		May be less burden on healthcare system and users	Pre-clinical
6	 Cabotegravir dissolvable pellets	CONRAD (USA)	Pellet implant	Cabotegravir Integrase strand inhibitor	Implanted under skin	9-12 months		Slowly dissolves over course of a year; Can be removed after 1-2 months if needed	Pre-clinical

7	 One month dapivirine vaginal film plus levonorgestrel (LNG)	8	 Cabotegravir injectable depot plus LNG	9	 Cabotegravir dissolvable pellets plus LNG
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Three products also to be developed as an MPT with the addition of a hormonal contraceptive

TAF/EVG Inserts



- Contains 2 anti-HIV drugs, tenofovir alafenamide (TAF) and elvitegravir (EVG) (**NRTI and Integrase inhibitor**)
- Designed to possibly be used on-demand, either before sex (as PrEP) or as PEP (post-exposure prophylaxis) after sex; may offer about 3 days of protection
- User can insert it into vagina or rectum themselves
- Potential to prevent HIV and HSV (Herpes) acquired through vaginal or anal sex
- MATRIX 001 - Phase 1 trial with vaginal use in US and Africa - 2023

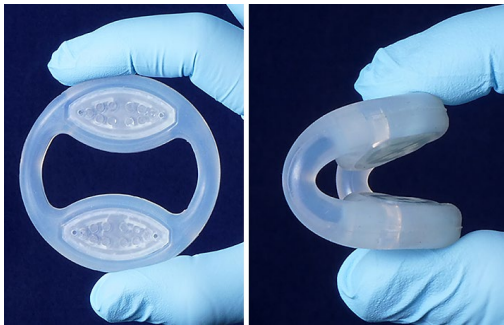
GRFT Fast Dissolving Insert (FDI)



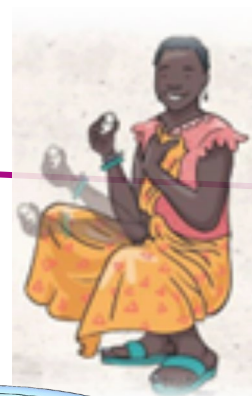
- Griffithsin (GRFT): Non-ARV anti-HIV ingredient derived from red algae that gets released from the insert – **Viral entry inhibitor**
- Non-ARV with low risk of HIV resistance, and no HIV testing required prior to use
- Individuals may be able insert FDI vaginally (or rectally) themselves shortly before sex
- Designed to provide protection against HIV for at least 4 hours after insertion
- Activity against Herpes Simplex Virus (HSV) and Human Papilloma Virus (HPV)
- Considered inexpensive, scalable, able to manufacture in LMIC

Oak Crest Non-ARV Non-hormonal MPT Ring

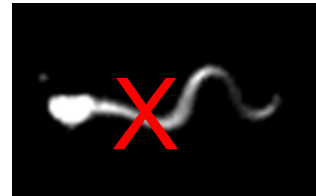
IVR is Soft and flexible;
Inserted with your finger



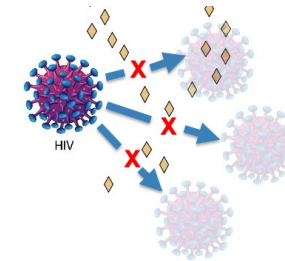
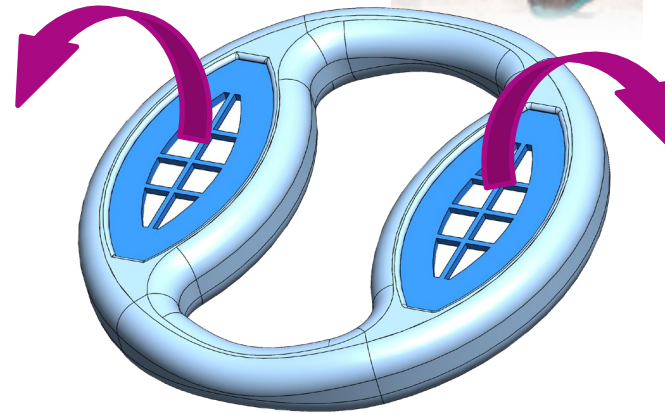
A provider will teach women how to insert and remove



Once in place, the IVR will release the two biomolecules into the vagina



One drug blocks sperm



One drug blocks HIV



IVR is left in place the whole month, then replaced

EVERY MONTH	
X	→
	→
	→
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	→
	→

One-month dapivirine (NNRTI) vaginal film for HIV prevention with and without Levonorgestrel (LNG)

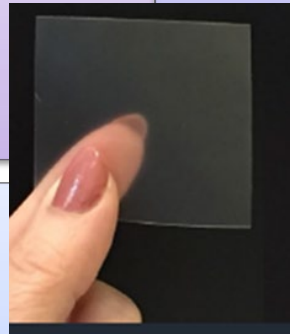


Ease of Use & Privacy:

Women control use and insertion of film
Can be used discreetly and inserted anytime in private
Not expected to impact sex

Superior & Convenient Platform:

Removal not required
Complete drug release
Small and portable



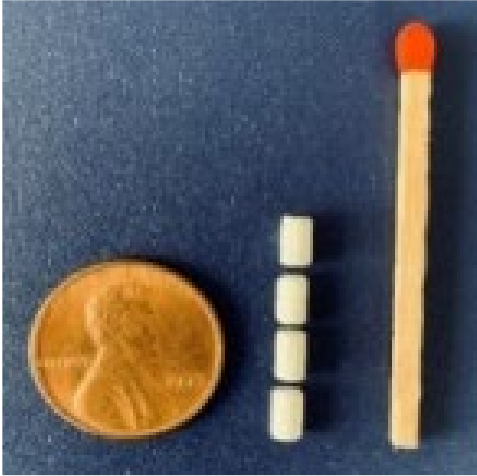
Low Cost:

Inexpensive to manufacture
No applicator required

Safe with No Messiness:

Minimal impact on vaginal health
Minimal to no additional vaginal discharge

CAB Pellets and CAB Depot with or without LNG



CAB Pellets



CAB Depot 1-1.5ml depot

- Both products contain cabotegravir (CAB), an ARV approved for HIV prevention- Integrase strand inhibitor
- Would be administered under the skin by a healthcare provider, similarly to contraceptive implants (pellets) or injectables (depot)
- Designed to provide ultra-long-lasting HIV protection (~6-12 months)
- May be used by people of all ages and gender
- Would limit health care system impact by reducing the number of clinic visits, cost, time, and monitoring

