



PEPFAR



USAID
FROM THE AMERICAN PEOPLE

Sustainable approaches to biomedical prevention: A unified approach for COP23 and beyond

4th Annual USAID Global Health Local Partner Meeting

Presenters:

Thomas Minior, USAID/HQ

Vincent Wong, USAID/HQ



Sustainable approaches to biomedical prevention

Biomedical Prevention

- VMMC
- Oral PrEP
- New Prevention Products
- Condoms

Social and Behavior Change



Despite global progress towards 95-95-95 goals, 1.5 million people still became newly infected with HIV in 2021, impacting especially vulnerable populations.



Southern & Eastern Africa accounted for 670,000 new HIV infections in 2021.



Asia and the Pacific accounted for 260,000 new HIV infections in 2021.

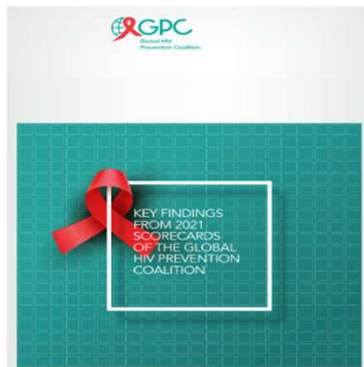
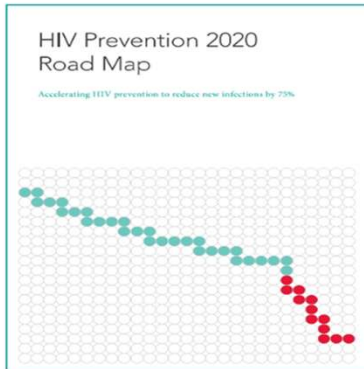


Women and girls accounted for about 49% of all new HIV infections in 2021.

Primary prevention is still needed to reduce HIV incidence beyond what is achievable with ART scale-up.

Source: UNAIDS Global AIDS Update 2022; [The case for prevention – Primary HIV prevention in the era of universal test and treat: A mathematical modeling study. Krijke et al, 2022.](#)

UNAIDS Global 2020 Prevention Targets: Where we landed in 2020

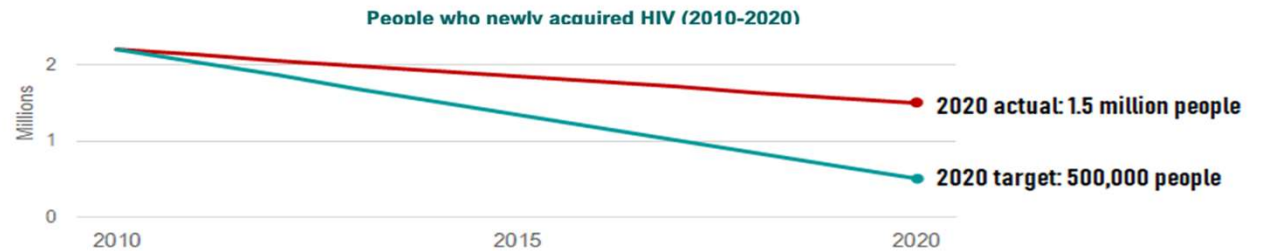


What Model Assumed (targets)

- 90% key populations reached
- 90% of young women in key locations
- >6bn condoms (SSA) per year
- 3m using PrEP
- 25m VMMC (2016-20)
- Increase in funding to 6.5bn per year in LMICs
 - Testing, treatment, viral suppression in PLHIV: 90-81-73

What Was Implemented (2020)

- 42% of sex workers, 41% for gay men & other MSM, 32% for PWID reached
- 44% of young women in key locations
- >3 bn condoms (SSA) per year
- 0.8m using PrEP
- 18m VMMCs (2016-20)
- Flat funding
 - Testing, treatment, viral suppression in PLHIV: 84-73-66



UNAIDS HIV Prevention 2025 Road Map

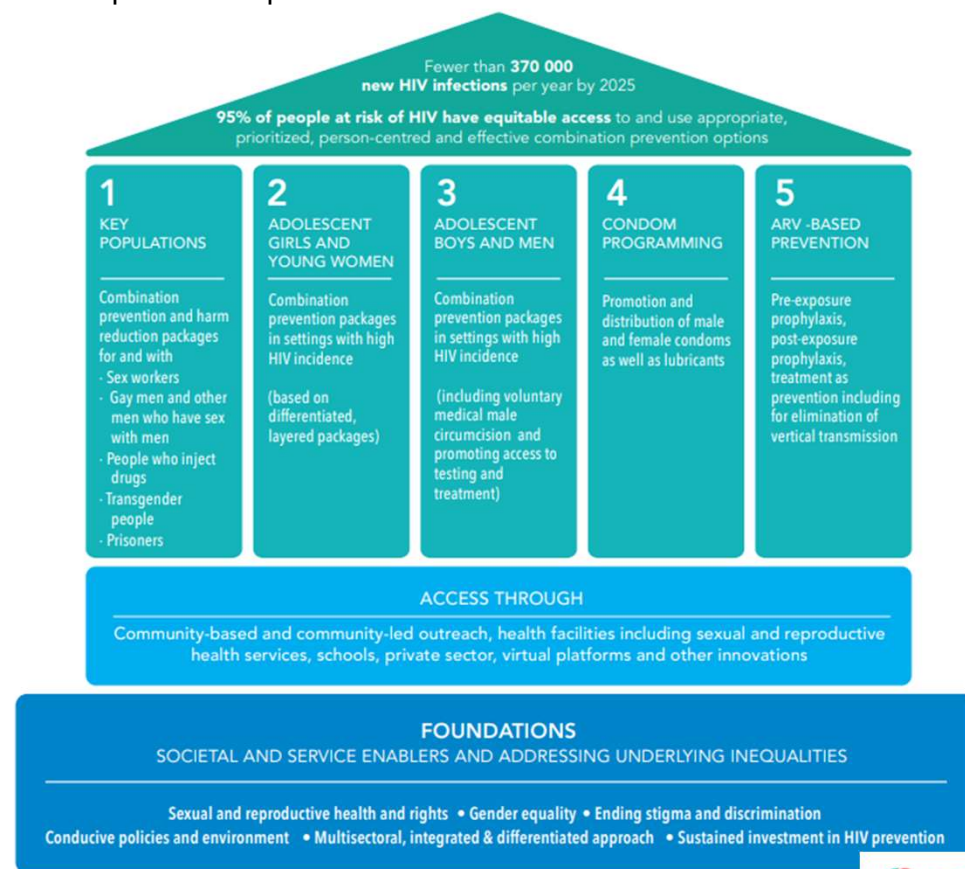


- Launched in October 2022 in Johannesburg with National AIDS Committee prevention leads, hosted by the Bill and Melinda Gates Foundation and UNAIDS
- Provides guidance to all countries - and for all populations - seeking to reduce new HIV infections
- Sets out principles, approaches, priority actions areas, and programmatic targets
- Charts country-level actions to achieve an ambitious set of targets by 2025
- Builds on findings of progress reports and on recommendations of an external review of the Global Prevention Coalition and previous Road Map

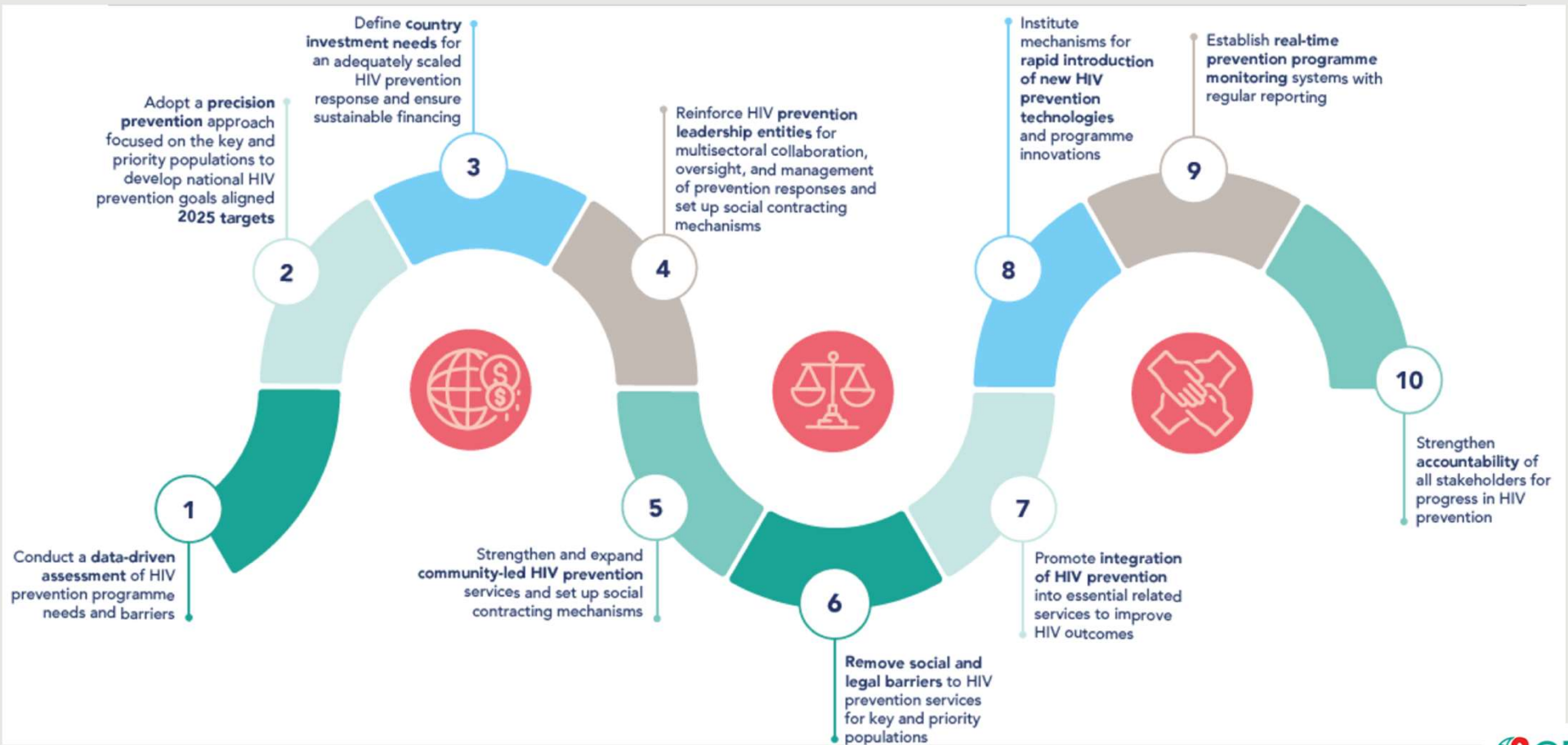
Global 2025 targets: Where we need to be

- High-level prevention target: **95% of people at risk of HIV use appropriate, prioritized, effective combination prevention** → fewer than 370,000 annual new HIV infections by 2025
- 10-10-10 targets for removing societal and legal barriers to HIV services: less than 10% of countries have legal and policy frameworks that lead to denial or limitation of access; less than 10% of PLHIV and KP experience stigma and discrimination; less than 10% of women, girls, PLHIV, and KP experience gender inequality and violence

The five prevention pillars for 2025



Global 2025 targets: How will we get there? 10 Point Action Plan



Reimagining PEPFAR | Strategic Pillars & Enablers





Biomedical Prevention



Current Prevention Programming and Focus Areas

INTERVENTIONS

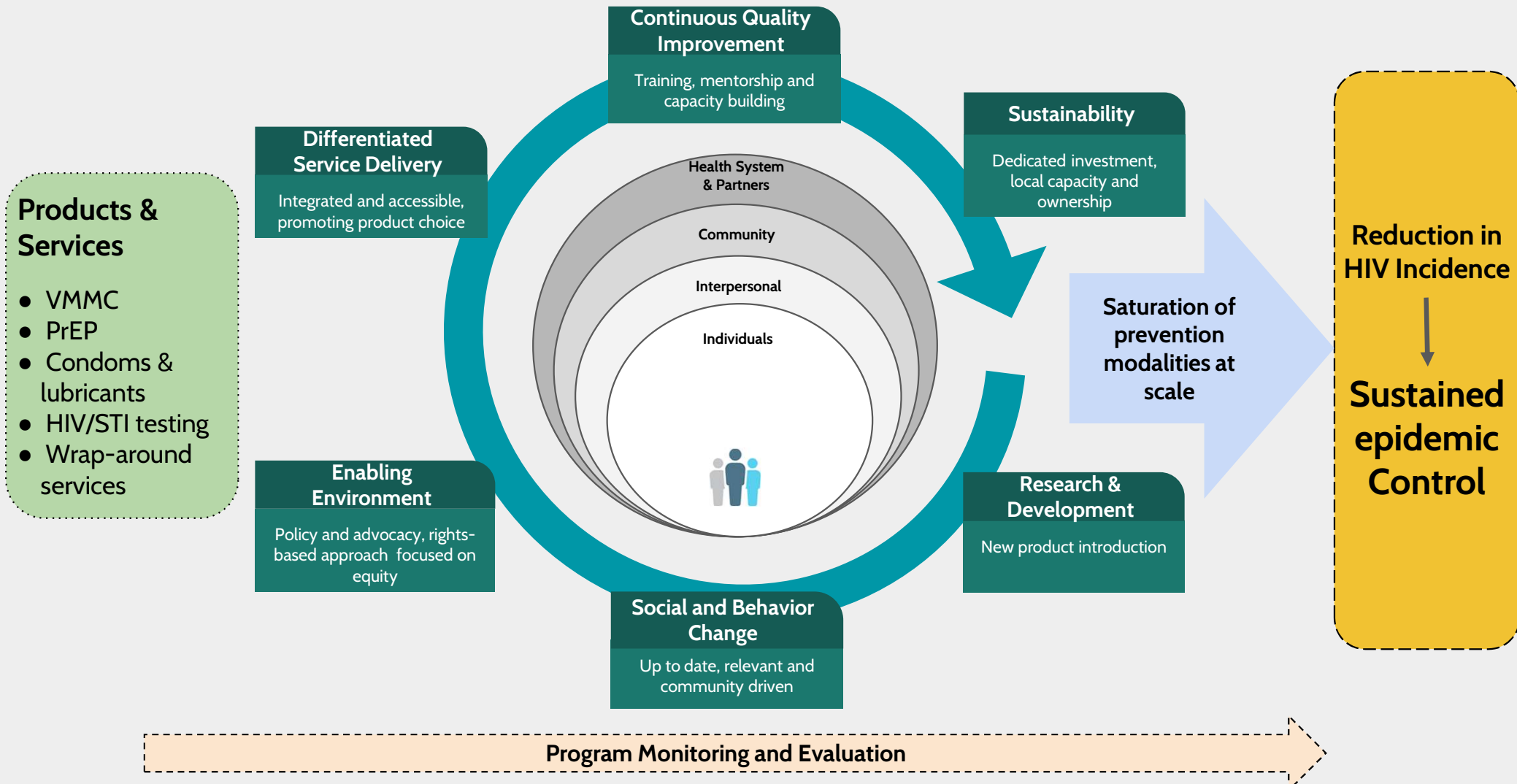
- ★ Pre- and post-exposure prophylaxis
- ★ Voluntary medical male circumcision
- ★ Male/female condoms and lubricants
- ★ New methods: dapivirine vaginal ring (PrEP ring), long-acting injectable PrEP + pipeline
- ★ Prevention of vertical transmission (i.e. PMTCT)
- ★ Harm reduction and medication-assisted treatment
- ★ Primary prevention of HIV & gender-based violence and violence against children
- ★ Viral suppression (i.e. U=U)
- ★ Structural interventions & social

