

Utilizing the Value Chain Situation Analysis (VCSA) to Launch Product Introduction Efforts

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What is the Situation Analysis?

The situation analysis is a rapid assessment of:

1. Current PrEP landscape within a country, including lessons from rollout of existing PrEP methods
2. What is needed to effectively introduce new PrEP methods – the PrEP ring and/or CAB PrEP

The analysis is conducted along a **structured framework** which was developed in 2015 as part of efforts to streamline the launch of oral PrEP, and thereafter adapted to include the existing PrEP market that new methods are layered on to.

The analysis is informed by a series of stakeholder consultations and desk review.



PrEP introduction framework

Value Chain for PrEP



PLANNING & BUDGETING

National and subnational plans are established to introduce and scale-up PrEP methods.



SUPPLY CHAIN MANAGEMENT

PrEP products are available and distributed in sufficient quantity to meet projected demand via priority delivery channels.



DELIVERY PLATFORMS

PrEP methods are delivered by trained providers in priority delivery channels to effectively reach end users.



UPTAKE & EFFECTIVE USE

End users know about and understand PrEP methods and know how to access and effectively use them.



MONITORING, EVALUATION & LEARNING

PrEP products are effectively integrated into national, subnational, facility, community, and program monitoring systems.

Conducting a VCSA: Why is it Important?

This is a foundational step in national planning for the introduction and scale-up of PrEP methods. It's needed to –

- Highlight critical gaps, opportunities, potential challenges etc. and using these insights to streamline the path towards efficient and effective product introduction
- Initiate crucial early discussions on product introduction strategies through TWGs to ensure all stakeholders are informed and aligned on the necessary steps for successful implementation

- ✓ Uganda – used the VCSA findings to develop a detailed activity matrix used by the TWG as a workplan to prepare for product introduction.
- ✓ Zambia, Namibia, Nigeria, etc. used findings from the VCSA to steer conversations around structured implementation plans/protocols used to guide new product introduction.

PrEP introduction situation analysis

PLANNING & BUDGETING

SUPPLY CHAIN MANAGEMENT

DELIVERY PLATFORMS

UPTAKE & EFFECTIVE USE

MONITORING, EVALUATION & LEARNING

Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning and private sector providers/pharmacies

- O Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working group**.
- O Identify **focus populations and set targets** for PrEP methods.
- O Engage **community stakeholders** to inform planning for PrEP rollout.
- O Develop impact, cost, and/or cost-effectiveness **analyses** to inform PrEP planning.
- O Include PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, FP).
- O Issue standard **clinical guidelines** for delivery and use of PrEP methods.
- O Develop an **implementation plan and budget** to guide initial PrEP introduction and scale-up.

- O **Register** PrEP products and include on the national essential medicines list, if needed.
- O Update **supply chain guidelines and logistics systems** to include PrEP products.
- O Conduct **forecasting and/or quantification** to inform procurement of PrEP products.
- O Establish **procurement, commodity monitoring, and distribution** for PrEP products and associated materials.
- O Establish **storage and distribution systems** that maintain temperature controls for PrEP products, if needed.

- O Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing PrEP use**.
- O Develop trainings and materials for **health care workers** on PrEP methods.
- O Establish **referral systems** to link clients from other channels to sites providing PrEP.
- O Integrate support for **partner communication** and services for intimate partner violence.

- O Develop and implement **demand generation strategies** that include PrEP promotion.
- O Address social norms/stigma to build **community and partner acceptance** of PrEP use.
- O Develop **information and tools for clients** to support product choice.
- O Support **effective use** of PrEP products.

- O Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.
- O Establish systems for **pharmacovigilance** and to monitor drug resistance.
- O Conduct **implementation science** research to inform policy and scale-up.