MATRIX Activity Hubs

Advancing R&D of Innovative
HIV Prevention Products for Women



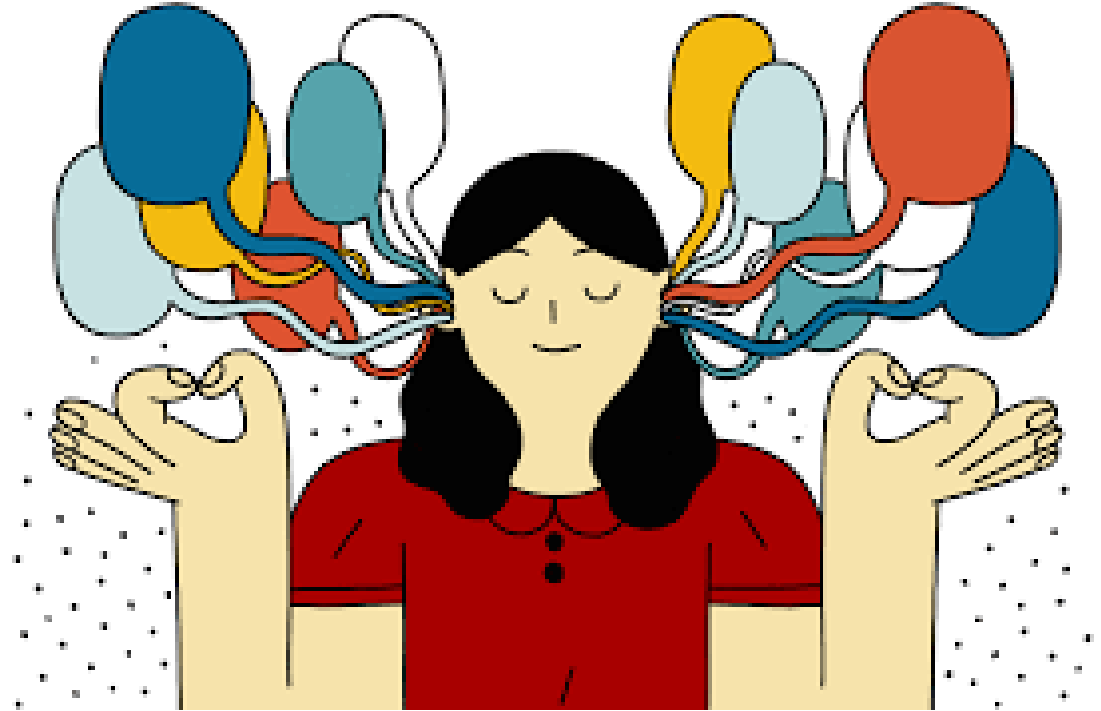
- **Technology Accelerator to support onboarding of innovations and mitigating unanticipated challenges for products**
- **Clinical Trials:** Matching PDs with clinical trial sites in SSA and providing input on trial design and study implementation
- **Design to Delivery (D2D; the end-user and stakeholder hub)**
 - **End-user acceptability of and preferences for HIV prevention products**
 - **Socio-behavioral research in clinical trials**
 - **Broad stakeholder engagement**
- **Business, Market Dynamics and Commercialization Hub (BACH; for business cases, investor linkages, and analytics)**
- **Capacity Strengthening, Engagement and Mentorship (CaSE) hub (for tailored mentorship and training)**

Reminder of MATRIX goals

Develop a range of HIV prevention products that are :

- **Acceptable:** integration of **end-users and stakeholders'** feedback from the earliest stages of product development and the deliberate intention to conduct early-stage clinical trials in Sub Saharan Africa to gain early insights on the acceptability of HIV prevention products.
- **Affordable** : Making products more **affordable** by **extending efficacy windows**, reducing costs from clinic visits, employing non-ARV based options to **reduce costs/burden** of HIV testing and leveraging scalable low-cost technologies.
- **Scalable** : Products prioritized which can be scaled up locally for **manufacturing** and issues such as **product stability and cold chain requirements** have been considered.
- **Deliverable:** MATRIX proposes an integrated program to gain input from Ministries of Health and SSA governmental bodies early **in product development** to meet needs of those in the Global South

Research Feedback loop :
Active listening, hearing and
supported synthesis of
findings and informed
incorporation is crucial to our
PDs and Critical path products
success!



Why is it so important ?



**WOMEN'S
LIVES
MATTER**



Because each of our own our lived realities is vastly different to the women and key stakeholders in Africa who need to be heard in order to inform development of products that are acceptable, affordable, scalable and deliverable !

Acknowledgements

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The contents in this presentation are those of the presenter and do not necessarily reflect the view of the U.S. President's Emergency Plan for AIDS Relief, the U.S. Agency for International Development or the U.S. Government.



PrEP-Family Planning Integration: Paving the way for the Dual Prevention Pill

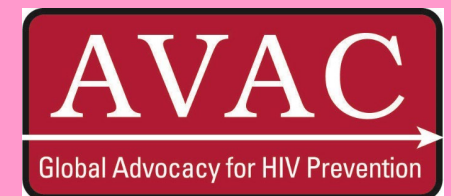
HIV Prevention Plus Plus: Developing Options that Meet the Full Range of our Sexual and Reproductive Health Needs

April 25, 2023

Ruth Akulu, AVAC Fellow 2022/23; ICWEA



International Community
of Women Living with HIV
Eastern Africa (ICWEA)



Background: ICWEA

ICWEA is a membership-based **regional advocacy organization**, founded in 2005, that exists to give visibility on issues that affect **women and young women living with HIV**.

Vision

A world where all HIV positive women:

- Have a **respected and meaningful involvement**
- Have full access to **prevention, care and treatment**; and
- **Enjoy full rights**

Background: Young People in Uganda

- **Young and rapidly growing populations**
 - 50% of the population is under the age of 15 years
 - 70% are less than 25 years of age
 - 3% HIV prevalence in young females; **3x higher than male counterparts**
 - 70% of new HIV infections occur in young females
 - More than 570 females acquire HIV weekly
 - 15% of young women experienced **sexual violence**
 - **43% of Ugandan girls are married before 18 years**

Background: Young Women in Uganda

- **High rates of pregnancy** among AGYW (25% by age 19, MOH)
 - 350,000 teen pregnancies annually, since 2018
 - 354,736 teen pregnancies registered in 2020 alone (UPHIA)
 - More than half of babies born to under 18 years
 - One in four young girls either pregnant or have given birth by age 19.
- **30% unmet need** for family planning

Gaps: PrEP and Family Planning Integration in Uganda

“I would rather get HIV than be seen pregnant”

- More young women (15-24 old) access contraceptives than oral PrEP
- Many FP providers are not trained to provide HIV services, including PrEP
- HIV risk screening, testing, and counseling is not a regular practice in FP services
- Provider attitudes toward PrEP provision, especially for AGYW, is a challenge for integrated services
- Monitoring and reporting systems are often siloes, with different registers for different services that are not always available across services

Other Barriers to PrEP and Family Planning Integration in Uganda

- Plans don't translate into implementation because it is not a core responsibility for any actor (e.g., no TWG, no local-level support) and dedicated resources to roll out integrated processes/systems are limited
- Many FP programs operate at/over capacity; integrating PrEP into FP without additional resources risks reducing the quality of both services
- In some settings, both HIV and FP programs experience regular commodity stock-outs, which can hinder integration efforts

Progress and Achievement through the Girl Power Project

National Dialogue with FP and PrEP Key Stakeholders

- Key discussion points:
 - Global perspective on PrEP/FP integration
 - Overview of HIV/SRHR integration in the country
 - Perspectives on PrEP/FP integration from panel of AGYW, health workers, human rights advocates, and MOH
 - Commitments were made towards advocating for PrEP/FP integration by CSOs
 - MOH to review HIV/SRH integration strategy clearly emphasizes PrEP/FP integration



Recommendations for MOH: PrEP-FP Integration

- Operationalize policies and guidelines—The National Strategy for Integration of SRH, GBV, HIV/AIDS, TB, and Nutrition Services 2022-2025—off the shelves & into the clinics!
- Ensure financing mechanisms by Global Fund and PEPFAR
- Create communications campaign
 - Create materials in local languages
 - Disseminate information on FP and PrEP services
 - Address stigma and discrimination
- Strengthen monitoring and evaluation
- Ensure supply chains, and human resource capacity
 - Consistent supply commodities to avoid stock out by JMS and NMS
 - Train health providers on PrEP distribution and counseling
- Engage young women involved in designing PrEP-FP integrated services
- Foster learning from countries that have successfully implemented PrEP/FP integration (e.g., Kenya)
- Partner with private sector to strengthen PrEP/FP integration

Steps Towards Achieving Effective PrEP and FP Integration

PLANS & POLICIES



Integration plans

National PrEP plan includes FP sites as PrEP delivery channels, supported by broader prioritization of HIV–FP integration in national HIV, FP, and/or SRH plans.

Coordination bodies & champions

National and subnational policymakers actively support HIV-FP integration, either as part of a coordinating body or as individual champions.