POPULATIONS

- ★ Inclusive of all individuals at risk
- ★ Key populations
 - Men who have sex with men
 - Female sex workers
 - Trans diverse people
 - People who inject drugs
 - People in prison and other closed settings
- ★ Youth, particularly adolescent girls and young women
- ★ Orphans and vulnerable children
- ★ Other priority populations (SDCs, PBFW)
- ★ At-risk men, particularly aged 24-35 years
- ★ Migrant workers

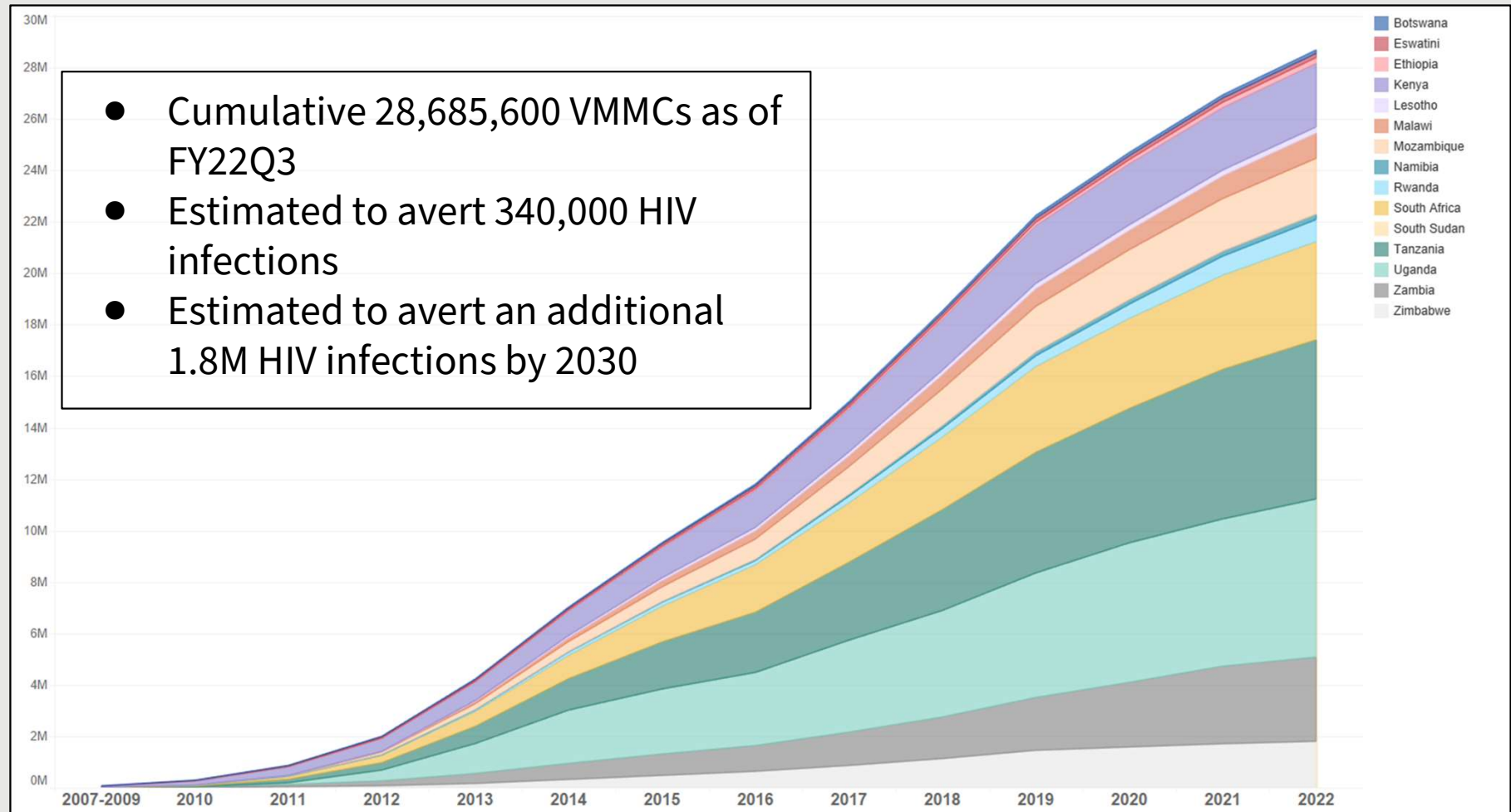
Cross-cutting efforts: continued expansion of community services and demedicalization of prevention services; rights-based approaches to prevention/services; improved prevention linkage with testing (incl. HIVST); integration of prevention with FP/SRH; normalization/rapid expansion of new and existing prevention products/interventions; collaboration and alignment with MoHs/DoHs and other stakeholders.

Biomedical HIV Prevention Theory of Change



VMMC

Over 28M VMMC's Have Been Supported by PEPFAR since 2007



Source: UNAIDS/WHO Progress Brief

VMMC by the Numbers

**COP22 PEPFAR
Target**

2,276,361

**PEPFAR COP21
Results
(FY22Q3)**

**1,745,791
(77%)**

**COP22 USAID
Target**

**652,225
(29%)**

**USAID Results
FY22Q3**

**553,472
(76%)**

of USAID OUs

10

**MLWH identified at
MC Sites (FY22),
*All Agencies***

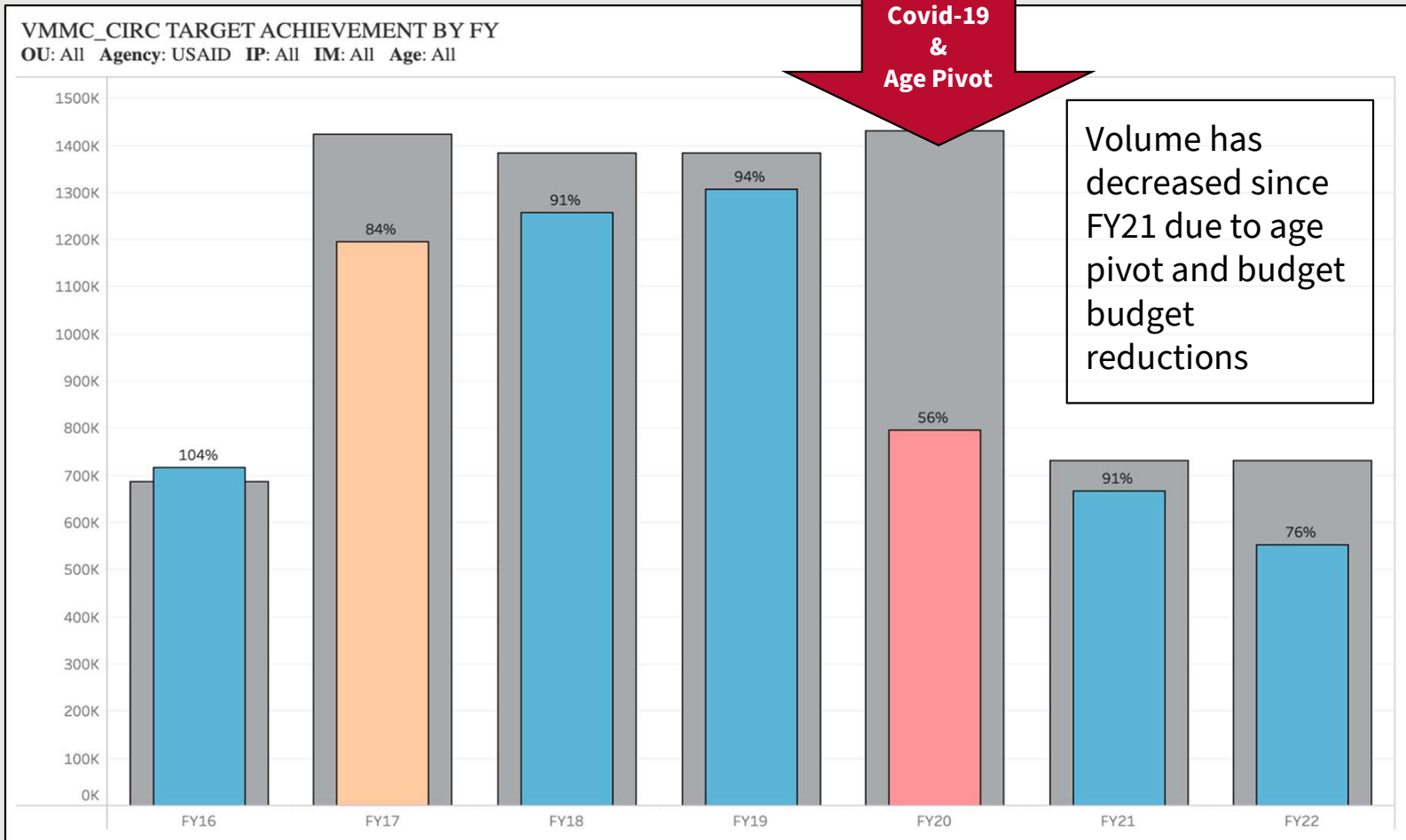
**6,550
(0.5%)**

Prevent
New HIV
Infections



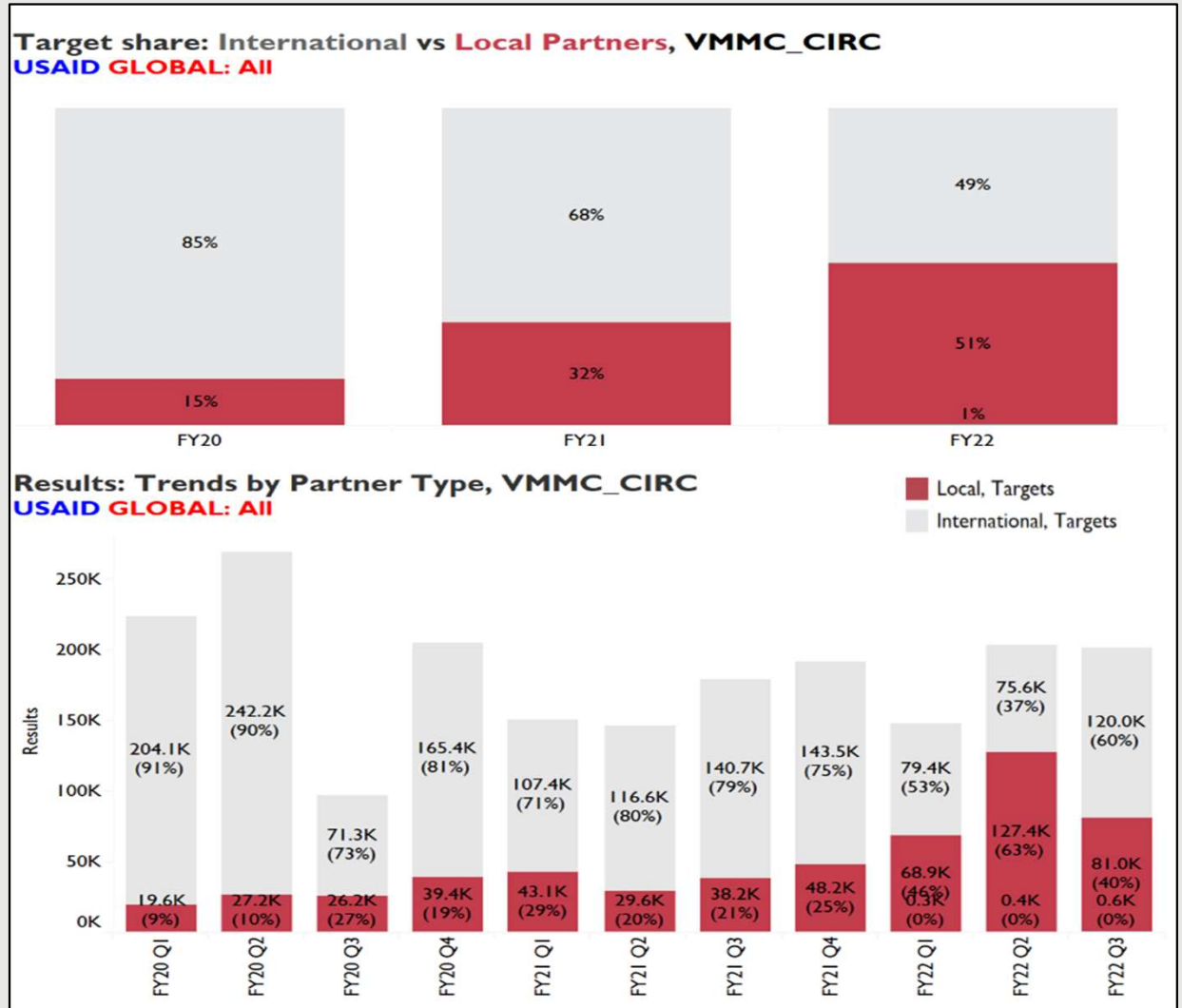
HIV
Epidemic
control

VMMC - USAID Performance Trends FY16-FY22



Local Partners: Trends in Target Shares

- Target share has been increasing among Local Partners
- In FY22, Local Partners accounted for 51% of the target share in all 10 USAID supported OUs