COLOR KEY

- Completed / underway
- Expected to be easily integrated
- Requires significant consideration

- Oral PrEP
- CAB PrEP
- PrEP ring

Process Overview

Share/review relevant documents and secondary research that capture the current state of the HIV epidemic and the PrEP program, as well as lessons learned from introduction of existing PrEP methods

Schedule & conduct 1:1 interviews with ~15 – 20 prioritized stakeholders to gather inputs

Continue research and interviews to fill-in gaps and develop a comprehensive, final analysis

Identify and consult stakeholders who can provide perspectives on the introduction of existing PrEP methods as well as the new PrEP methods along the five elements of the framework

Synthesis/analysis the data and use findings to draft initial report, share with key partners, and refine as needed



Step 1: HIV in [Country]

Step 1A: HIV prevention context

GOAL: Understand the HIV prevention context in the country relevant to the introduction of the PrEP method.

INSTRUCTIONS

Collect data and summarize the current situation for HIV prevention using the templates on the following slides. Key topics include:

- Indicators for HIV prevalence, incidence, and new infections for adults by age, gender, and population group (e.g., from PHIA surveys, UNAIDS estimates, national policy documents)
- Indicators for HIV prevalence, incidence, and new infections for subnational regions (e.g., from PHIA surveys, UNAIDS estimates)
- An overview of existing HIV prevention policies, systems, and delivery

The Kenyan HIV epidemic is geographically concentrated – just 13 of 47 counties are home to most of those living with HIV

HIV Prevalence reaches hyper epidemic levels in 5 counties: Homa Bay (~20%); Kisumu (~18%); Siaya (~15%); Migori (13%); Busia (~10%)

Just 8 counties account for 57% of new infections And with the inclusion of 5 counties, account for 3 of 4

ESTIMATED HIV INCIDENCE BY COUNTY, 2020

Analysis conducted by Mann Global Health

HIV risk for women in Nigeria remains high

EPIDEMIC CONTROL AND UNAIDS 95-95-95 GOALS

- HIV prevalence is 1.8% among women ages 15–64, 0.8% among young women ages 15–24, 1% among men ages 15–64, and 0.2% among young men ages 15–24.¹
- Adolescent girls and young women are disproportionately affected by HIV, especially high among 20–24-year-old females.²

HIV PREVALENCE BY SEX AND AGE, NAHS 2018

New HIV infections have remained steady in Nigeria over the past decade

KEY STATISTICS

- Approximately 1.9 million people are living with HIV in Nigeria, accounting for an overall prevalence of 1.4%.¹
- Nigeria continues to report a significant number of new HIV infections annually — remaining steady at around 100,000–20,000 new infections annually.
- The HIV epidemic in Nigeria is the 2nd largest in the world and has the fastest rising number of HIV-positive cases in sub-Saharan Africa, although Nigeria has low prevalence and incidence rates relative to other countries in the region.²
- Low HIV testing coverage among men, young people, and other vulnerable populations such as key populations (KPs) remains a major challenge to the HIV response in Nigeria.¹
- Other challenges include stigma and discrimination related to HIV, poor attitudes of health care workers (HCWs), and the distance between communities and facilities.¹

TREND IN NEW HIV INFECTIONS, 2010 – 2019

ESTIMATE OF HIV PREVALENCE OVER TIME, AGES 15–49

Sources: (1) Federal Ministry of Health, Nigeria, Nigeria HIV/AIDS Indicator and Impact Survey (NAHS) 2018. (2) UNICEF/UNFPA, HIV Programming in Adolescents and Young People in Nigeria, July 2021. Source: Nigeria National HIV and AIDS Strategic Framework 2021–2025.

Completed situation analyses from other countries can be found on [PrEPWatch](#).

Step 1: HIV in [Country]

Step 1B: Oral PrEP rollout

GOAL
Understand the current situation for existing PrEP product (oral PrEP) rollout in country.

INSTRUCTIONS

Before conducting interviews, collect data and use secondary research methods to understand the situation. For example, you can collect data on the oral PrEP rollout, build a timeline of rollout milestones, and/or pull together the key lessons learned through oral PrEP rollout that may influence how CAB PrEP should be introduced.

When information is limited, conducting interviews with key national stakeholders and implementing partners for oral PrEP programming will be a necessary starting point to understanding the situation for oral PrEP rollout.