Guidelines for differentiated delivery

Guidelines enable PrEP delivery across FP sites by allowing non-HIV providers to offer PrEP, not requiring creatinine clearance testing, and allowing multi-month dispensing for PrEP.

Eligibility criteria

PrEP is available for general population women and AGYW, in alignment with FP eligibility.

RESOURCE MANAGEMENT



Financing

Financing for HIV prevention, and oral PrEP specifically, is available to be used in FP settings to support integration.

Procurement

HIV and FP procurement are centralized and coordinated so that PrEP can be easily procured in FP facilities and programs.

Supply chain management

FP sites have effective mechanisms for forecasting demand, avoiding stock-outs, and managing PrEP stores.

SERVICE DELIVERY



Risk screening & HIV testing

FP providers and/or counselors regularly provide risk screening, HIV tests, and referrals to HIV services for FP clients in accordance with guidelines and/or standard operating procedures.

Provider training

PrEP training is widely available to FP providers (e.g., FP providers are invited and able to attend training, and training time is not prohibitive).

Ongoing mentorship/supervision

Regular mentorship/supervision exists for integrated service providers (e.g., by cross-cutting teams at subnational level).

Support staff capacity

Support staff (e.g., counselors, peer educators, navigators, community health workers) enable provider task-shifting to support integrated service delivery.

Dual Prevention Pill: Progress and Achievement through the Girl Power Project

Information & Education around Dual Prevention Pill Research

- Meeting with Uganda's National Drug Authority
- DPP advocacy platforms were identified and education was conducted:
 - DVR meetings
 - HIV Prevention Research Committee & Coalition
 - AGYW Forum meetings
 - SRHR-related meetings
- PrEP/FP integration was emphasized to pave way for DPP



Paving the Way for the Dual Prevention Pill and other MPTs

- Currently undergoing bioequivalence testing for DPP
 - Regulatory submission in 2024; could be in Uganda in 2025
- PrEP/FP integration could increase uptake of both commodities
 - Could pave the way for DPP demand and other future MPTs
- Diversifying service delivery of integrated PrEP/ FP package through pharmacies could lay the ground work for DPP/MPTs introduction
 - CSOs and MOH have advocated for funding for pharmacy-based PrEP delivery through PEPFAR
 - Discussions around modality of implementation still ongoing

Expected Outcomes of PrEP-FP Integration

- Reduced HIV-related stigma and discrimination
- Better utilization of scarce human resources for health
- Dual protection against unintended pregnancies and STIs including HIV
- Decreased duplication of effort
- Better understanding and protection of individuals' rights
- Enhanced programme effectiveness and efficiency
- Increased market for PrEP (oral, ring and injectables) and the Dual Prevention Pill

Thank You for Listening

Multipurpose Prevention Technology for Key Populations

Greg Millett

Director of Public Policy

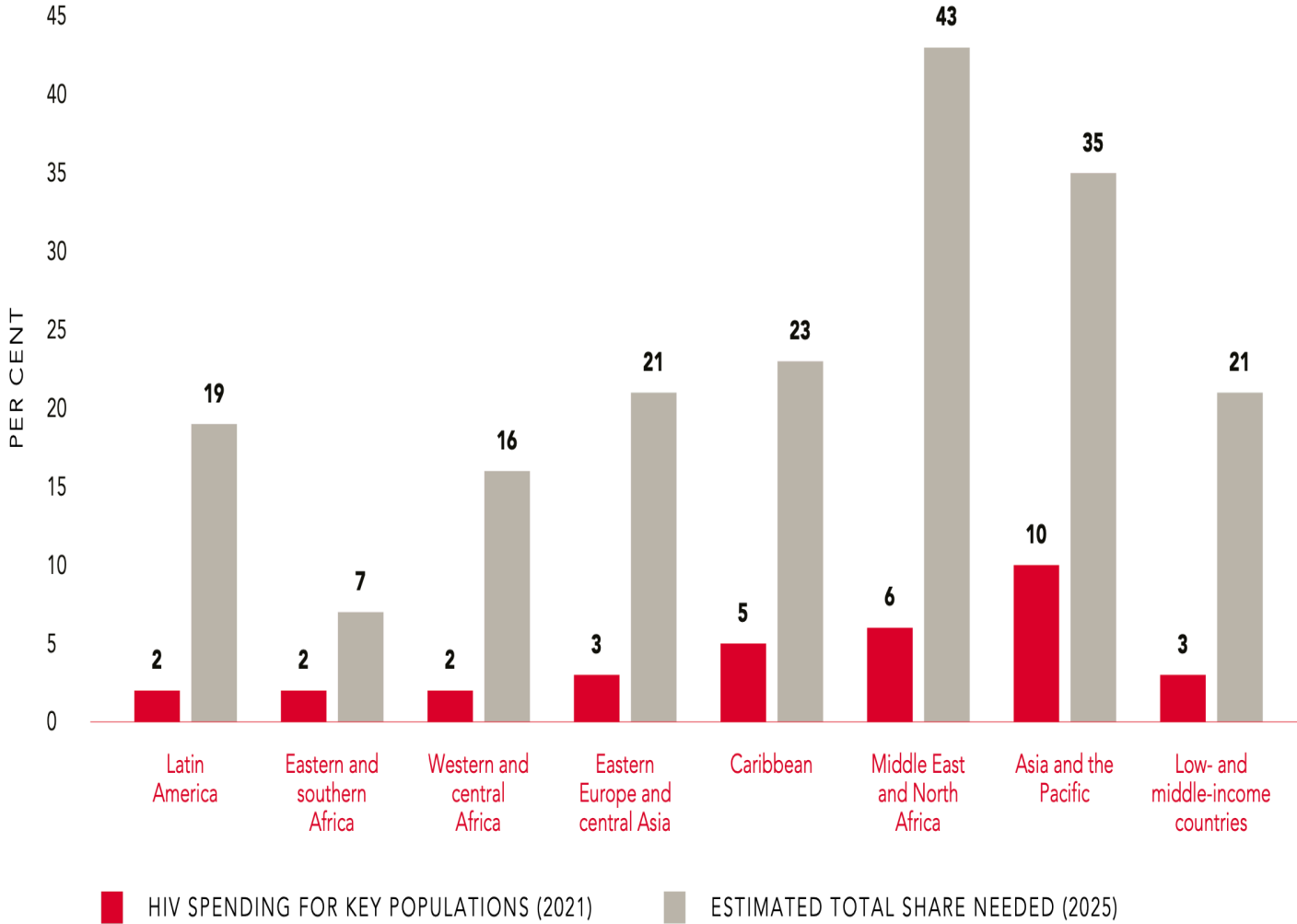
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April 25, 2023

KPs and HIV Globally

- KPs are less than 5% of the global population
- but 70% of all new HIV infections worldwide were among key populations and their sexual partners.