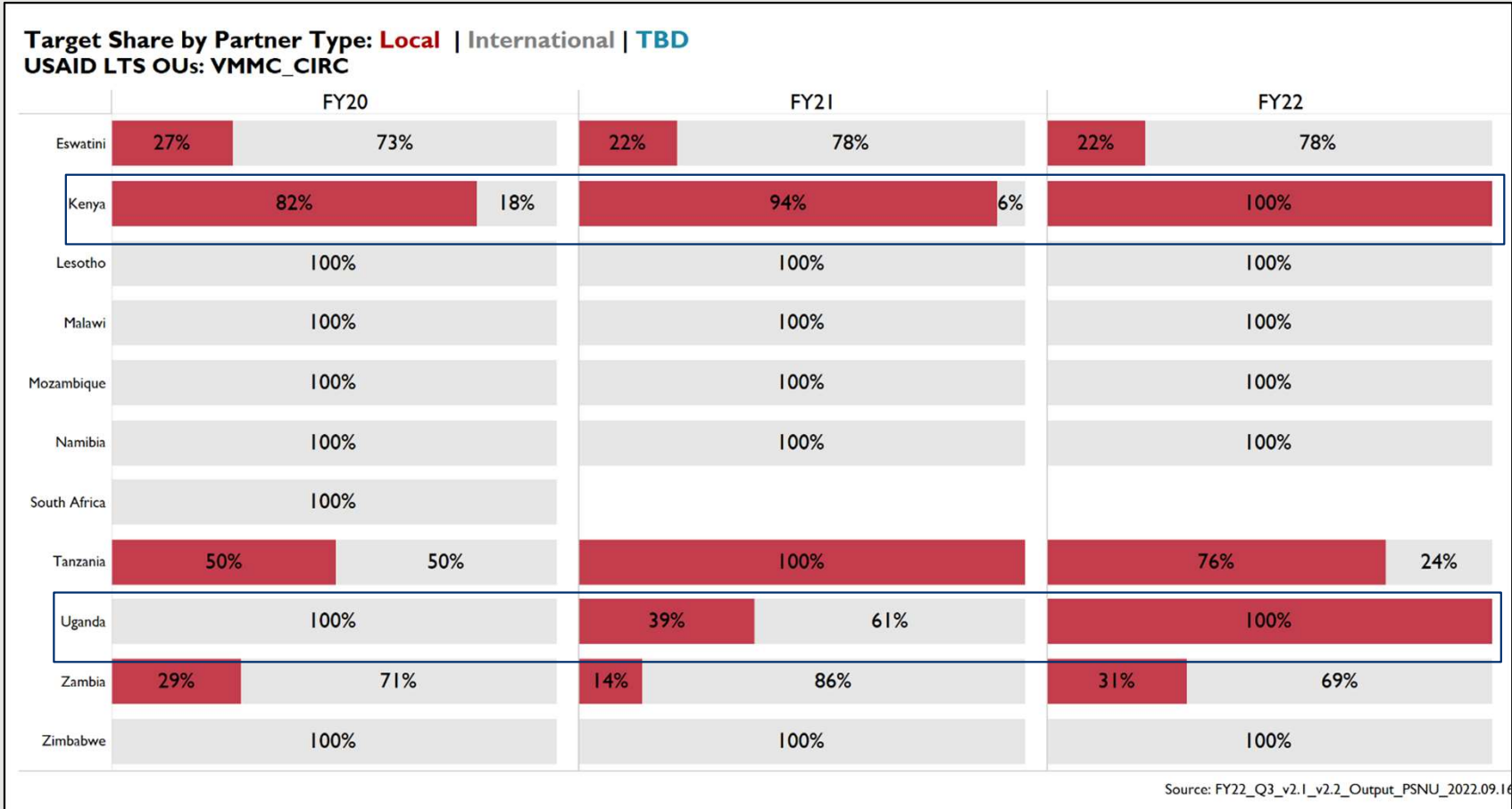


Local Partners Target Trends by OUs

Kenya & Uganda: 100% LP implementation in FY22

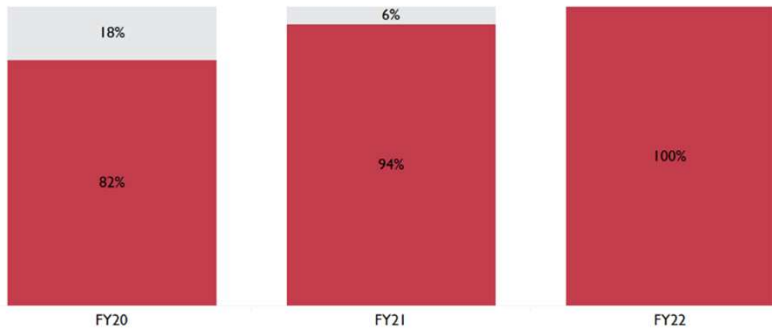
* The visual does not accurately show all the LP:

9/10 OUs have LP's contributing but the reporting is done by the Prime award recipient

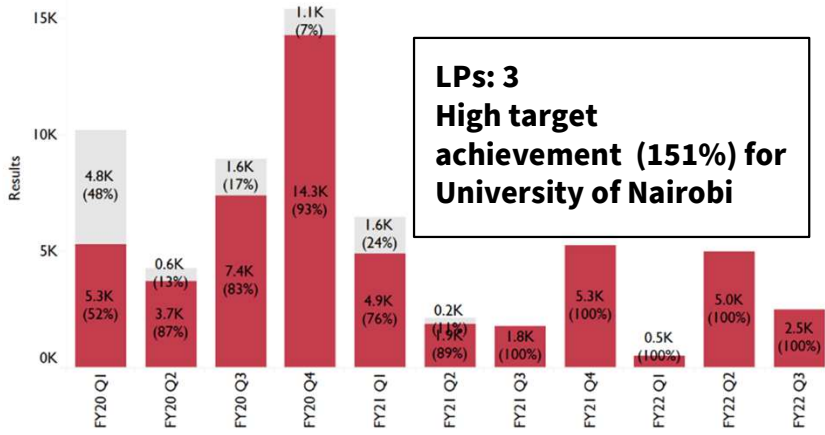


Local Partners Performance Trends: Kenya and Uganda, FY22Q3

Target share: International vs Local Partners, VMMC_CIRC
 USAID Kenya: All

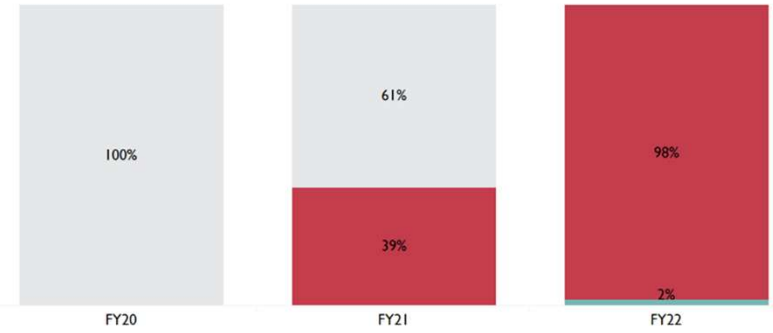


Results: Trends by Partner Type, VMMC_CIRC
 USAID Kenya: All

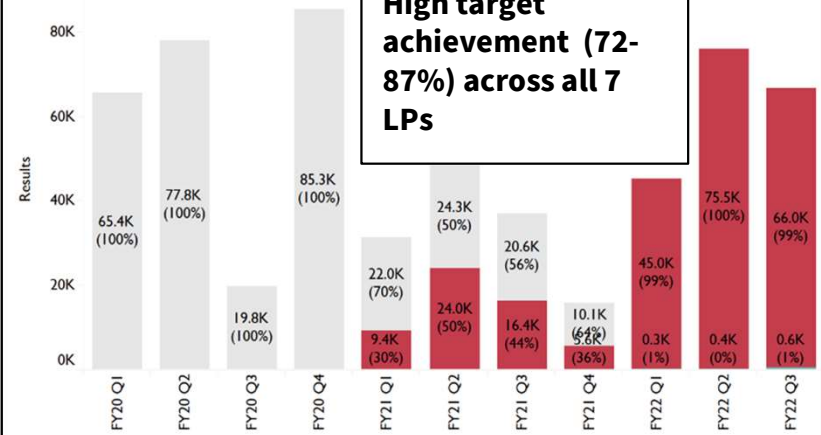


TBD Local, Targets
 Local, Targets
 International, Targets

Target share: International vs Local Partners, VMMC_CIRC
 USAID Uganda: All



Results: Trends by Partner Type, VMMC_CIRC
 USAID Uganda: All



Local Partners: Successes and Challenges

Successes:

- Full Transition to LP implementation in Kenya, Uganda in FY22
- Most OUs have LP actively involved in program implementation

Factors contributing to successes:

- ✓ Use of grants vs other award types facilitated transition
- ✓ Use of phased approach allowed for smooth and efficient transition
- ✓ Use of above site 3rd party for capacity building
- ✓ Split areas of work between International Partner and LP to allow capacity building and target achievement for LP

Organizational Challenges:

- Striking balance between capacity building activities and achieving targets
- HRH shortages: Covid-related interruption in services and staff attrition requiring new staff and retraining

Financial Challenges:

- Cost of meeting the high standards of the VMMC minimum requirements
- Private sector engagement (i.e., inadequate provider reimbursement)

VMMC Priorities for COP22 and beyond

Use of innovative DG approaches to increase MC coverage



- Scale up to saturation (90%) in geographic areas where feasible
- Tailored approaches to reach older men (i.e. VIP program, weekend appts)

Safety/Quality



- Enhanced Shang Ring surveillance for <15.
- Use of external quality assessment (EQAs) and continuous quality improvement, provider training and supportive supervision

Supply Chain



- Increase use of reusable kits
- Scale up Shang Ring implementation
- Kits for surgical circumcision

Plan for sustainability

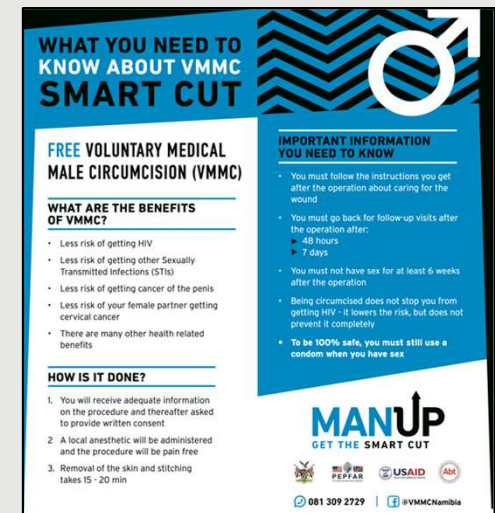
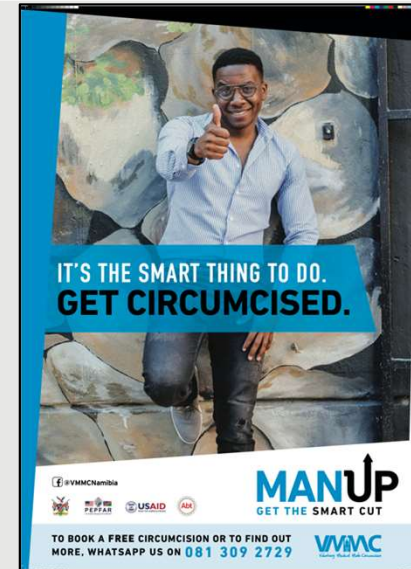


- Integrate VMMC services into combined prevention programming (KP, MenStar, DREAMS, PrEP, Condoms)
- Accelerate integration and transition to government and local partners

Meeting Demand for VMMC

Understand the needs, aspirations and wants from our audiences to align with the demand and to reach VMMC saturation:

- Identify barriers and influences men face to get circumcised
- Target men based on those barriers. Moving away from the socio-demographic segmentation
- Use a human centered design (HCD) approach to develop new prototypes and adapt existing tools
- Leverage existing resources (qualitative and quantitative research results, tools and materials)
- Map men's journey to VMMC through the barriers they face



Source: USAID/Abt Associates

Quality and Safety in VMMC

- As a preventive procedure performed on young healthy men, **safety** is the top VMMC priority
- **Notifiable Adverse Events Reporting System** (NAERS) is critical to monitor safety at the global level; it however does not replace other monitoring especially at country level
- **Key future considerations:** electronic reporting, strengthen analytic capability, support dissemination of findings, and ensure field engagement and OU capacity to manage/prevent NAEs

Quality and Safety Activities in VMMC

- **Training** according to WHO standards
- **Re-training and in-services** (MC procedure, emergency management, adverse events management and reporting)
- Mentoring and supportive **supervision**
- **Quality improvement** (QI) and **quality assurance** (QA)
- Development and adherence to **SOPs** include ICP and referrals
- **Adverse event (AE) monitoring**
 - Implementing partner
 - Government
 - PEPFAR

Transitioning to Sustainability in VMMC programming

As countries scale up to 90% coverage, the focus of national VMMC programmes should shift to the sustainability of services

Core principles

- 1 Adolescent-focused** Programmes may focus on adolescents as a sustainable, effective, and acceptable approach towards wellbeing that maximizes **near-term impact on the epidemic**³
- 2 Embedded within routine systems** VMMC integration has the potential to enable efficiencies and **spur relationships** with adolescent programs, a small, but emerging aspect of health systems⁴
- 3 High quality and people-centered** Services should put **people and communities**, not diseases, at the **center of health systems**, empowering people to take charge of their health, supported with education and support²
- 4 Widely Accessible Services** In alignment with UHC principles, all people should have **access to necessary, affordable, and effective health services** (including prevention)¹
- 5 Co-produced** A key consideration for adolescent leadership includes meaningful involvement and engagement as leaders and stakeholders in VMMC at national, district and community levels.

- VMMC moving from vertical towards more integrated, routine services
- 2020 WHO guidelines include chapter and framework on sustainability.
- USAID-supported programs have made great strides with LP transition
- LPs implementing VMMC program in a majority of priority OUs (9/10 OUs)
 - 2/10 OUs have LPs implementing 100% of the program (Kenya, Uganda)

Oral PrEP in COP22 and beyond



When scaled-up, PrEP has a high impact - but we are not yet at normalization

PrEP prevents an estimated three-quarters of HIV infections in people at risk in large African study

Big drop in incidence, despite low use of PrEP, because people used it when needed

Gus Cairns | 4 July 2020

PrEP decreases HIV incidence by nearly 80% in west African men, despite suboptimal adherence

Krishen Samuel | 23 June 2021

HIV incidence among west African men taking PrEP fell by 79%, when compared to an earlier cohort of men who did not have access to PrEP. This is despite adherence not being optimal for most men, especially among those taking event-driven PrEP. This PrEP demonstration study was conducted in four west African cities by Dr Christian Laurent from the University of Montpellier and colleagues and published in *The Lancet HIV*.

Huge fall in new HIV infections after roll-out of PrEP in Scotland

Roger Pebody | 21 January 2021

New HIV diagnoses in gay and bisexual men fell by 20% after the implementation of a publicly funded PrEP programme in Scotland, while HIV incidence in a large cohort of men attending sexual health clinics fell by 43%, Professor Claudia Estcourt of Glasgow Caledonian University and colleagues report in *AIDS*.