CAB PrEP is an opportunity to expand the reach of HIV prevention interventions to populations in need

Analysis conducted by Mann Global Health

Zimbabwe's current HIV prevention strategy identifies populations for PrEP at high risk of HIV infection including AGYW, male and female sex workers (FSW); and men who have sex with men (MSM). Truck drivers, prisoners and sero-discordant couples, and pregnant and breastfeeding people (PBF) are also identified¹.

Priority groups (KPs)	Who are they?	Considerations
	<ul style="list-style-type: none"> Female sex workers (FSW) Men who have sex with men (MSM) Transgender people 	<ul style="list-style-type: none"> FSW in particular are recognized as being at highest risk of getting infected with HIV

"Don't repeat the mistakes of stigmatizing the product through association with..."

Oral PrEP rollout in Uganda

KEY MILESTONES¹

- In 2017, the rollout of oral pre-exposure prophylaxis (PrEP) began in 2017 in six antiretroviral therapy (ART) facilities.
- An initial demonstration project informed the development of the PrEP Technical Policy in December 2016, which resulted in the development of a training curriculum and monitoring and evaluation (M&E) tools for oral PrEP.
- A modeling exercise was conducted early in oral PrEP integration to identify priority populations for oral PrEP and map where they were located. This exercise greatly informed implementation.

Oral PrEP Implementing Partners in Uganda 2022²

Agency	Oral PrEP Implementing Partner
	Holma Region – Baylor Uganda
	Kampala Capital City Authority (KCCA) Urban Strategy
	MOH
	Uganda Episcopal Conference (UEC)
	Uganda Protestant Medical Bureau (UPMB)
CDC	Uganda Prisons Services (UPS)
	Soroti Region – The AIDS Support Organization of Uganda (TASO)
	Masaka Region – Rakai Health Sciences

Government support of oral PrEP led to a quick rollout; however, delivery and uptake remain bottlenecks

KEY SUCCESSES

- At the outset, there were concerns from key stakeholder groups that bringing on a biomedical HIV prevention method would divert funding from HIV treatment. However, **government buy-in and coordination at the national and local levels** were critical to quickly scale implementation.
- The sizeable investment for oral PrEP from donor organizations allowed for a quick integration in the KP-focused programs in **public HIV facilities**, as well as **one-stop-shops (OSS)**. Now the program has expanded to public health facilities

KEY CHALLENGES

- The focus on programs for KPs during the initial rollout led to **confusion and inaccurate information dissemination** on who is eligible for oral PrEP. Demand generation strategies were also not well adapted to reach SDCs and AGYW due to the focus on the KP groups.
- Stigma and misconceptions** persist among providers.

Nigeria has made significant progress on oral PrEP rollout

After oral PrEP was approved for use in Nigeria in 2016 and demonstration projects showed high acceptability among priority populations (2017–2018), the Government of Nigeria (GoN) quickly integrated oral PrEP in HIV prevention plans and began rollout in 2020.

Timeline for key milestone of Nigeria's national response: Biomedical HIV prevention

- 2016:** The GoN recommended the use of oral PrEP and updated the National Guidelines for HIV Prevention, Treatment and Care.
- 2017/2018:** Demonstration projects began to test the acceptability of oral PrEP in Nigeria in three states (Calabar, Jos, and Newwi).
- 2018:** The Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS), a population-based survey, provided improved data on the HIV epidemic in Nigeria.
- 2019:** HIV self-testing (HIVST) was approved for use in Nigeria.
- 2019:** The Revised National AIDS and HIV Strategic Framework 2019–2021 was published to fast-track the national AIDS response based on NAIIS findings.
- 2020:** The HIV Prevention Technical Working Group (TWG) was convened by the National Agency for the Control of AIDS (NACA). A subcommittee was formed to meet each quarter to lead the introduction of oral PrEP and develop the national guidelines.
- 2020:** USAID Nigeria and AIDSFree organized and facilitated virtual PrEP training for partners implementing PrEP, using the Oral PrEP eLearning course developed by WHO and Jhpiego.
- 2020:** Scale-up of oral PrEP began in early 2020, primarily through donor-funded projects across Nigeria. Integration of oral PrEP was informed by a value chain situation analysis.
- 2021:** The National HIV and AIDS Strategic Framework 2021–2025 was developed to include oral PrEP in HIV prevention policies and plans.
- 2021:** National monitoring, supportive supervisory visits began to support facilities and community centers providing PrEP services.
- 2021:** The HIV Prevention TWG reviewed the National HIV Strategy for Adolescents and Young People.
- 2022:** Several guidelines and policies were developed, including:
 - National HIV Self-Testing and Pre-Exposure Prophylaxis Communication Strategy
 - National Oral PrEP Implementation Plan
 - National Oral PrEP Training materials
- 2022:** The first national Training of Trainers on oral PrEP service delivery was conducted; capacity building workshops were facilitated on the use of digital strategies for condom use, oral PrEP and HIVST; and the first youth-focused HIV Prevention Campaign Gen-N was launched.
- 2022:** A stakeholder mapping for oral PrEP implementation was conducted.