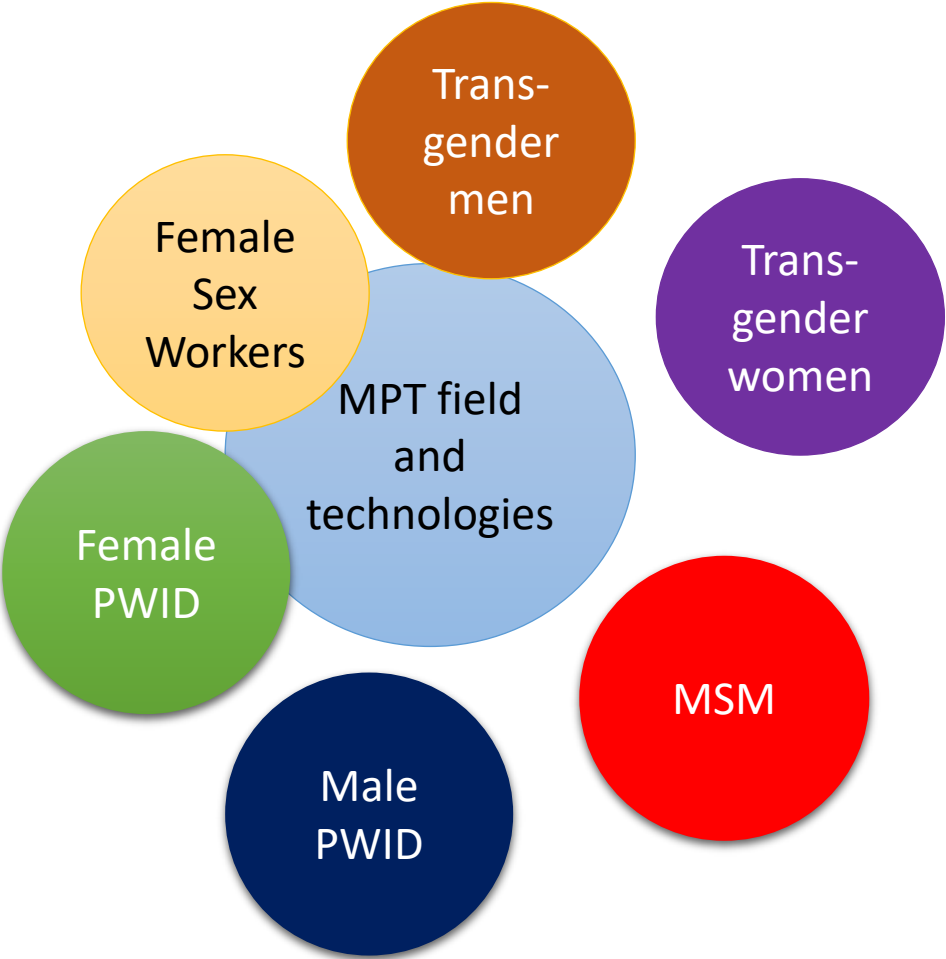
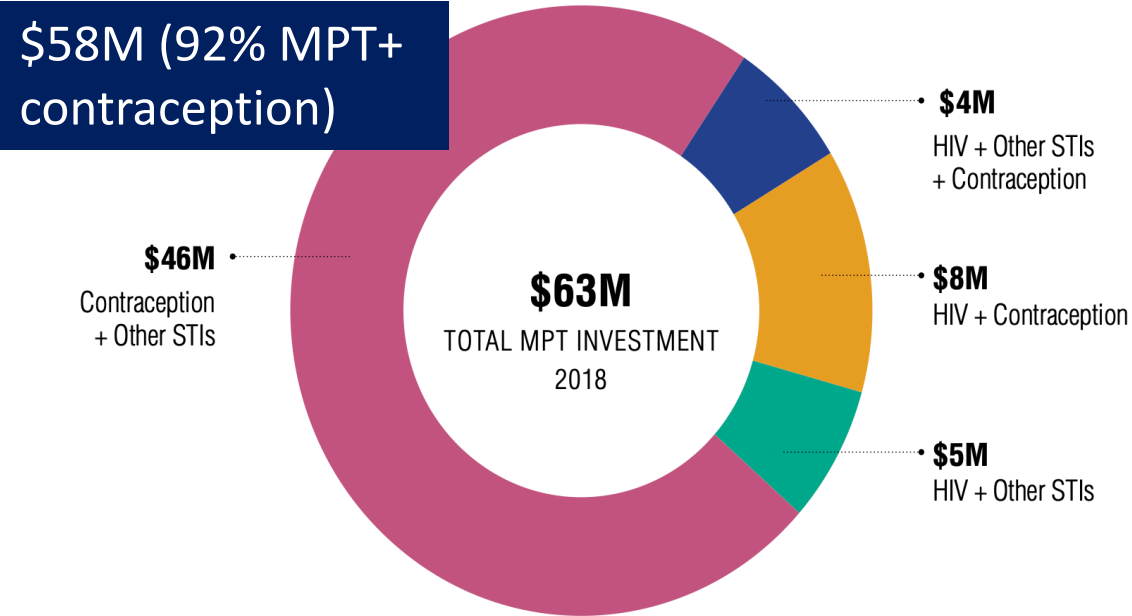
FIGURE 4.4 Percentage of total HIV spending for prevention and societal enabler programmes for key populations, 2021, and estimated total share needed, 2025, in low- and middle-income countries and by region



Multipurpose Prevention Technologies Investment Lag for Some Key Pops More than Others



INVESTMENT BY MPT INTERVENTION, 2018
(USD Millions)



*2019 data is not yet fully available; graphic will be updated when possible

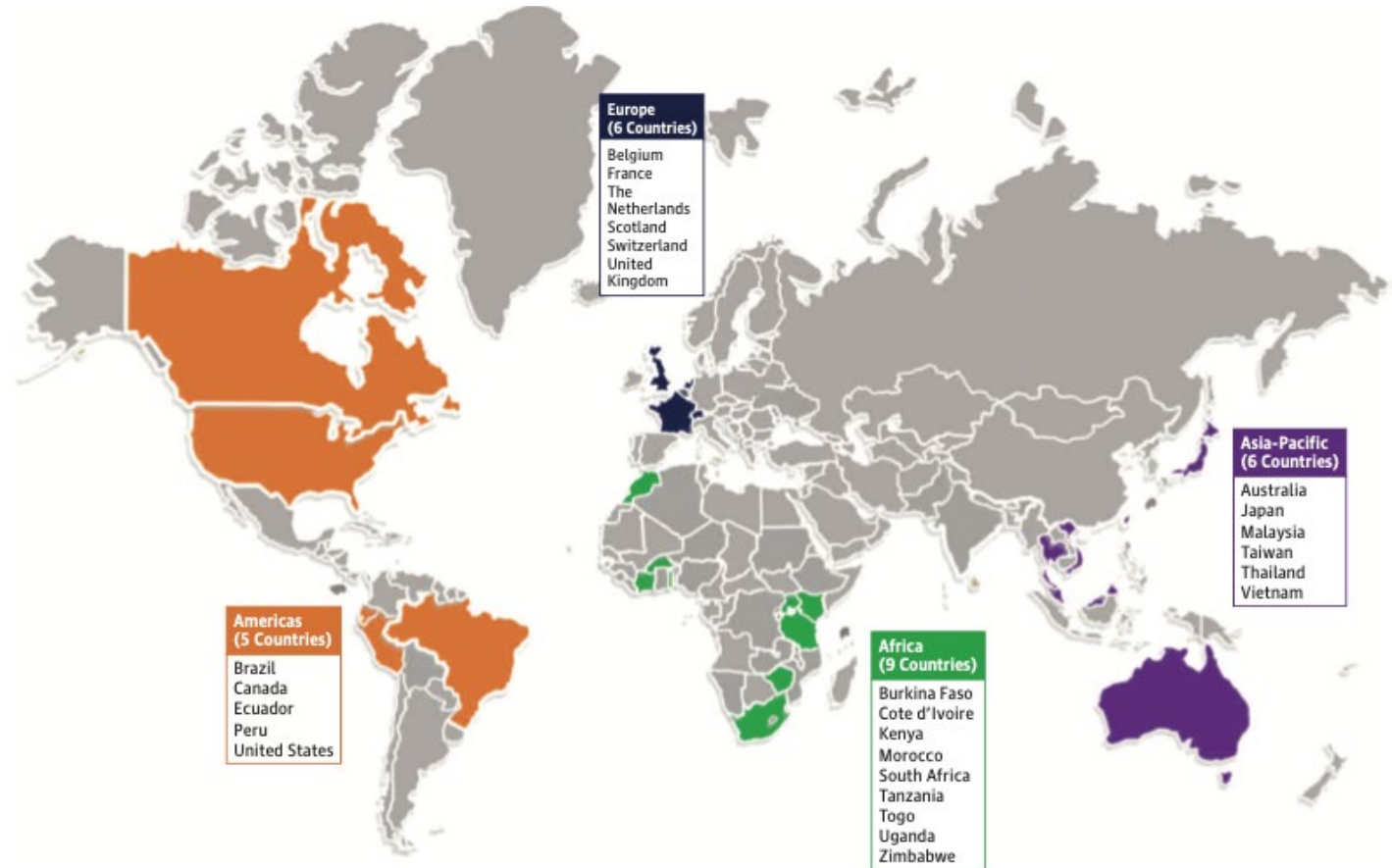
Source: Resource Tracking for HIV Prevention R&D Working Group, 2018 Report; The Initiative for MPTs (IMPT)