Evidence of an Association of Increases in Pre-exposure Prophylaxis Coverage With Decreases in Human Immunodeficiency Virus Diagnosis Rates in the United States, 2012–2016 ^{FREE}

Dawn K Smith ✉, Patrick S Sullivan, Betsy Cadwell, Lance A Waller, Azfar Siddiqi, Robertino Mera-Giler, Xiaohong Hu, Karen W Hoover, Norma S Harris, Scott McCallister

Clinical Infectious Diseases, ciz1229, <https://doi.org/10.1093/cid/ciz1229>

Published: 25 February 2020 Article history ▼

Rapidly declining HIV infection in MSM in central London

Published Online October 20, 2017 [http://dx.doi.org/10.1016/S2352-3018\(17\)30181-9](http://dx.doi.org/10.1016/S2352-3018(17)30181-9) In 2016, there were 1.8 million new HIV infections worldwide. Although the annual number of new HIV infections has fallen by 16% since 2010, the rate of new infections has been increasing since 2007.^a The reduced incidence in gay and bisexual men was most pronounced in London, in whom there was a 29% decrease with an overall

What happens when PrEP is scaled up? Results from EPIC-NSW



In *The Lancet HIV*, Andrew E Grulich and colleagues¹ describe the rapid roll-out of pre-exposure prophylaxis (PrEP) in New South Wales, Australia (the EPIC-NSW study). The challenge of reaching all

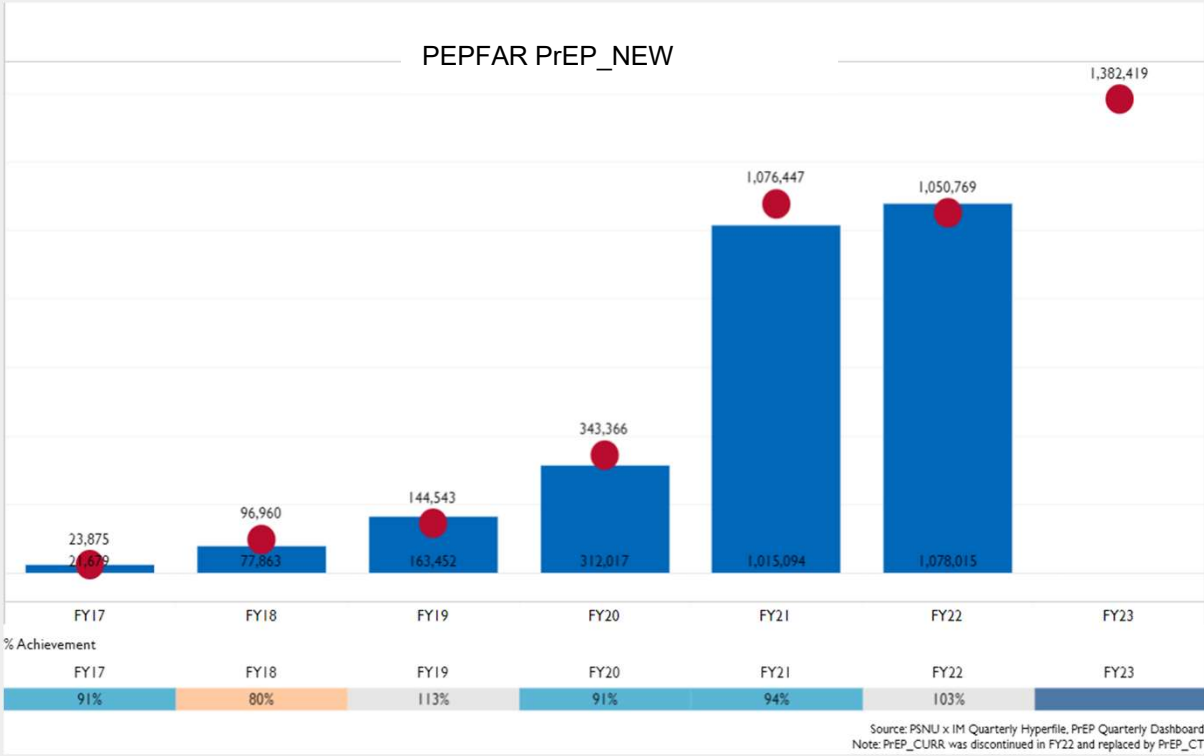
Published Online October 17, 2018 [http://dx.doi.org/10.1016/S2352-3018\(18\)30181-9](http://dx.doi.org/10.1016/S2352-3018(18)30181-9)

"These results provide evidence that in generalised epidemic settings, offering universal access to PrEP can reduce HIV incidence."

"Just a 25% uptake of PrEP by women in the ECHO study produced a more than 50% fall in the rate of HIV infection."

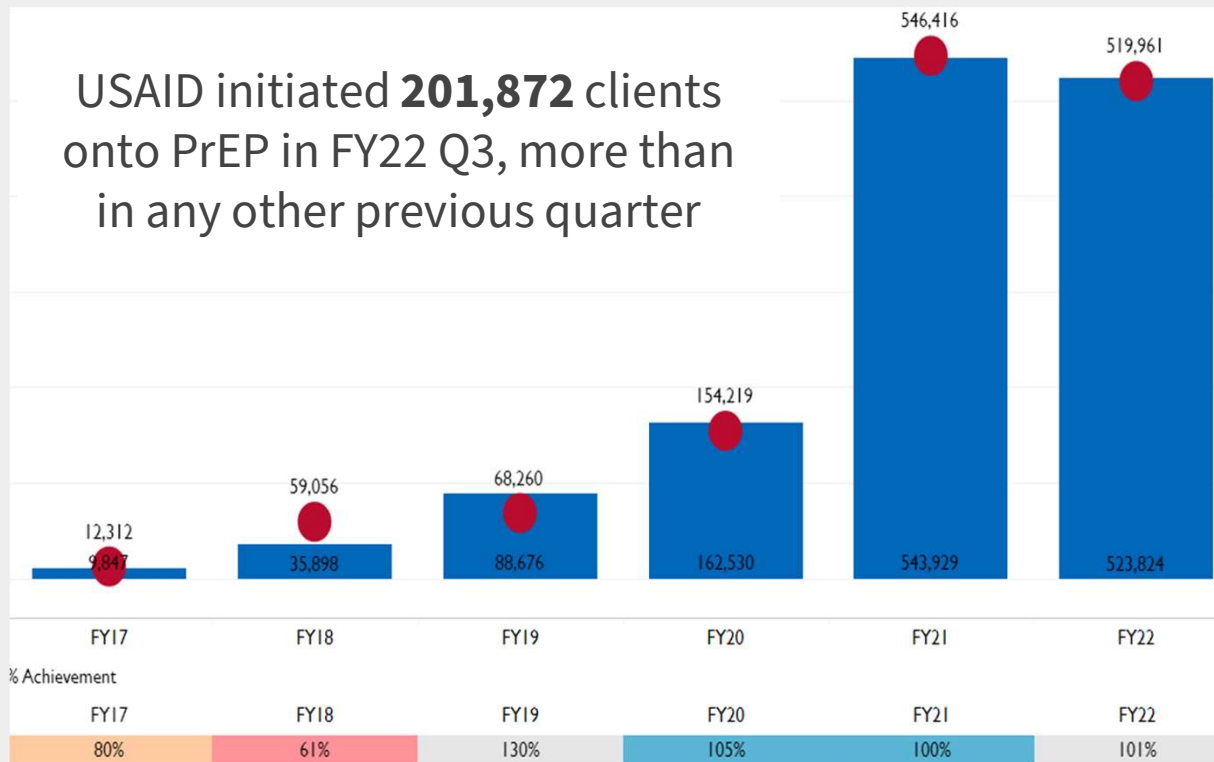
All studies found results despite imperfect adherence

Global 2025 Goal: 10 million people on PrEP



- To date PEPFAR has started 2,269,376 people on PrEP - which is 81% of total global PrEP initiations
- PEPFAR will need to initiate ~5 million people on PrEP to reach UNAIDS goal:
 - ~1.38 million in COP22
 - ~1.75 million in COP23 and COP24
- USAID contributes about 48% of all PEPFAR results
- In FY23, Local Partners will hold 70% of USAID PrEP_NEW targets

By FY22 Q3, USAID is already at 101% achievement of FY22's PrEP_NEW target, and nearly reaching FY21's annual result

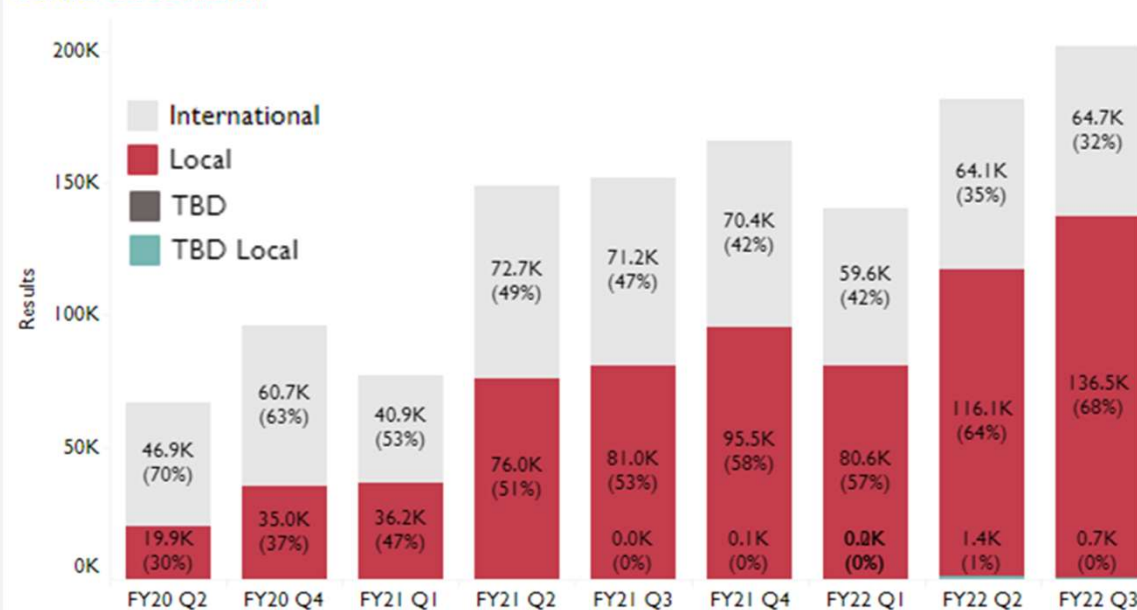


As of FY22 Q3:

- More KP has been initiated onto PrEP than in any other previous quarter, already reaching 118% overall achievement of PrEP_NEW
- 193,290 AGYW have initiated PrEP in FY22 thus far, reaching 71% of the target
- 7,886 PBFW returned for a PrEP follow-up visit

Quarter over quarter, Local Partners make up an increasing % of PrEP results

Results:Trends by Partner Type, PrEP_NEW
 USAID GLOBAL:All



LPs have initiated 333,185 clients on PrEP in FY22, surpassing this year's target at 101% achievement

In FY22, LPs account for 67% of target shares, and 64% of total PrEP_NEW results thus far.

PrEP Priorities for COP22 and beyond

DIFFERENTIATED AND INTEGRATED SERVICES



- **Integrate and strengthen PrEP** linkages and/or direct service delivery at all entry points: HTS/HIVST, FP, MCNH, primary care, ART, VMMC, STIs, PEP, harm reduction, youth friendly services, gender-affirming healthcare
- **Differentiate and demedicalize PrEP service delivery** through community models for PrEP initiation and continuation (e.g., home delivery, community pick-up points, drop-in centers, mobile vans, lockers, PrEP starter packs, PrEP through pharmacies)
- **Simplify PrEP** through same-day initiation; removing burdensome labs and exams (as aligned with WHO's updated guidelines); supporting clients to effectively and safely start, use, and stop PrEP (PrEP cycling)
- **Offer PrEP** to all who test negative as part of comprehensive prevention services; moving away from risk assessments towards supportive, gain-framing counseling that promote informed choice
- Grow **private sector delivery of PrEP** where there is national buy-in and demand
- Build off the oral PrEP platform to **offer product and method choice** (e.g., ED or daily, oral PrEP; PrEP ring; injectable PrEP)
- **Integrate GBV** training for providers and services for clients (LIVES)
- Offer **alternative PrEP packaging** (e.g., smaller pill boxes, labels)

CONTINUOUS QUALITY IMPROVEMENT



- Conduct quality assurance activities to ensure safe, comprehensive, and the highest quality of PrEP SD
- Integrate clients' evaluations of services into programming
- Capacitate facility and community-based staff and providers in PrEP service delivery
- Utilize multi-faceted training models to reach all levels of staff
- **Service quality is an equity issue!**

PrEP Priorities for COP22 and beyond

SOCIAL & BEHAVIOR CHANGE



- Normalize PrEP** by building wide awareness and acceptability of PrEP in communities (i.e., parents, partners, providers, local stakeholders); integrate gain-framing PrEP messaging into all other services (provision and communication)
- Develop interventions that address barriers to PrEP uptake and relevant to different populations, focused on empowerment, health, and PrEP as a public good
- Use diverse platforms/strategies to reach people: social media, radio, health talks, outreach at hot spots
- Collaborate and consult with ministries, TWGs, stakeholders, and beneficiaries to develop and implement PrEP demand creation strategies
- Embed SBC principles in all prevention programming

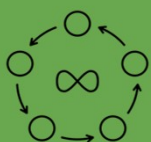
ENABLING ENVIRONMENT



- Strengthen an enabling environment for improved health and well-being by addressing critical policy, programmatic, social, and structural barriers (e.g., stigma, punitive laws, and gender-based violence) and inequities in HIV prevention services access, uptake, and continuity
- Ensure policies and practices allow for all ages, genders, and population groups vulnerable to HIV receive evidence-based, equitable, people-centered, and gender-affirming HIV prevention services that incorporate a **rights-based approach to PrEP** (i.e., anyone who wants PrEP can access it, with the understanding that PrEP use is flexible)
- Collaborate with ministries, TWGs, and other stakeholders to ensure guidelines are fully operationalized
- Update policies** to align with international standards/WHO (e.g., ED PrEP for all people assigned male at birth; updated guidelines for renal screening; incorporate new PrEP products; HIVST integration with prevention programs) to ensure prevention programs support informed choice of biomedical prevention options

PrEP Priorities for COP22 and beyond

SUSTAINABILITY



- Ensure efficient procurement and distribution of commodities through coordination with host **government and other stakeholders** (Global Fund)
- Increase proportion of programs held by local partners
- **Integrate PrEP services** into as many other existing services as possible, including in **private sector** mechanisms, to **establish PrEP and HIV prevention as a common standard of care**
- Share and institutionalize** best practice prevention delivery models within local, national, and international platforms (eg. MMD, community PrEP service delivery, telehealth, same-day initiation)
- Update and implement hybrid models of training and **standardize pre-service models for providers**
- Ensure comprehensive prevention (including PrEP) is included in new program designs
- Appropriately document PrEP expenditures to inform future planning
- Promote innovative prevention financing and leverage across funders to institutionalize sustainability

RESEARCH AND DEVELOPMENT/ INTRO AND ACCESS



- MOSAIC CATALYST and other new product implementation studies underway in several countries
- Work on regulatory approval, updating policy/guidance/SOPs, and developing an enabling environment ahead of new product introduction
- Consider implications of method mix on PrEP/prevention budgets
- Support implementation science of new products in diverse settings, geographies, and populations
- Ongoing gaps should inform development of new products**

WHO Guideline Updates 2022

Highlights:

- Differentiated and Simplified PrEP Service Delivery
- Implementation Tool for Integrating STI Services
- Person-centered HIV Strategic Information
- Consolidated Guidelines for Key Populations



WHO Guidelines Update 2022

Highlights:

- Differentiated and Simplified PrEP service delivery
 - DSD and community models
 - Event-drive PrEP (ED-PrEP)
 - Starting and stopping PrEP
 - HIVST
- Long-acting injectable Cabotegravir (CAB-LA)
- Consolidated Guidelines for Key Populations
- Person-centered HIV Strategic Information
- Implementation Tool for Integrating STI Services



Differentiated PrEP Service Delivery Approaches

- PrEP initiation and dispensation in **fixed and mobile community settings**
 - PrEP on Wheels
 - DICs
 - Moonlight clinics
- **Telehealth** for PrEP
- **At home** prevention kits with HIV self-testing (HIVST)
- PrEP delivery in **pharmacies**
- Task sharing service delivery
 - **Key population** and **community led services**
 - **Nurse** led service delivery
- **Multi-month dispensing**
- **Integrated** services with STI, FP, and other services.

Fig. 2. PrEP on Wheels in Dong Nai province, Viet Nam (January 2021)



Photo credit: PATH.

Source: [WHO Guidelines on differentiated and simplified pre-exposure prophylaxis for HIV prevention, July 2022](#)

Differentiated and Simplified PrEP Service Delivery: Building Blocks

Building block	PrEP initiation, initial follow-up (0–3 months), and re-initiation			PrEP continuation (3+ months)	
	Initiation	Initial follow-up (0–3 months) (if required)	Re-initiation after discontinuation	PrEP refill	Follow-up
Where? Service location (e.g., primary health care facility, community setting, virtual setting)	Locations for PrEP assessment and initiation	Locations for initial follow-up	Locations for PrEP re-initiation	Locations where PrEP refills can be collected	Locations where follow-up services will be provided
Who? Service provider (e.g., physician, nurse, pharmacist, peer)	Service provider/s authorized to assess for and initiate PrEP	Service providers who can carry out initial follow-up visit/s	Service provider/s authorized to re-initiate PrEP	Service provider/s who can dispense PrEP refills	Service provider/s who conduct follow-up
When? Service frequency (e.g., monthly, every 3 months)	Timing of PrEP assessment and initiation	Timing of initial follow-up	Timing of PrEP re-initiation	Frequency of PrEP refill visits (length of supply)	Frequency of follow-up services
What? Service package (including HIV testing, clinical monitoring, PrEP prescription and dispensing, and comprehensive services)	Service package for PrEP assessment and initiation	Service package at initial follow-up	Service package for PrEP re-initiation	Service package with PrEP refill	Service package with follow-up

- Enables people and communities who could benefit from PrEP services to be at the center of service delivery
(person- and community- centered)
- Adaptable to needs and preferences of those interested in and could benefit from PrEP while maximizing impact and health system efficiency
- Increases acceptability and accessibility to support uptake, persistence, and effective use
- Examples of PrEP DSD:
 - PrEP in fixed and mobile community settings (PrEP on Wheels), tele-health, at home prevention kits with HIVST, PrEP in pharmacies, task sharing (KP-led, nurse-provided), MMD, integrated services (e.g., STI, FP)

Differentiated and Simplified PrEP Service Delivery: HIV Self-Testing (HIVST) for Oral PrEP

- May increase uptake, persistence, and effective use by removing barriers, although evidence is limited
- Complements existing HIV testing strategies for PrEP support in differentiated service delivery approaches for oral PrEP by reducing clinic visits
- HIVST may be appropriate to support the continuation of the DVR, particularly as there is no systemic absorption of PrEP that could impact the sensitivity of HIVST, but evidence is limited
- Provides an additional testing choice and may be preferred for convenience, privacy, and self-managed care
- **HIVST can be considered as part of PrEP delivery for:**
 - Demand generation and linkage to PrEP: may reach individuals who may not otherwise test or access health facilities
 - PrEP initiation, although current evidence is limited. Evidence shows risk of initiating a person on PrEP while acutely HIV infected are low and likely similar for HIVST and provider-administered RDT. Demand generation and linkage to PrEP (**Note: PEPFAR does not currently support HIVST for PrEP initiation**).
 - PrEP continuation, re-initiation, and to support effective use for more experienced PrEP users

Differentiated and Simplified PrEP Service Delivery: Starting, Stopping, and Using TDF-based Oral PrEP Safely

Population	Starting oral PrEP	Using oral PrEP	Stopping oral PrEP
Cisgender men and trans and gender diverse people assigned male at birth ^a who: <ul style="list-style-type: none"> • have sexual exposure AND • are not taking exogenous estradiol-based hormones 	Take a double dose 2–24 hours before potential sexual exposure (ideally closer to 24 hours before potential exposure)	Take one dose per day	Take one dose per day until two days after the day of the last potential sexual exposure
Cisgender women and trans and gender diverse people assigned female at birth ^a Cisgender men and trans and gender diverse people assigned male at birth ^a who are taking exogenous estradiol-based hormones People using oral PrEP to prevent HIV acquisition from injecting practices	Take one dose daily for seven days before potential exposure	Take one dose per day	Take one dose daily for seven days after last potential exposure
PrEP: pre-exposure prophylaxis; TDF: tenofovir disoproxil fumarate.			
^a “Trans and gender diverse people” is an umbrella term for those whose gender identity, roles and expression does not conform to the norms and expectations traditionally associated with the sex assigned to them at birth; it includes people who are transsexual, transgender, or otherwise gender nonconforming or gender incongruent. Transgender people may self-identify as transgender, female, male, transwoman or transman, trans-sexual or one of many other gender nonconforming identities.			

Oral event-driven PrEP (ED-PrEP) can be used to prevent sexual acquisition of HIV by **cisgender men and trans and gender diverse people assigned male at birth who are not taking exogenous estradiol-based hormones**

Hepatitis B virus (HBV) infection is not a contraindication for ED-PrEP.

Differentiated and Simplified PrEP Service Delivery: Laboratory tests for oral PrEP and the PrEP ring

- **Hepatitis B and C:** Lack of HBV and HCV testing should not be a barrier to PrEP initiation or use. PrEP can be initiated before HBV and HCV test results are available. HBV or HCV testing are not a requirement for PrEP use. TDF-based daily or event-driven oral PrEP and the dapivirine vaginal ring (DVR) can be safely offered to people with HBV or HCV infection.
- **Kidney function:** PrEP initiation or continuation should not be delayed while waiting for kidney function test results.

Table 2. Suggested procedures for measuring kidney function for TDF-containing oral PrEP

Population	Measurement of kidney function:	
	At initiation	At follow-up
Individuals aged under 30 years and no kidney-related comorbidities ^a	Optional	If no initiation test conducted or if initiation test is normal, ^b follow-up is optional If initiation test result suggests at least mild loss of kidney function, ^c follow-up measurements every 6–12 months are suggested
Individuals aged 30–49 years and no kidney-related comorbidities ^a	Optional/conduct once, at or within 1–3 months of initiation ^d	If initiation test is normal, ^b follow-up is optional If initiation test result suggests at least mild loss of kidney function, ^c follow-up measurements every 6–12 months are suggested
Individuals aged 50+ years and no kidney-related comorbidities ^a Individuals of any age with kidney-related comorbidities ^a Individuals with previous measurement of kidney function suggesting at least mild loss of kidney function ^c	Conduct once, at or within 1–3 months of initiation	Follow-up measurements every 6–12 months

eGFR: estimated glomerular filtration rate; PrEP: pre-exposure prophylaxis; TDF: tenofovir disoproxil fumarate.

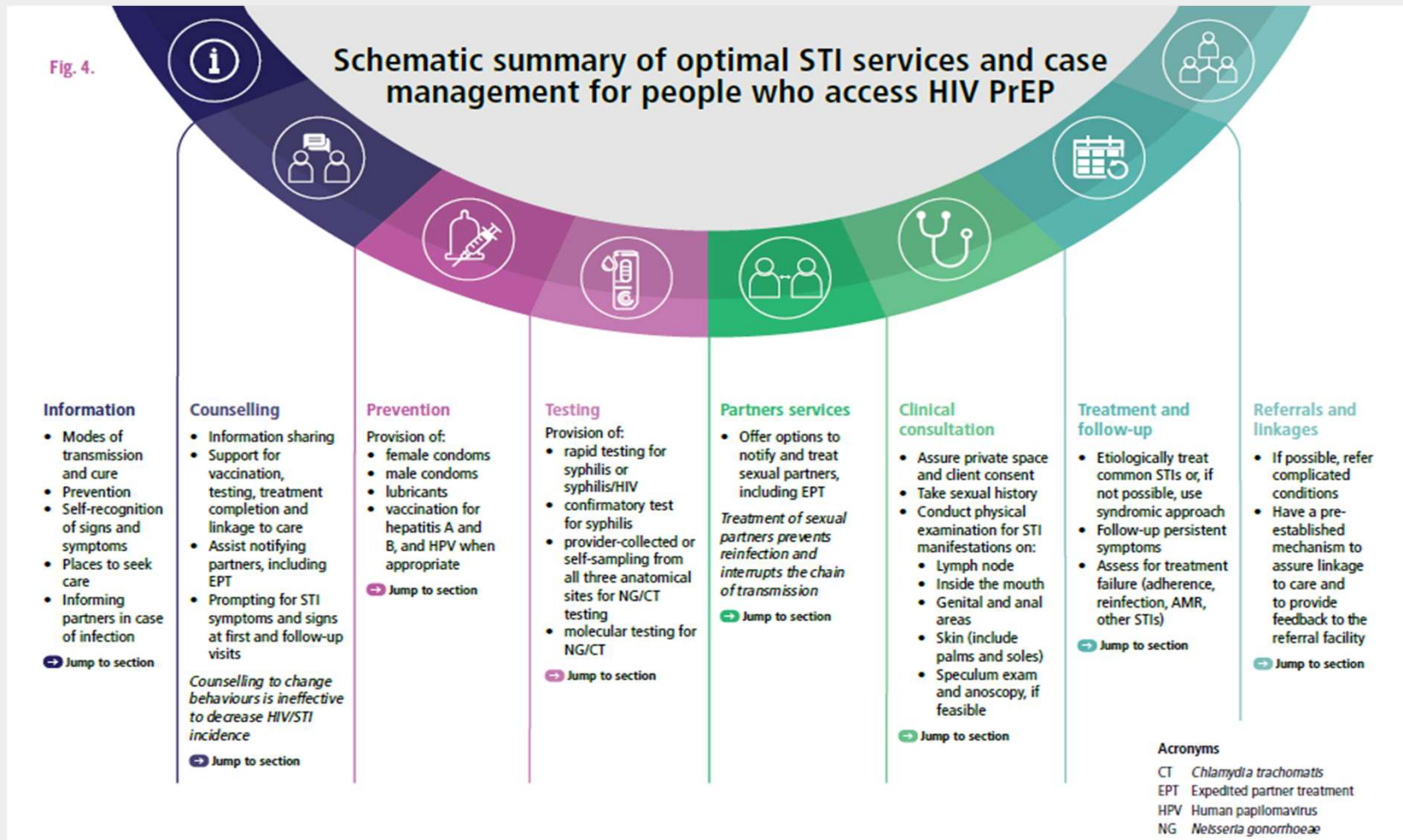
^a Kidney-related comorbidities include chronic kidney disease or risk factors such as diabetes or hypertension. There may be an increased risk of kidney-related adverse events during pregnancy, and conditions such as preeclampsia may cause kidney impairment, so more frequent kidney function testing may be considered during pregnancy.

^b eGFR ≥ 90 mL/min per 1.73 m² or creatinine clearance of ≥ 90 mL/min.

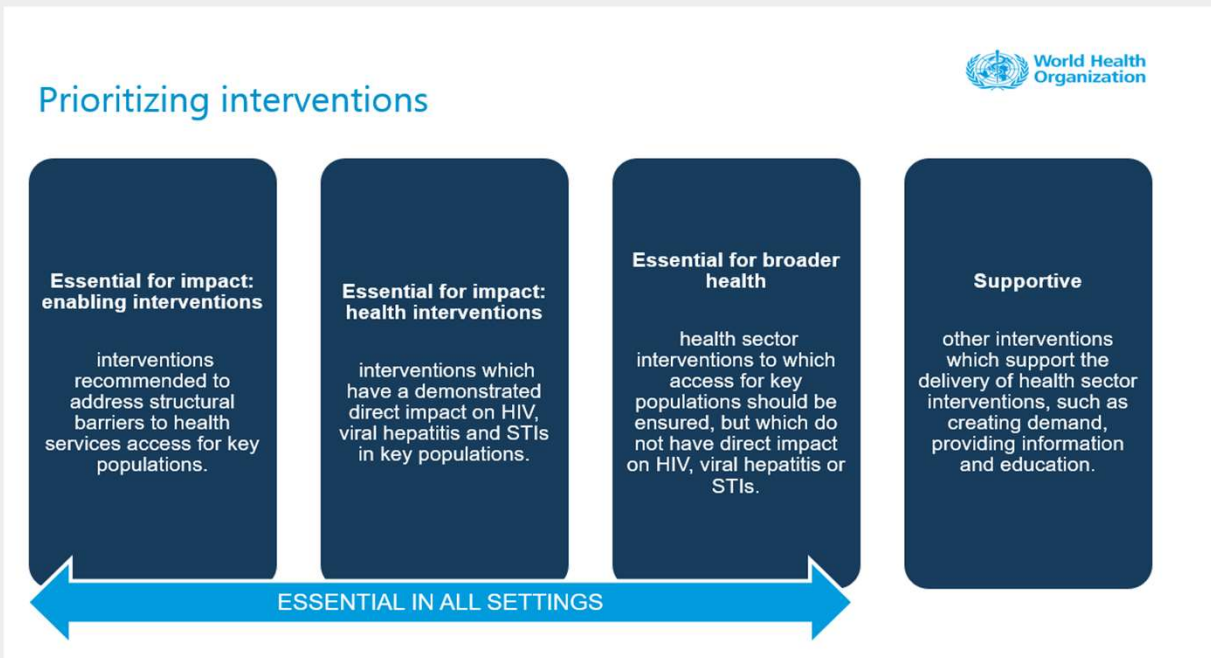
^c eGFR < 90 mL/min per 1.73 m² or creatinine clearance of < 90 mL/min.

^d Risks of kidney impairment and kidney-related adverse events remain low among those aged 30–49 years without kidney-related comorbidities, particularly those aged 30–39, so kidney function monitoring can be considered optional in this group, too, depending on available resources.

Implementation Tool for PrEP - Integrating STI Services



Key Populations



New recommendations around HCV testing and treatment, CAB PrEP, peer navigation, online delivery of HIV, viral hepatitis and STI services, chemsex, and behavioral interventions for KPs

Essential for impact: enabling interventions

- Removing punitive laws, policies and practices
- Reducing stigma and discrimination
- Community empowerment
- Addressing violence

Essential for impact: health interventions

Prevention	Diagnosis	Treatment
<ul style="list-style-type: none"> Harm reduction Condoms and lubricant Pre-exposure prophylaxis (PrEP) for HIV Post-exposure prophylaxis (PEP) for HIV and STIs Prevention of vertical transmission of HIV, hepatitis and STIs Hepatitis B vaccination Addressing Chemsex 	<ul style="list-style-type: none"> HIV testing services STI testing Hepatitis B and C testing 	<ul style="list-style-type: none"> HIV treatment HBV/HCV STI treatment HIV and HCV treatment

Essential for broader health: health interventions

- Anal health
- Addressing alcohol and substance abuse
- Conception and pregnancy care
- Contraception
- Gender affirming care
- Mental health
- Prevention and treatment of cervical cancer
- Safe abortion
- TB screening and prevention

Person-Centred HIV Strategic Information

2.2.4 Understanding person-centred HIV prevention need

Conversations between service providers and clients during a consultation are key to understanding an individual's HIV prevention needs. Such conversations may take place before or after HIV testing, during a sexual health consultation, or when providing HIV prevention services. It should be noted that discussing issues such as sexual behaviours, sexual identity and expression, and drug use can be uncomfortable for both client and provider, especially when these behaviours are stigmatized or criminalized. Providing privacy and confidentiality are key; community-led services and peer workers have an important role in providing trusted and safe settings to have these conversations.