KPs and the case for MPTs

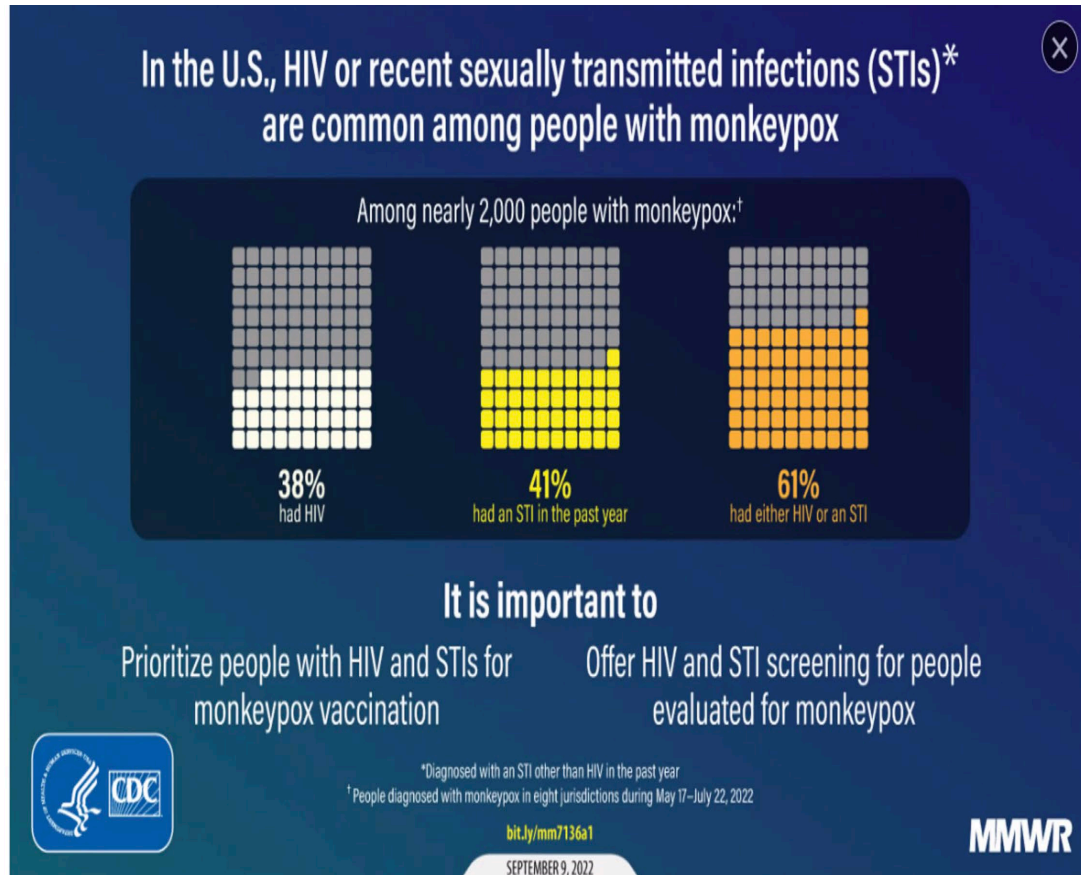
Systematic Review and Meta-analysis of STI among People who use PREP

88 studies

- Composite outcome any chlamydia, gonorrhea, and early syphilis
 - pooled prevalence was 23.9% (95% CI, 18.6%-29.6%)
 - pooled incidence was 72.2 per 100 person-years (95% CI, 60.5-86.2 per 100 person-years)
- Gc greater in MSM studies
- Ct or Gc highest in the anorectum compared to genital or oropharyngeal sites
- Ct and Gc higher in HICs than LICs



Concurrent STI, MPOX among PrEP Users

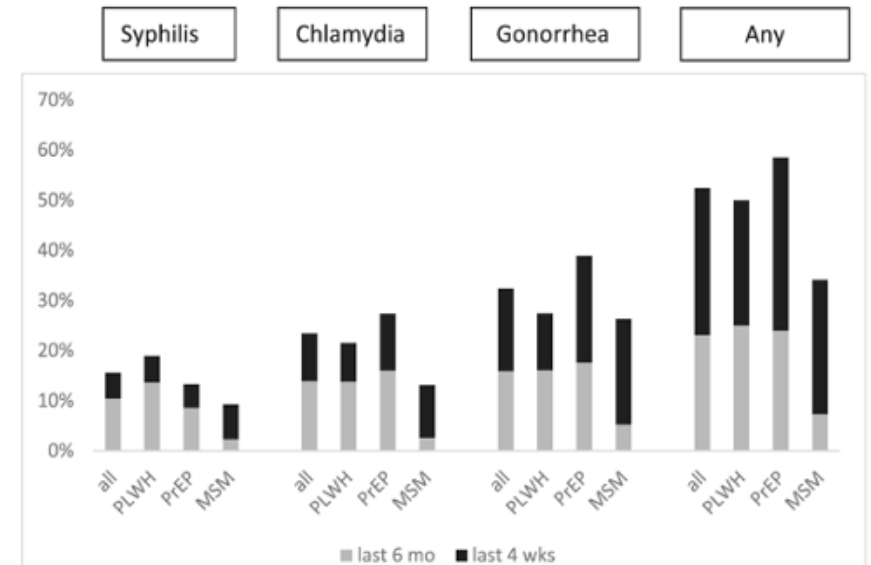


- 41% STI in past year
- 67% HIV- PrEP
- 38% HIV+
- 61% HIV or recent STI

Viral storm

52.4% dx STI last 6 months; 29.4% dx STI last 4 weeks

Clinical characteristics of monkeypox virus infections among men with and without HIV: A large outbreak cohort in Germany



- New STI diagnoses should prompt MPXV testing (and vice versa)
- Fewer proportion of recent STIs (last 4 weeks) among HIV+ and PrEP users; more among non-HIV+/non PrEP users
- Less accurate risk self-assessment/ routine care non-HIV+/non PrEP users?

MPOX Reinfection Reports

Clinical Infectious Diseases

BRIEF REPORT

A case of mpox reinfection

Stefano Musumeci¹, MD; Iris Najjar^{2,3}, MD; Emmanuelle Boffi El Amari⁷, MD; Manuel Schibler^{2,4}, MD; Frédérique Jacqueroiz^{3,5,6}, MD, MPH; Sabine Yerly⁴, MS; Adriana Renzoni, PhD⁴; Alexandra Calmy¹, MD, PhD; Laurent Kaiser^{2,3,4}, MD, PhD

1 HIV/AIDS Unit, Division of Infectious Diseases, Geneva University Hospitals, Geneva, Switzerland; 2 Division of Infectious Diseases, Geneva University Hospitals, Geneva, Switzerland; 3 Geneva Center for Emerging Viral Diseases, Geneva University Hospitals, Geneva, Switzerland; 4 Division of Laboratory Medicine, Laboratory of Virology, Geneva University Hospitals, Geneva, Switzerland; 5 Division of Tropical and Humanitarian Medicine, Geneva University Hospitals, Geneva, Switzerland; 6 Primary Care Division, Geneva University Hospitals, Geneva, Switzerland; 7 Emmanuelle Boffi El Amari Private Practice, Geneva, Switzerland.