Providers should offer prevention interventions to all people who request HIV prevention services, even if they are unwilling to discuss their reasons for concern; these persons may recognize their own potential exposure to HIV. Some people may not be able or willing to discuss HIV, either due to fear of stigma or reticence to talk to providers about sexual and drug using behaviour. Young people may be reluctant to disclose sexual activity in settings with laws that restrict adolescent access to sexual and reproductive health services. In such situations, where individuals have chosen the services best suited to them, the fact that an individual has self-identified as needing services should be captured in a data system, without requiring other information.

Providers should offer prevention interventions to all people who request them.

Focus on PrEP offer

Questions to ascertain a person's risk factors for HIV **can be helpful as a programmatic counselling tool to expand or extend access to HIV prevention...risk differentiation questions should not be used to exclude access** for individuals who request HIV prevention services. Health care providers can use questions on risk factors for HIV to begin conversations about HIV, prioritize prevention services and prompt regular follow-up, where appropriate, for individuals who may not recognize their own risk for HIV. If people self-identify as requiring services, or if an individual is from a key population and their prevention needs are already clear, asking multiple questions on HIV risk might be an unnecessary encumbrance to easy access.

New Prevention Products

PrEP Ring (DVR)

- [PEPFAR FAQs](#) released by S/GAC June 2022
 - “...S/GAC will not utilize PEPFAR funds to procure the PrEP Ring (monthly Dapivirine Vaginal Ring) for programmatic implementation at this time...Although PEPFAR will not procure the Ring commodity, PEPFAR will actively work with other donors who can procure the PrEP Ring and will support programmatic implementation when procured by these other parties (e.g. the Global Fund). As part of PEPFAR’s commitment to informed choice, procurements of the PrEP Ring for PEPFAR-funded implementation science studies may proceed.”
- The Population Council acquired IPM and IPM South Africa, and now [owns the intellectual property](#) of the 30 day ring, 90 day ring, and MPT ring
- South Africa NEMLC decision to not procure based on product cost concerns
- PEPFAR SAB Discussion on September 8, 2022 (recording posted [here](#))

WHO Guidelines on Long-acting Injectable Cabotegravir (CAB-LA) for HIV Prevention

“Long-acting injectable cabotegravir (CAB-LA) may be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches (*conditional recommendation, moderate-certainty evidence*).”

- Long-acting injectable cabotegravir (CAB-LA) is an integrase strand-transfer inhibitor (INSTI). It is given to people who do not have HIV infection, at a dose of 600 mg, intramuscularly, four weeks apart for the first two injections and every eight weeks thereafter for the prevention of HIV acquisition.
- The greater efficacy of CAB-LA in randomized control trials is likely due largely to better adherence to the injectable CAB-LA than to the oral TDF/FTC.
- PrEP products, including CAB-LA, should be used during periods of substantial HIV risk and may be stopped if an individual is no longer at risk or decides to use an alternative PrEP product or HIV prevention strategy. Important to counsel clients on the need to **receive injections on schedule to assure that CAB-LA is most effective**, on the risks for drug resistance and on the importance of using other prevention options (such as condoms, PEP and other PrEP products) if CAB-LA is discontinued and the client remains at risk of HIV acquisition. A range of PrEP options should be available to provide choice to people who could benefit from PrEP.

CAB-LA: More Research is Needed

- **Key populations**
 - Clinical trials did not include service delivery for trans and gender-diverse people, sex workers, or people who inject drugs
 - More research is required on how to integrate CAB-LA with gender affirming care services, and individuals with buttock implants and fillers
- **Adolescents under 18**
 - Many in the study were < 30 years of age, but no one < 18 was included
 - Studies on adolescents can provide evidence on the acceptability and safety of CAB-LA
- **Safety in pregnancy and breastfeeding**
 - All pregnant and breastfeeding women were originally excluded from the study, but those who became pregnant later on were included when the use of contraception was removed
 - CAB-LA was safe during pregnancy and breastfeeding but due to a small sample size, more research is needed
- **Optimal HIV testing strategies and drug resistance**
 - Risk of delayed HIV diagnosis and treatment when initiating someone already infected with HIV
 - Implications for HIV drug resistance
 - Optimal strategies for establishing HIV infection post CAB-LA initiation
 - Feasibility and acceptability of HIV testing approaches and frequency in real-world implementation
- **Service delivery methods**
 - Restrictions on who can administer injections and where may lead to the re-medicalization of PrEP services
- **Population-level impact and costs and cost-effectiveness**
 - More research needed on the population-level impact of CAB-LA across setting and populations
 - Should consider cost-effectiveness and costs of different potential HIV testing approaches and schedules, and other additional costs as it relates to CAB-LA

ViiV HEALTHCARE AND THE MEDICINES PATENT POOL SIGN NEW VOLUNTARY LICENSING AGREEMENT TO EXPAND ACCESS TO INNOVATIVE LONG-ACTING HIV PREVENTION MEDICINE

[ViiV Press Release](#) (July 28, 2022): “ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, and the Medicines Patent Pool (MPP) today announced the signing of a new voluntary licensing agreement for patents relating to cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP) to help enable access in least developed, low-income, lower middle-income and Sub-Saharan African countries.”

Allows selected manufacturers to develop, manufacture, and supply generic versions of CAB-LA in 90 countries.

Pill-based products

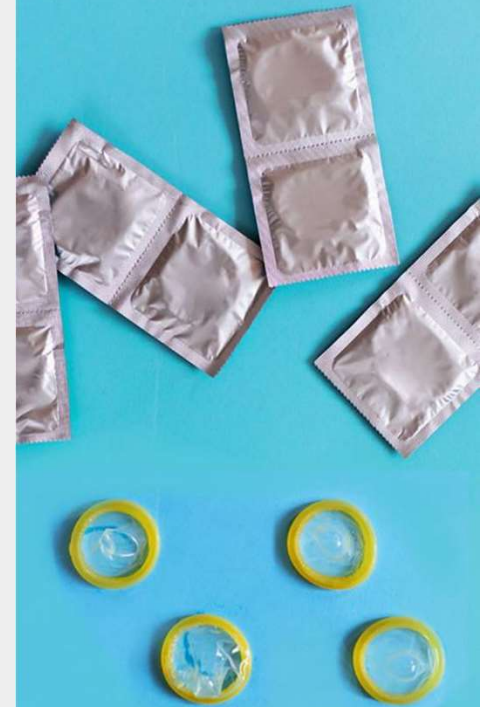
- **Islatravir:**
 - Merck released [statement](#) about re-starting its clinical development program with Islatravir for HIV treatment
 - Merck is ending its work on Islatravir for PrEP (monthly oral PrEP)
- **Dual Prevention Pill (DPP):** co-formulated, daily oral pill containing oral PrEP and combined oral contraception (COC) by PopCouncil.
 - Two randomized, crossover studies are taking place in South Africa and Zimbabwe to evaluate the adherence and acceptability of DPP versus two separate tablets (PrEP and COC)
 - South Africa study funded by USAID & CIFF, implemented by PopCouncil & Wits RHI
 - Viatrix developing DPP as a smaller pill

MOSAIC overview slide

PrEP and New Prevention Product Resources

- [PrEPWatch website](#)
 - [Global PrEP Learning Network Webinar Series](#)
 - WHO-led stakeholder consultations, in collaboration with MOSAIC
 - [Final Report Presentation](#)
 - [Summary of the Meeting](#)
 - Country-specific consultation reports for [Eswatini](#), [Kenya](#), [Lesotho](#), [Namibia](#), [Nigeria](#), [South Africa](#), [Uganda](#), [Zambia](#), and [Zimbabwe](#)
- [New Prevention Product brief](#)
- [PrEP Ring brief](#)
- [PrEP and Family Planning Integration](#)
 - [Envision FP-PrEP Integration in Lesotho](#)
 - [OPTIONS-USAID Paper on Integrating PrEP into FP Services](#)
 - [OPTIONS Integrated Service Delivery Multicountry Analysis of PrEP FP Integration](#)

Condoms



Triple Benefits of Condoms

- Integrate condoms programming into broader HIV prevention programming for additional protection:
 - HIV *and* STI prevention
 - Unintended pregnancies
- Condoms can provide extra assurance and peace of mind for HIV prevention, when used in combination with VMMC and PrEP
 - Additional considerations: PrEP initiation or discontinuation, ED-PrEP and unplanned sex, missed doses/injections or suboptimal PrEP adherence, etc.
- Can be used when PrEP disclosure is difficult (due to anticipated PrEP stigma, GBV, etc)
- Condoms and personal lubricants should be promoted as part of a combination prevention strategy



COP/ROP22 Guidance for Condoms/Lubricants

- **PEPFAR goal: High levels of use and equitable access to and sustained demand for condoms/ lubricants among key and priority populations and low-income groups**

- Integrate with other service platforms as part of an informed choice and client-centered approach: VMMC, HTS, C&T, PrEP, DREAMS, KPs, harm reduction, programs to engage men, and other community venues
- Prioritize demand generation and employ a range of approaches to identify and reduce barriers
- Include technical support to governments for greater stewardship, leadership, and oversight
- Foster an enabling environment for a total market approach and, where needed, identify a “market facilitator” to support this
- Phase out procurement and supply support for branded social marketing of condoms (e.g., through financing from other donors, social enterprise activities, and/or use of program income)
- Avoid investments in branding free condoms, except where data suggest it would help drive condom use without drawing users away from other more sustainable options
 - Capacitate host country governments to fund and manage free brands through training and use of domestic resources



Discussion



Questions and Discussion

- What are your perspectives on biomedical combination prevention?
- Can countries share experiences in advancing BMP over the past year and visions for the future?
- What experiences can you share in transitioning BMP to local partners?
- How have countries that have surpassed targets achieved this?
- What strategies for sustainable prevention have been discussed in our countries?

Prompts for Discussion (VMMC)

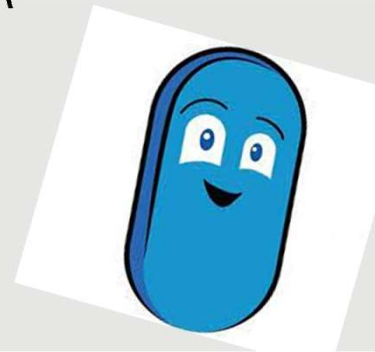
1. What are the strategic opportunities for COP23-24?
 - a. Post-COVID ramp-up with 15+
 - b. Integration to other prevention programs
 - c. Expanding USAID's share of the VMMC targets
 - d. Sustainability/transition to LPs/G2G

1. What are the game changers that are emerging?
 - a. Demand creation
 - b. COVID-19 Innovations
 - c. ShangRing

Contributors!

- Cross-OHA technical experts, leadership, and many others across OHA
- Mission prevention and other experts

Thank you!!



Social & Behavior Change

Presenter:





PEPFAR



USAID
FROM THE AMERICAN PEOPLE

Supporting Prevention and Treatment Outcomes Through Social and Behavior Change

Technical Guidance

LPM4 Meeting, November 2022

Dr. Vincent Wong, USAID/OHA

Behavioral Science as PEPFAR and USAID Priority



Behavioral and social science is a cornerstone of the [HIV] response

- Amb Nkengasong, Speech at PEPFAR Annual Meeting and IAS 2022



When we apply behavioral insights, we are much better equipped to make a difference.

- USAID Administrator Power, June 21, 2021

Objectives

- Define social and behavior change
- Illustrate how social and behavior change (SBC) supports clients and outcomes throughout the HIV Continuum
- Highlight key principles of effective SBC
- Share examples and resources

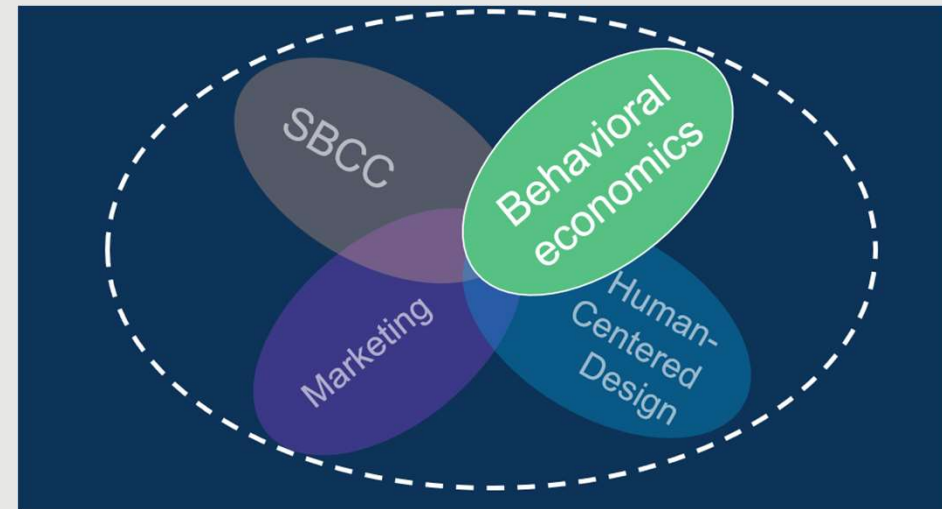


Background

- SBC or Behavioral Science expansion in COP23 TBD! (COP22 was v limited)
- SBC/Behav Sci advances with prevention and demand generation for condoms, PrEP and VMMC
- Increasing opportunities to apply to testing and treatment
- Guidance provided here is drawn from best practice in the field and recommendations based on technical assistance provided
- IEC approaches which are common in PEPFAR programs assume that conveying knowledge is sufficient (if you know benefits you will do) but behaviors are influenced by a wide range of factors including emotional and social drivers

Defining Social and Behavior Change (SBC)

- **Social and Behavior Change (or Behavioral Science)** is a systematic, evidence-driven approach to improve and sustain changes in behaviors, norms, and the enabling environment that underpin the achievement of HIV outcomes along the prevention and treatment continuum.
- **Behavioral Science and SBC** interventions may be grounded in a number of different disciplines, including social and behavior change communication (SBCC), marketing, advocacy, behavioral economics, or human-centered design.



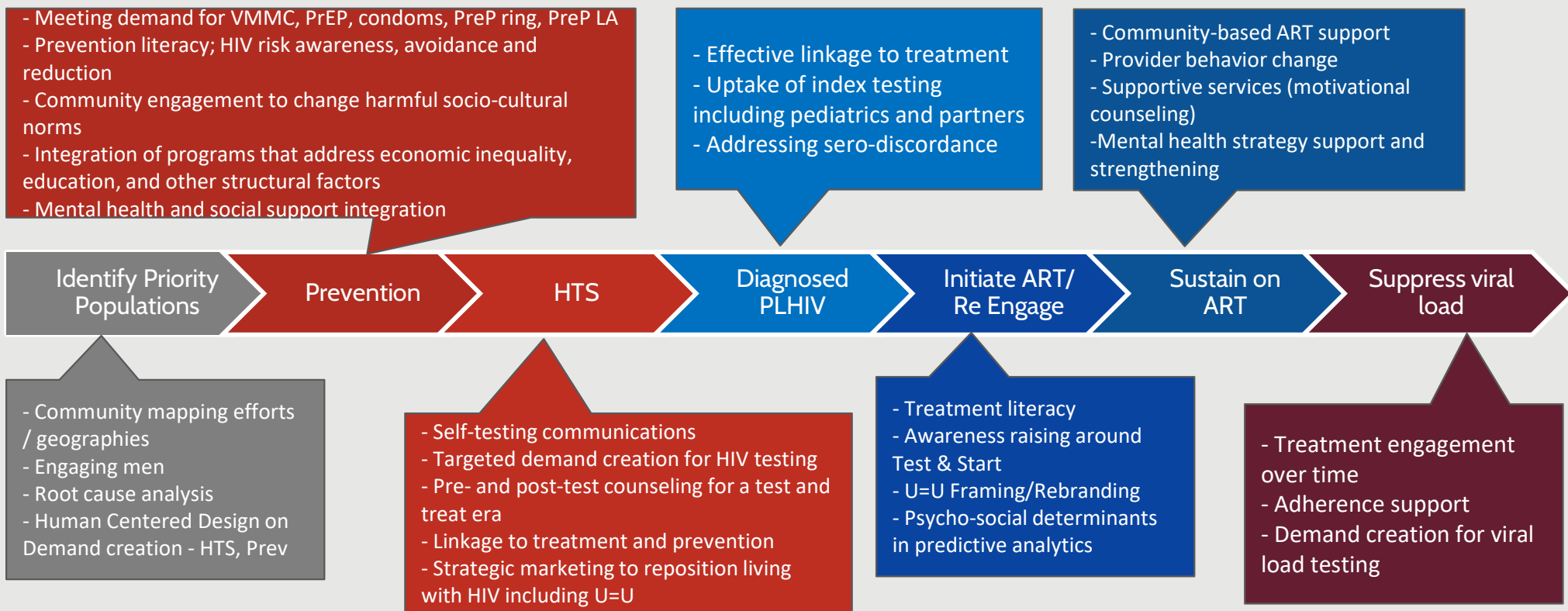
Principles of Effective SBC

- *Clarify the desired behavior(s) and target populations*
- *Use best available evidence on barriers and drivers*
- *Recognize the role of emotions, non-health and non-conscious drivers, and social norms*
- *Develop an explicit theory of change*
- *Get the right expertise at the table*
- *Use mutually reinforcing interventions*
- *Ensure stakeholder coordination*
- *Apply principles from EAST Framework: Make the desired behaviors Easy, Attractive, Social, and Timely*
- *Pre-test materials (ideally co-design) with target audiences*
- *Allocate sufficient budget*
- *Plan for and implement monitoring and evaluation*

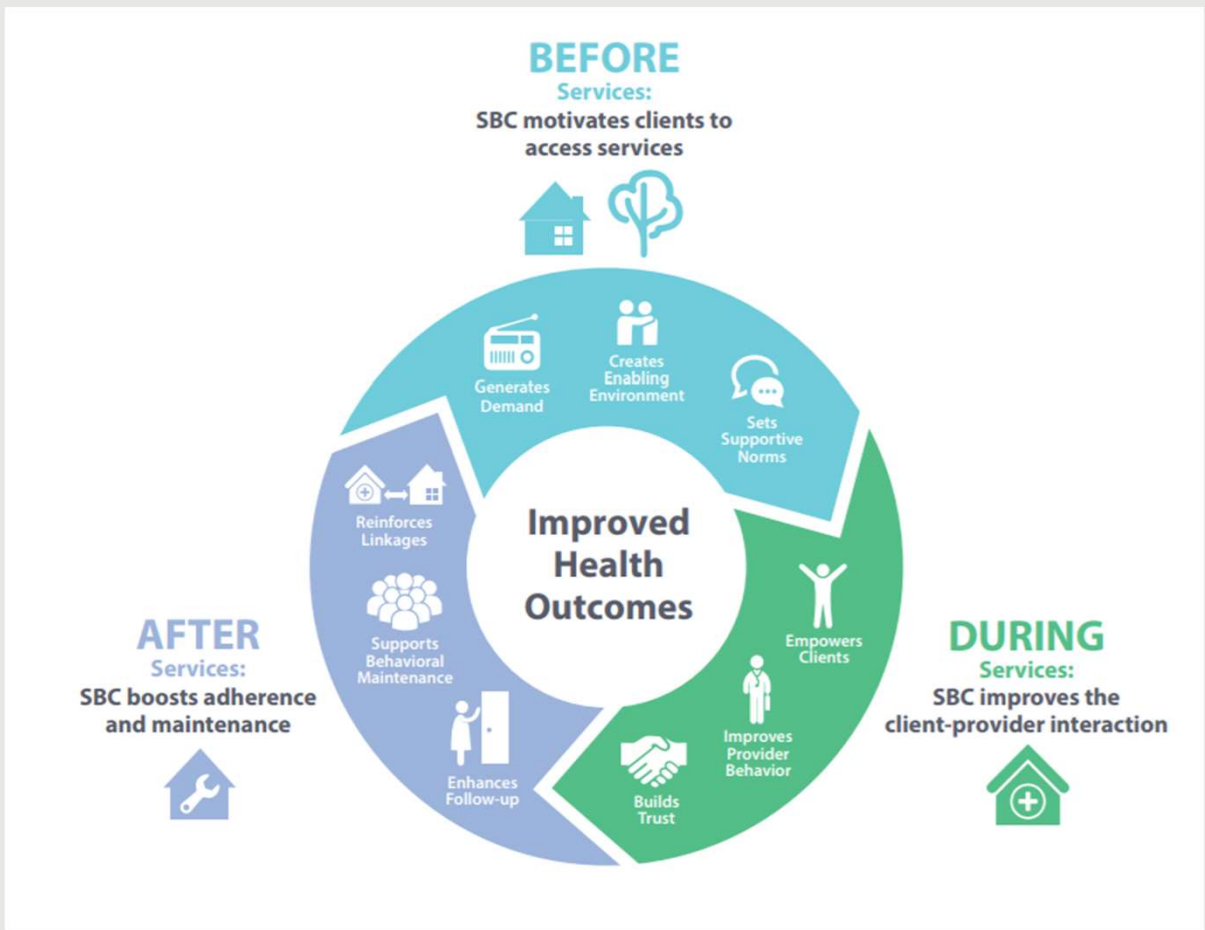


Behavioral Science and SBC Approaches Across the HIV Continuum


Client-centered approaches in all key areas...




Supporting Clients' Journeys Through SBC Along The HIV Continuum





Changing the narrative around men and HIV in SA



MINA is a brand and a movement to support, motivate and encourage men living with HIV to start and stay on treatment



Coach Mpilo is a re-imagined peer navigator/ case manager model for men living with HIV



B-OK bottles are a simple visual tool for explaining the power of treatment and U=U

- Men 15-29Y had 27% growth in testing
- Men's initiation grew 10% nationally
- Men's linkage rates nationally remained above 90% in the first 2 quarters after campaign launch.

Starting with the cost: the annual investment in developing and executing MINA, Dablapmeds and U=U is estimated as 0.81% of PEPFAR's total South Africa COP investment



Annual Investment Profile	Proportion of total SA HIV expenditure	Proportion of total PEPFAR SA COP Investment
Clinical Care and Treatment	52%	28%
Community based care, treatment, and support	11%	7%
Prevention of MTCT	2%	5%
HIV Testing Services	7%	14%
VMMC	5%	15%
Priority population prevention	4%	8%
Key population prevention	2%	2%
OVC	7%	9%
Laboratory	1%	3%
SI Surveys and surveillance	2%	7%
Health SyStems Strengthening	1%	2%
Other HIV Spending (not in COP table)	8%	28%
U=U Strategic Marketing COP20 Investment	0.21%	0.81%

Assumptions: PLM has leveraged published available COP18 annual investment levels included in COP20 strategy, with U=U Investment based on PEPFAR COP20 investment in U=U campaign development, execution, and M&E

Behavioral Science Example: iMpilo and U=U

Where: South Africa

When: 2020

Who: Men were approached in urban area and encouraged to get tested at

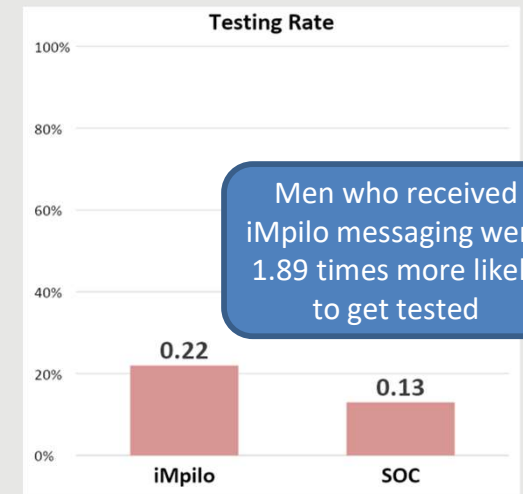
What:



“It protects you even if you don’t use a condom. Even if you’re drinking... Your life stays the same and doesn’t change.”

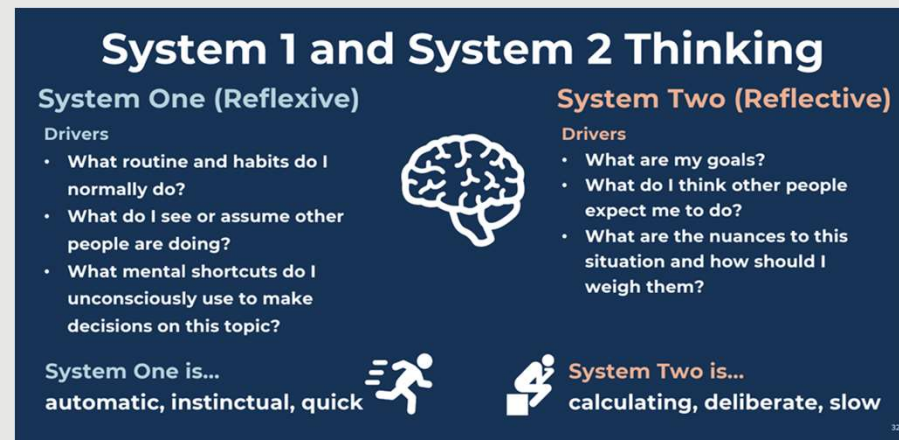
[Smith, P., Bottenheim, A., Schmucker, L., Bekker, L. G., Thirumurthy, H., & Davey, D. L. J. \(2021\). Undetectable= untransmittable \(U= U\) messaging increases uptake of HIV testing among men: results from a pilot cluster randomized trial. *AIDS and Behavior*, 25\(10\), 3128- 3136.](#)

Outcomes:



The Next Frontier in HIV: Behavioral Economics (BE)

- BE recognizes we don't always act in our best self-interest due to predictable cognitive biases (such as present bias, status quo bias, etc.)
- BE uses “nudges” which are small, low cost interventions that address these biases
- Small effect sizes from nudges may help move needle on selected HIV outcomes
- Not a silver bullet - holistic approach still needed to tackle all the relevant behavioral determinants



Behavioral Science Example

Febrisol scratch stickers: addressing early loss

Problem: 15 OUs have >5% IIT rates at 3-5 months. Some OUs are losing over 1 in 10 newly initiated on treatment in 3-5m

- Clients “flying blind” on self-monitoring; “forgetfulness” as one major barrier (Shubber et al. 2016. Patient-Reported Barriers to Adherence: Systematic Review PLoS Med)
- Feedback is crucial to habit formation
- Febrisol = customizable solution for ARVs, PrEP - clients scratch off each day they take a pill
- Country adaptation through HCD “light” to identify preferred layout and design
- Data forthcoming from Studio Fundi (patent-holder); ongoing studies with private sector partners

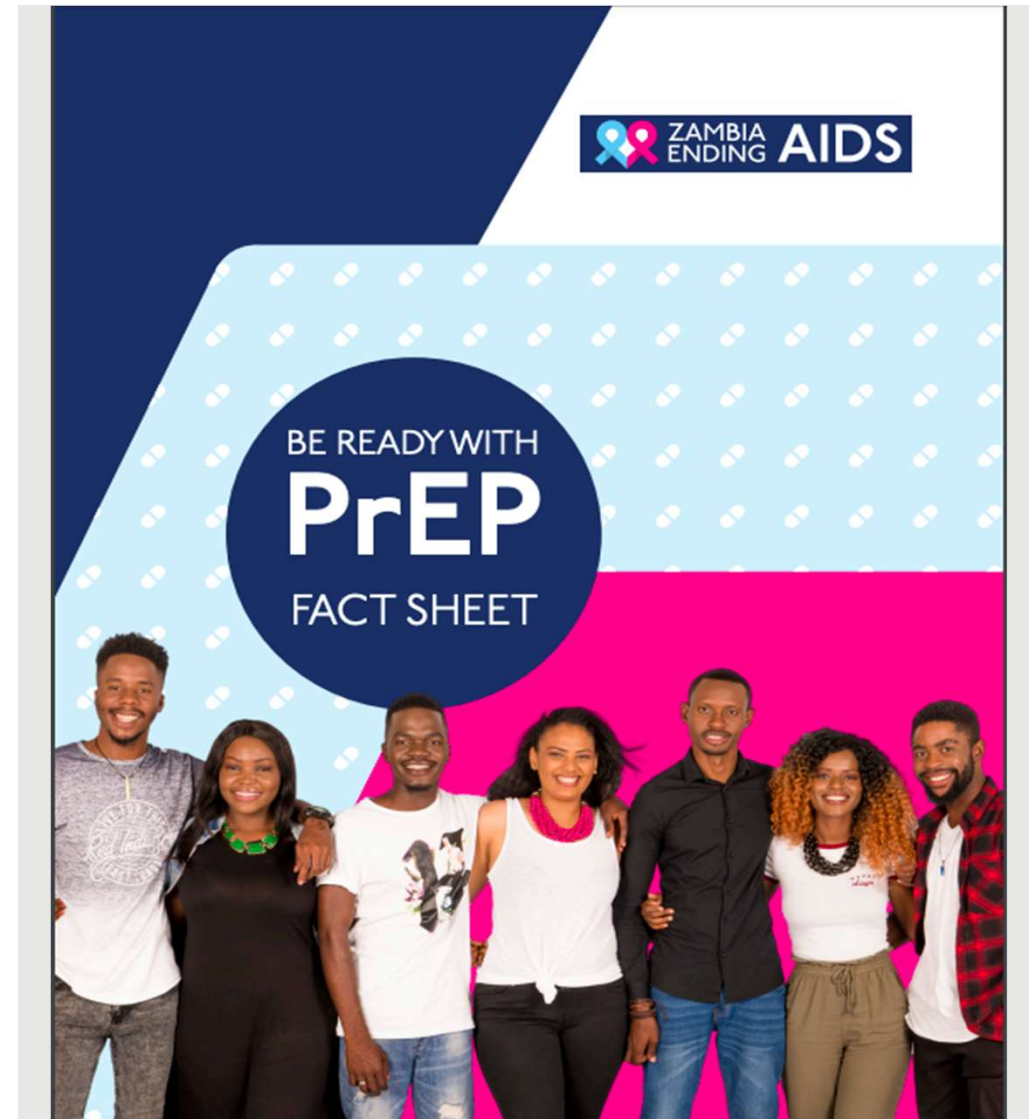


Enabling clients to track and self-manage their adherence through early habit formation
<https://studiofundi.com/febrisol>