A healthy young man first diagnosed with mpox in May 2022 presented again in November 2022 with anal proctitis and a positive PCR on a rectal swab for MPX virus (MPXV) after a recent trip to Brazil, w

Keywords:

INTRODU

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31 year old man on PrEP diagnosed with MPOX and asymptomatic urinary Chlamydia in May 2022

In December 2022, again diagnosed with Chlamydia and tested positive for MPOX

Case report

Case of apparent mpox reinfection

John Golden¹,² Lindsey Harryman,² Megan Crofts,² Peter Muir,³ Matthew Donati,³ Sophie Gillett,³ Charles Irish³

¹56 Dean Street, Department of GUM/HIV, Chelsea and Westminster Hospital NHS Foundation Trust, London, UK
²Unity Sexual Health, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK
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Received 27 December 2022
Accepted 7 January 2023

ABSTRACT

We present an apparent second episode of mpox (monkeypox) genital ulcerative disease in a non-immunosuppressed MSM (man who has sex with men) patient who had completely recovered from a primary mpox infection 4 months previously. The patient had also received a complete two-dose course of smallpox vaccination between the two presentations. This case highlights the importance of continuing to include mpox in the differential diagnoses for individuals presenting with genital or mucosal ulceration, regardless of assumed immunity derived from prior infection or vaccination.

BACKGROUND

In 2022, the first multicountry outbreak of mpox (monkeypox) was recognised outside of Africa,¹ with the majority of cases being managed in sexual health services. Most people have presented with genital, perianal or non-genital skin lesions and lymphadenopathy,² but there have also been atypical presentations³ such as proctitis.^{4,5} It is unclear

whether primary mpox infection leads to lasting immunity from reinfection.⁶ We present a case of laboratory-confirmed second mpox infection diagnosed 12 weeks after recovery from the initial infection.

PRESENTATION AND INVESTIGATIONS

A white man in his early 30s presented in July 2022 to a sexual health clinic in South West England with a recent history of inguinal lymphadenopathy, rectal discharge and rectal pain. Examination revealed obvious rectal discharge only and no external or mucosal skin lesions. He was treated empirically for proctitis with 2 weeks of doxycycline and 1 week of aciclovir. A rectal swab taken on this occasion tested positive for mpox, and he was given routine isolation advice, making an uncomplicated recovery within 2 weeks. He received two doses of Jynneos smallpox vaccination as part of the nationwide programme—the first dose given subcutaneously 1 week after this presentation and the second dose given subcutaneously 10 weeks after that. In November 2022, he re-presented with a 3-day

Table 1 Results of investigations in relation to clinical presentation, attendance and vaccination

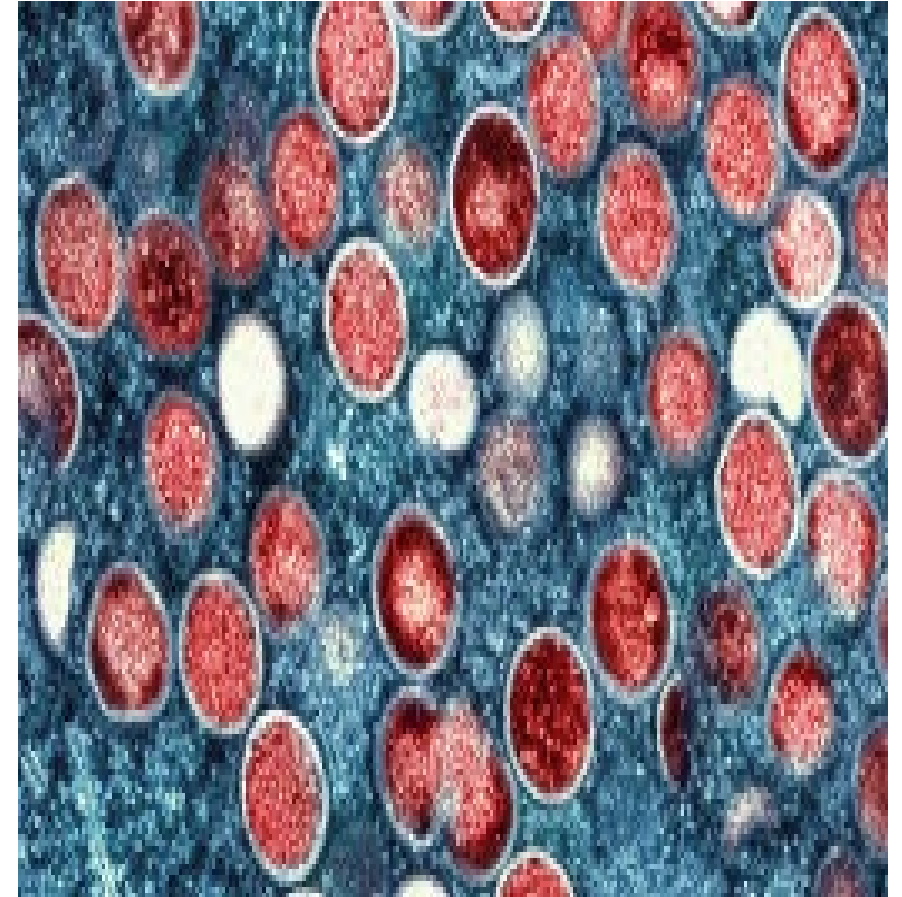
Timeline	T1*	T1††	T1&‡	T20§
	First attendance	Vaccine dose 1	Vaccine dose 2	Second attendance

Check

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To cite: Golden J, Harryman L, Crofts M, Muir P, Donati M, Gillett S, Irish C. Case of apparent mpox reinfection. *Clin Infect Dis* 2023;76:e1234. doi:10.1093/cid/ciac123

- Man in his 30s on PrEP reinfected with MPOX 4 months apart.
- HSV-2 positive
- Patient had a history of Chlamydia and Gc



DoxyPEP Significantly Reduces STIs in MSM and Transgender Women

- The risk of acquiring three common bacterial sexually transmitted infections (STIs)—gonorrhea, chlamydia, and syphilis—is significantly reduced (60%) when one 200-mg dose of doxycycline is taken within 72 hrs after condomless sex



The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE

Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections

Anne F. Luetkemeyer, M.D., Deborah Donnell, Ph.D., Julia C. Dombrowski, M.D., M.P.H., Stephanie Cohen, M.D., M.P.H., [et al.](#), for the DoxyPEP Study Team*