Meeting Demand for PrEP

USAID DISCOVER-Health (Zambia):

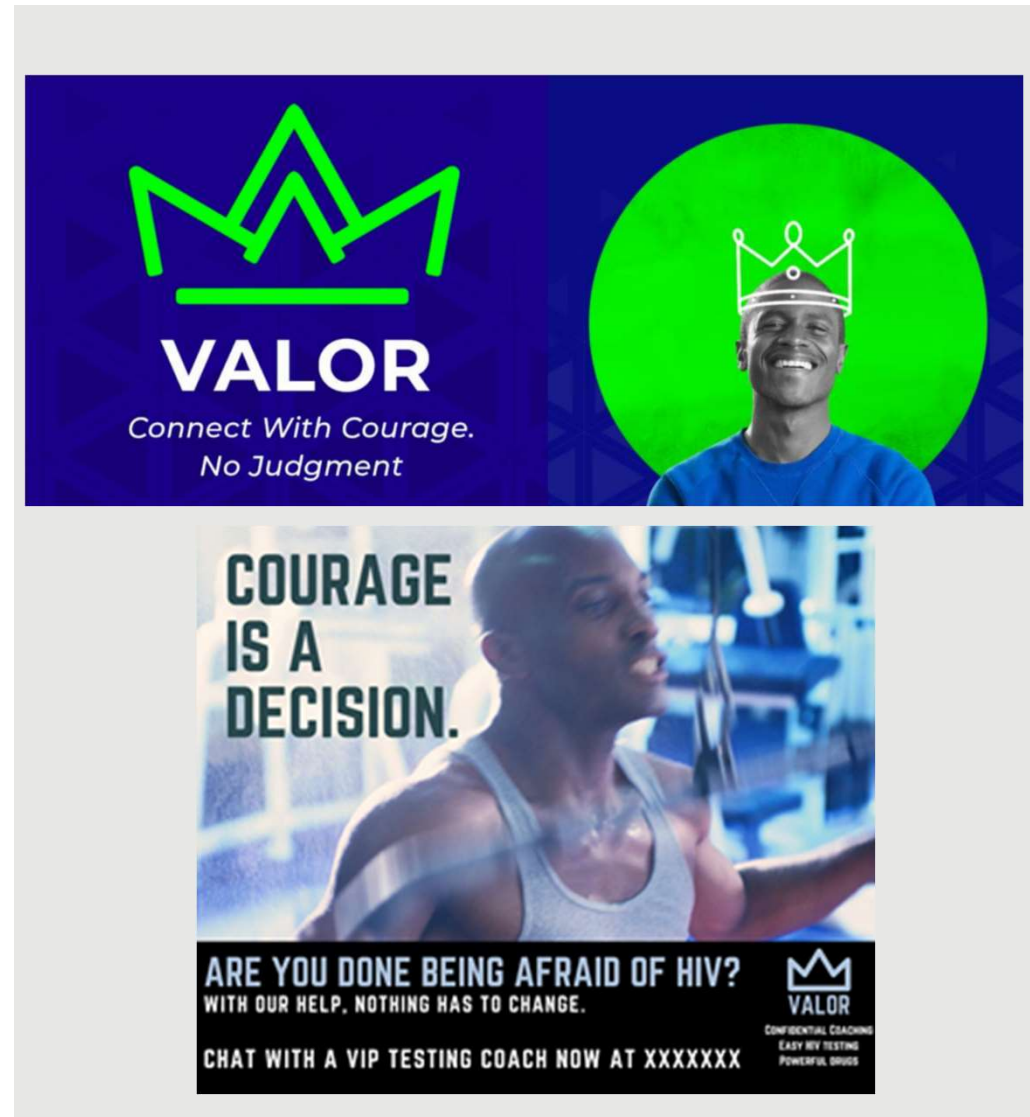
- SBC to promote PrEP uptake and adherence
- HCD to support rapid expansion of PrEP services
- Digital solutions to meet demand (PrEP management system, electronic adherence support, automated appointment reminders, and a toll-free telephone information service)



Meeting Demand for Testing

Valor (RISE/Nigeria):

- Virtual peer-navigation to meet demand for testing and to support linkage among young adult men
- Audience insights collected through human-centered design (HCD) “lite”
- Creative agency used to translate insights into concepts which were refined through iterative process
- Social media partner placed PSAs
- VIP Guides trained to engage with men and support client



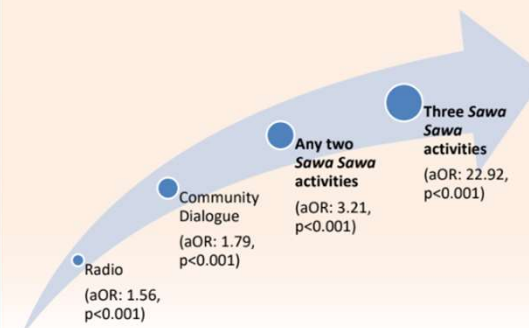
Addressing Stigma to Support Service Uptake

Sawa Sawa (Mozambique):

- Integrated SBC project to address stigma
- Included radio, dialogues and testing at community level as well as facility focal points
- Increased odds of HIV testing among men associated with the intervention (OR: 1.32; 95%CI: 1.01-1.74; p=0.049)



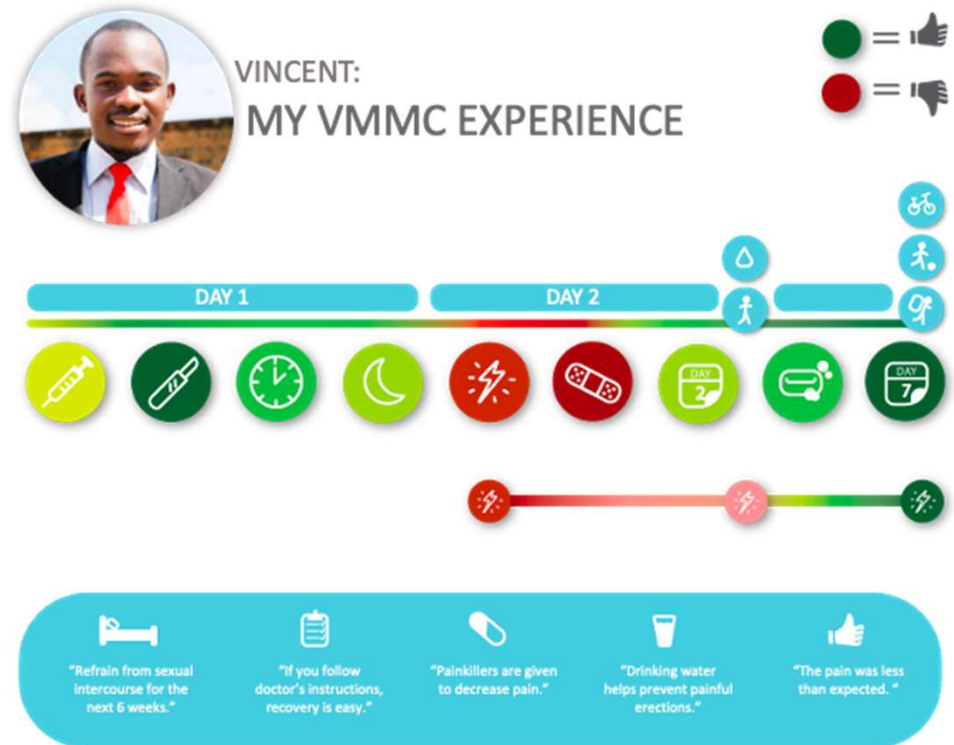
Intervention impact: HIV testing among men associated with Sawa Sawa



Meeting Demand for VMMC

VMMC for older men (Malawi):

- Work with well-trained and well equipped community mobilizers
- IPC through long-term skilled mobilizers to address barriers to behavior change
- Use of job aids and clients' tool to address myths and misconceptions (pain tool)
- Use of community mobilizers and targeted outreach communication as catalysts
- Partners and friends are primary motivators as men decide to undergo circumcision
- Change in mobilization strategy resulted in reaching 105% against target



Job Aids to Nudge Provider Confidentiality

Ni Zii (Breakthrough-ACTION Zambia):

- HCD and behavioral economics applied to identify relevant insights around confidentiality among men and adolescent clients
- Job aids designed to provide environmental cues (reminders) for HCW and provider pledges to drive commitments
- Short training to support use



Creating a Norm for Continuity of Treatment

UC Berkeley (Tanzania) :

- HCD used to profile client journeys and develop personas
- Behavioral economics used to inform intervention of 3 “nudges”: a social proof, a prime and a cue
- PLHIV exposed to the intervention were significantly more likely to be in care after 6 months (87% vs. 79%, ORa = 1.73, 95% CI: 1.08, 2.78, $p < 0.05$)
- Note: This was NOT PEPFAR-funded



Key Take-Away Messages

- ❖ What motivates behavior change is not always the impact - focusing only on awareness raising of rational benefits (IEC) is not sufficient
- ❖ What your clients know, believe, feel matters - collecting insights around individual, social and structural barriers and drivers is the foundation of a client-centered approach
- ❖ SBC can be applied at all points along the HIV Continuum
- ❖ SBC can produce measurable results for improved HIV outcomes and sustained epidemic control
- ❖ Behavioral economics nudges may be useful for moving the needle to 95-95-95 and beyond

Some SBC/Behavioral Science Resources If You Want to Learn More

- [PEPFAR Solutions](#)
- [Menstar](#)
- [PreP Watch](#)
- [Breakthrough ACTION-RESEARCH](#)
- [Health Communication along the HIV Continuum](#)
- [Engage HCD](#)

Who is Supporting Behavioral Science and SBC in PCT/OHA?



Jacqueline Devine

Senior Social & Behavior Change Advisor

jadevine@usaid.gov



Suzanne Leclerc-Madlala

Senior Social & Behavior Change Advisor

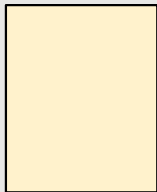
sleclerc-madlala@usaid.gov



Esther Braud

Senior Social & Behavior Change Advisor

ebraud@usaid.gov



Vacant

Senior Advisor, SBC/Behav
Science



Kaitlin Powers

Program Analyst

kapowers@usaid.gov



Vincent Wong

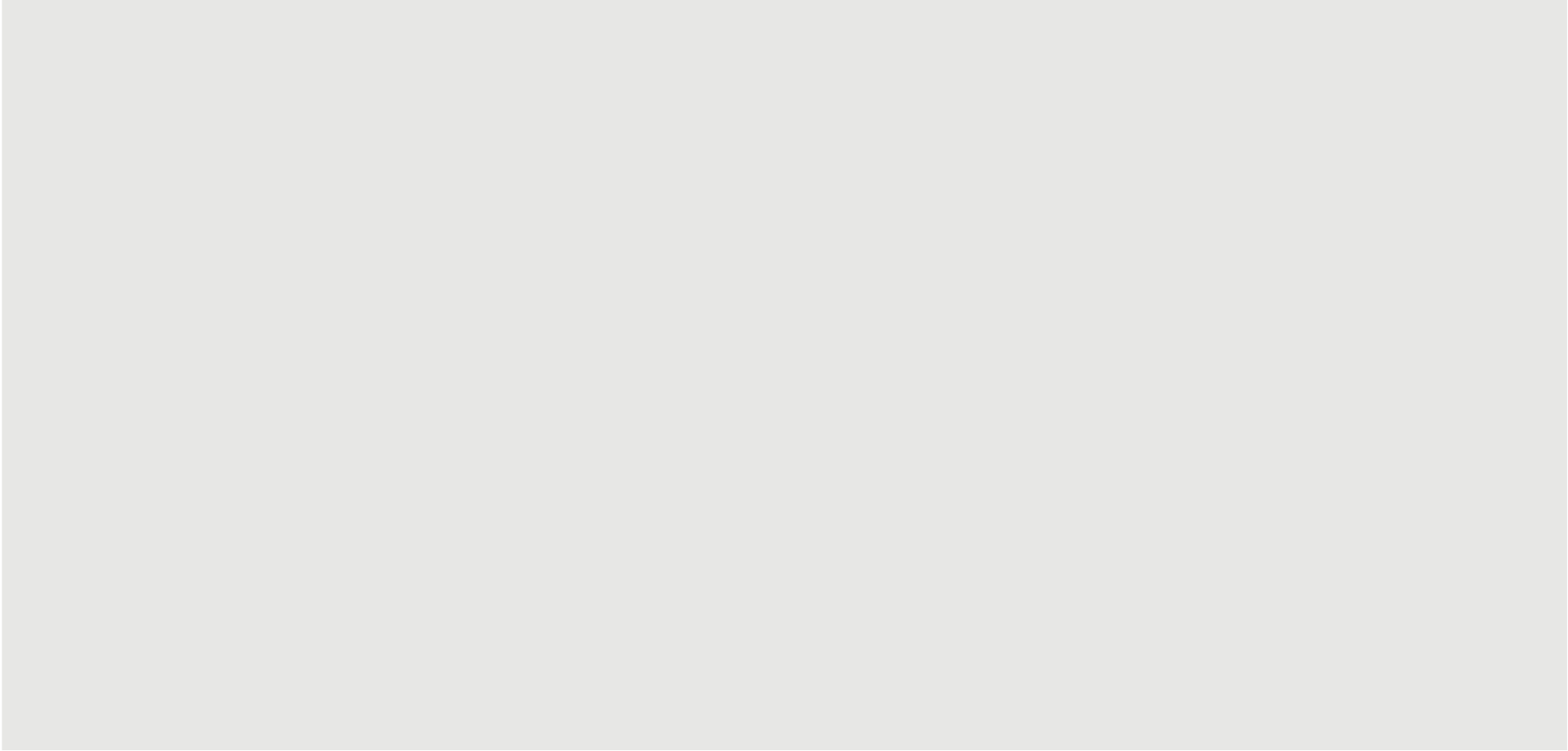
BSI Branch Chief

vwong@usaid.gov

Elizabeth Long,
BSI Behavioral Economics
Consultant

Beth Deutsch
BSI Digital Health Consultant

Vacant - Recruiting
Behavioral Science Consultants





Discussion and Questions





Thank you!



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