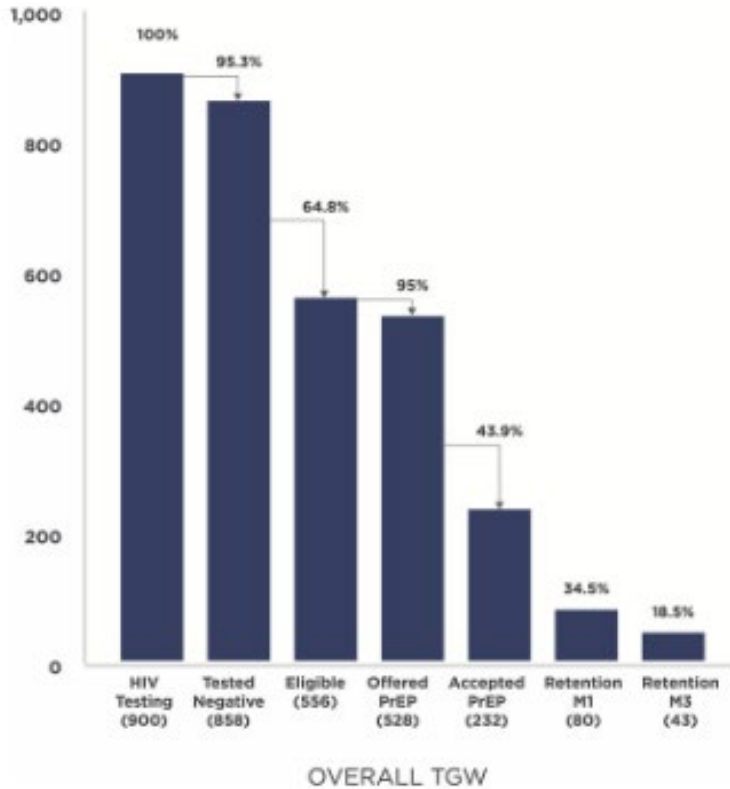
The incidences of the three evaluated STIs were lower with doxycycline than with standard care

In the PrEP cohort, the relative risks were

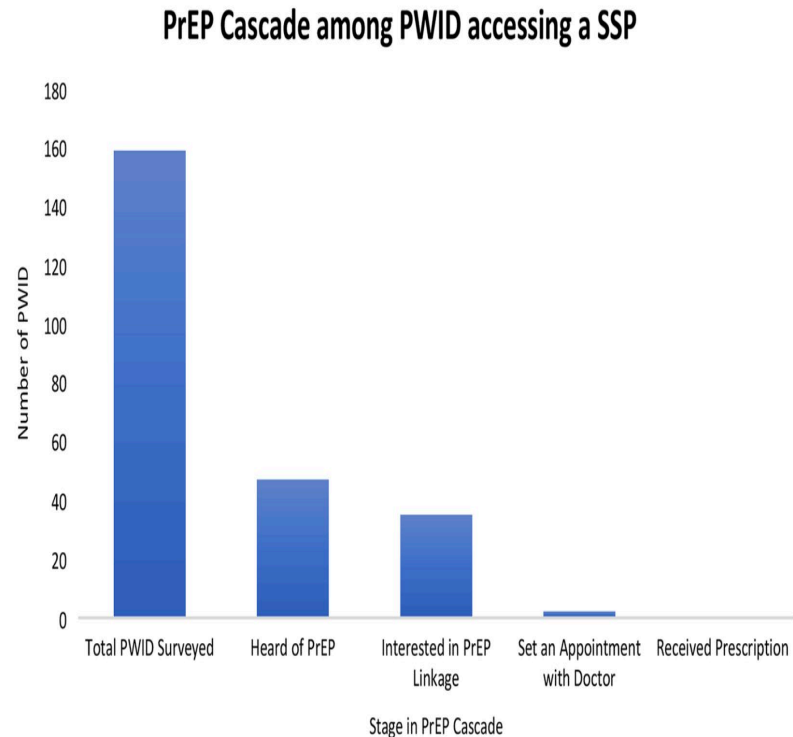
- 0.45 (95% CI, 0.32 to 0.65) for gonorrhea
- 0.12 (95% CI, 0.05 to 0.25) for chlamydia
- 0.13 (95% CI, 0.03 to 0.59) for syphilis,

Accessing, taking and remaining on daily oral PrEP is not working for KPs

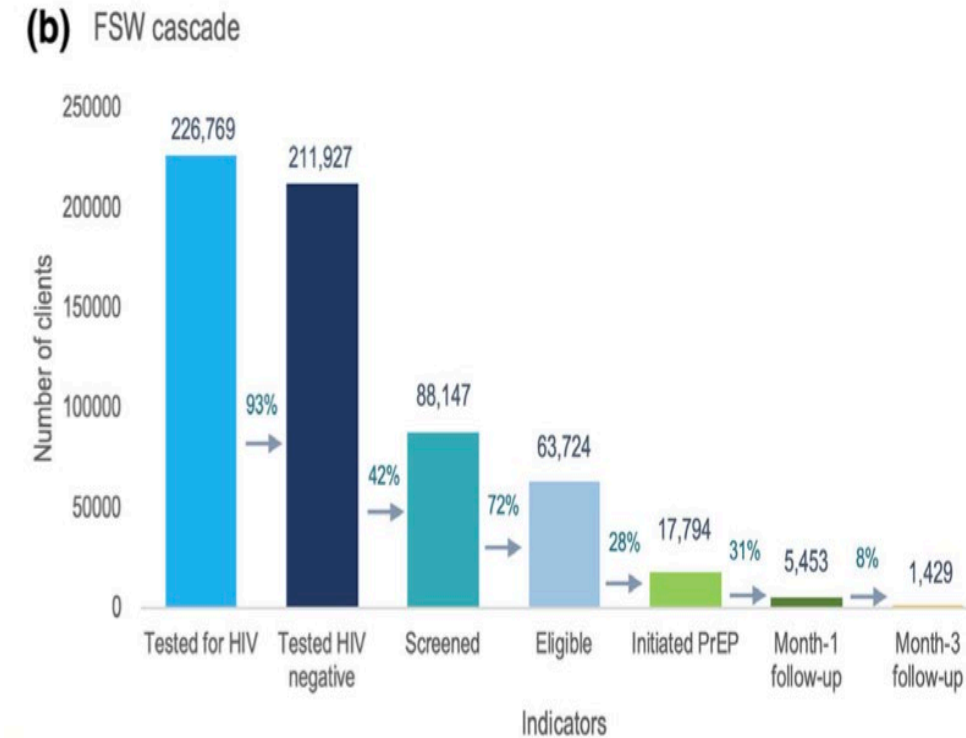
Transgender women (Thailand; Ramautarsing et al., 2020)



PWID (Miami; Jo et al., 2020)



Female sex workers (Kenya; Were et al., 2020)



Beyond HIV: Causes of Mortality among Trans Populations

- PTSD
- Cardiovascular risk
 - Stress, stigma, discrimination
- Suicide
- Homicide
- Endocrine, nutritional and metabolic diseases (3x greater risk of death compared to cisgender women)

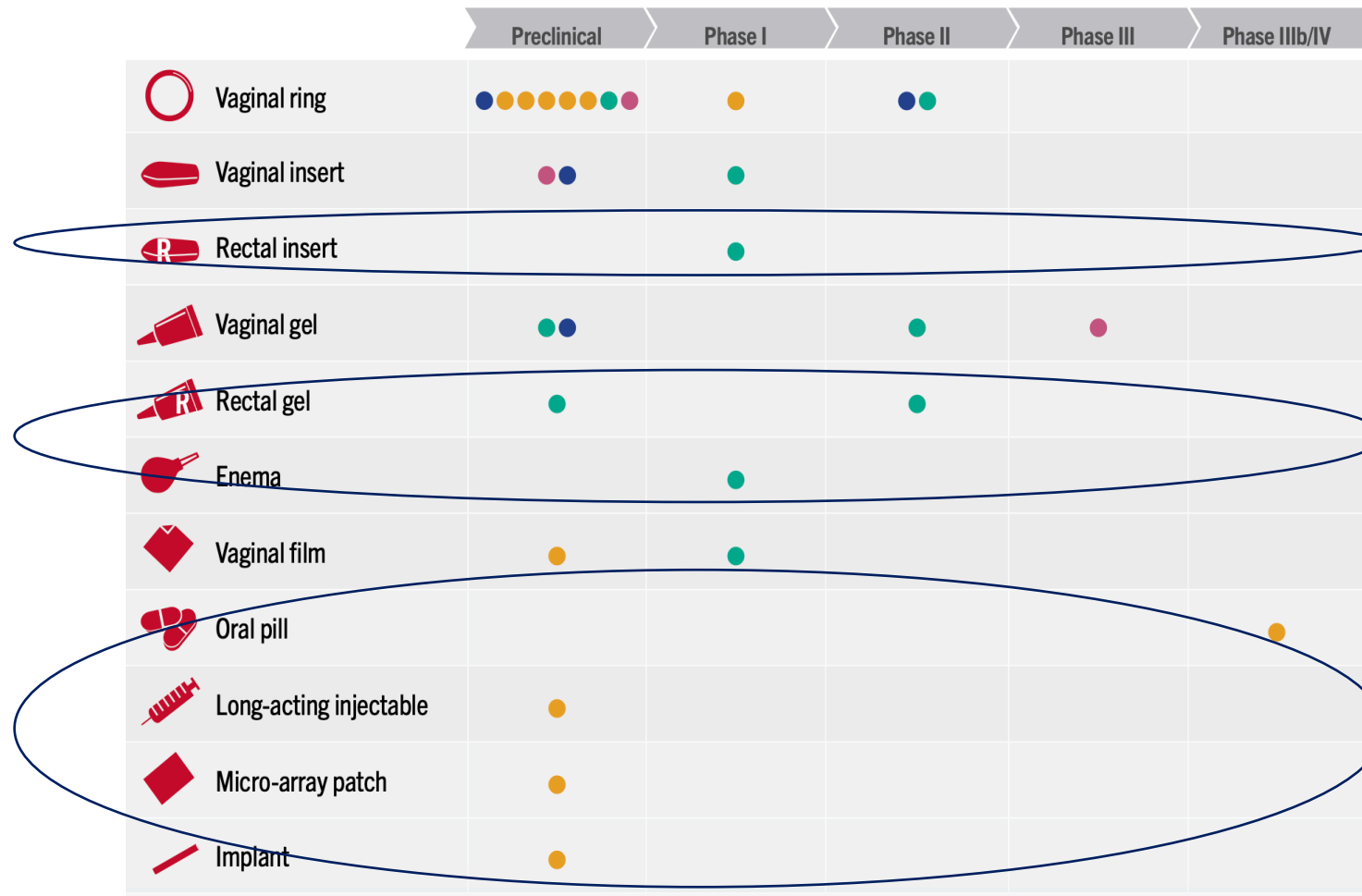
Overall and Cause-Specific MMRs for Transgender and Gender Diverse Individuals Compared with Cisgender Individuals in the UK's Clinical Practice Research Datalink^a

Cause of death	Transfeminine individuals		Transmasculine individuals	
	No. who died	MRR (95% CI) Compared with cisgender men	No. who died	MRR (95% CI) Compared with cisgender women
Overall	102	1.34 (1.06-1.68)	34	1.75 (1.08-2.83)

Advocates' Guide to Multipurpose Prevention Technologies (MPTs)

AT A GLANCE: THE MPT R&D PIPELINE

Status of products in development



Possible MPTs for Transwomen

Silicone injections

- Body enhancements (thighs, breasts, cheek bones, buttocks)
- Paired with long-term injectable PrEP

Hormone replacement therapy

- Estradiol valerate injection (every two weeks) paired with injectable PrEP
- Daily Oral 17B-estradiol (paired with PrEP, anxiety depression meds, nutritional/metabolic treatments)
- 17B-Estradiol patch every 3- 5 days, paired with meds for other ailments

Future technology

- Rectal gels, inserts, enemas



Possible MPTs for People Who Use Drugs

Inhalants

- Used to fight colds, COVID-19
- Paired with inhalant form of event driven PrEP or Doxy PEP

Patches

- That address skin conditions (e.g. psoriasis, dermatitis)
- Pair event driven PrEP

Injectables

- PrEP



Possible MPTs for Men Who Have Sex With Men

Pills

- Anxiety/ depression/ Doxy-PEP/ PrEP

Long-acting injectables

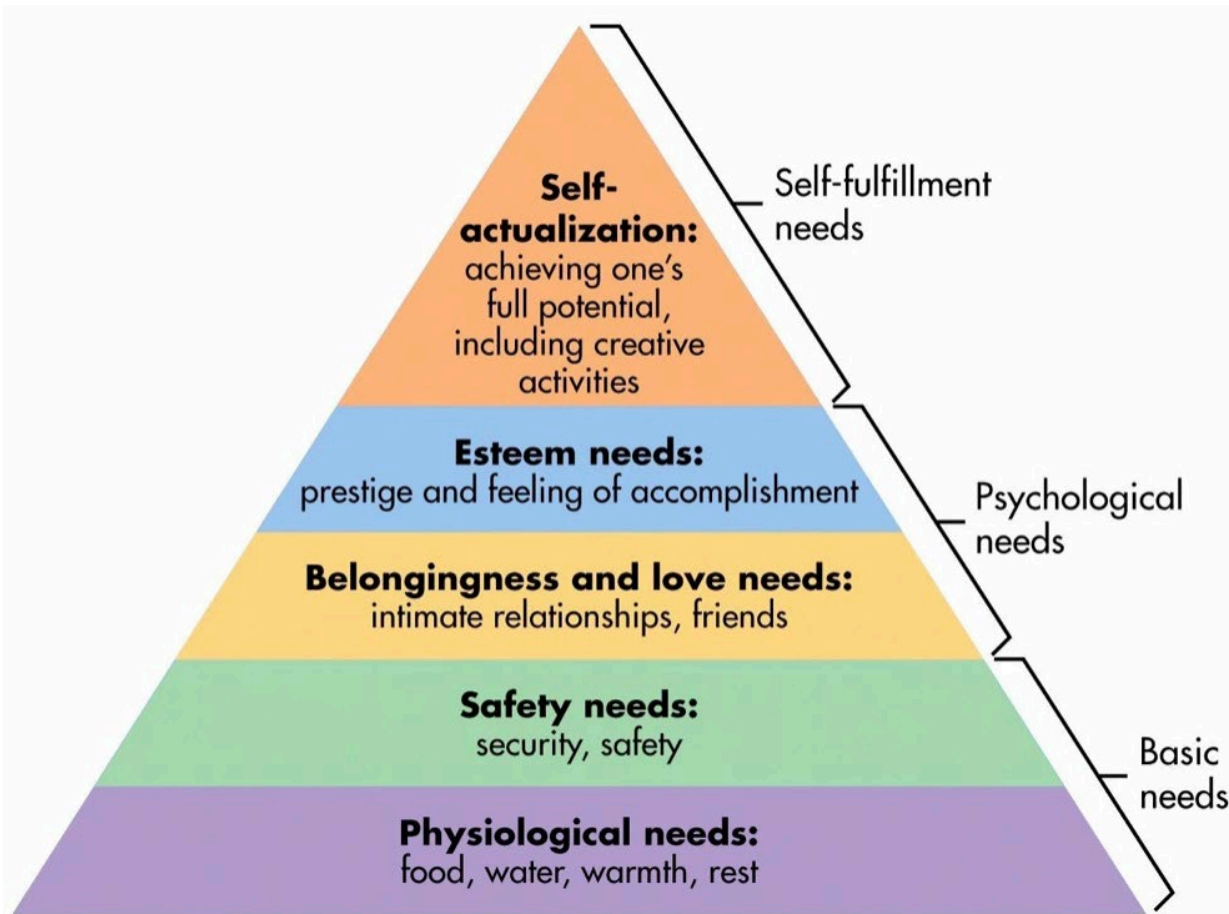
- Anxiety/ depression/ PrEP

Future innovations

Patches, implants, rectal gels, enemas, creams (e.g. testosterone)



For All Key Populations.....



- Structural level issues to address safety and basic needs (food, water, warmth rest)
- Access to affirming and non-judgmental providers
- Space for and respect community-based advocacy
- A right to live