Sources: MOSAIC interviews and desk research; PrEPWatch, November 2022.

Step 2

Stakeholder Interviews

GOAL: Gather input from key stakeholders to inform an assessment of the current situation for new PrEP product (CAB PrEP, etc) rollout in your country along a structured framework.

INSTRUCTIONS

Based on your research in Step 1:

1. Build a stakeholder map to identify organizations and individuals who can provide informed perspectives on the past rollout of oral PrEP and potential future rollout of CAB PrEP on topics along the PrEP Introduction Framework
 - Customize guides for your interviews based on the Interview Question Bank included in this tool; note it may be necessary to adapt questions to your context
 - Conduct interviews and take notes as the primary method of collecting the data you will analyze in Step 3.

Interview Outreach List

TEMPLATE

DIRECTIONS: Track outreach for interviewees and plan which areas to ask questions about across the PrEP Introduction Framework. Interviews may need to be planned in waves to identify remaining questions or missing information when completing the situation analysis.

Organization	Interviewee(s)	Areas to probe across the PrEP Introduction Framework	Status	Interview date
Organization 1	Name	Planning & budgeting, supply chain management, monitoring	Outreach sent	Pending
Organization 2	Name	Planning & budgeting, delivery platforms, uptake & effective	Scheduling	Feb 2, 2022

Stakeholder Map for CAB- LA

TEMPLATE

Map stakeholders across the PrEP Ring Introduction Framework to plan for interviews that will inform the situation analysis.

Type	Organization(s)	Role in PrEP ring introduction	PrEP Introduction Framework				
			Planning & budgeting	Supply chain mgmt	Ring delivery platforms	Uptake & effective use	Monitoring
Governmental organizations	Organization 1		Currently involved				
	Organization 2		Currently involved				
	Organization 3		Potential/future involvement				
Development and implementing partners			Currently involved				
Civil society organizations and community-based organizations			Potential/future involvement				
Private sector and/or community-based providers			Potential/future involvement				
Bilateral organizations and funders			Potential/future involvement				

GOAL: Identify the organizations that are currently involved or should be involved in CAB-LA introduction along the PrEP Introduction Framework. This will help you plan stakeholder interviews to build the situation analysis.

DIRECTIONS: Specify the name and describe the current or expected role of each stakeholder. You can categorize stakeholders by type, Framework component, and involvement status.

Step 3

Analysis and synthesis

GOAL: Synthesize interview inputs to assess the current situation for new PrEP product (CAB PrEP) rollout in your country.

INSTRUCTIONS

Review the data you collected during the interviews to pull out the key findings for each element of the CAB PrEP Introduction Framework.

The following slides include templates for data analysis and synthesis across the framework. Follow the directions on each slide and track where you may need to plan additional interviews to collect any missing information.

Analysis & Synthesis

TEMPLATE Remaining key questions

- PLANNING & BUDGETING
- SUPPLY CHAIN MANAGEMENT
- DELIVERY PLATFORMS
- UPTAKE & EFFECTIVE USE
- MONITORING

Analysis & Synthesis

TEMPLATE [Country] situation analysis summary findings

Findings from the [Country] situation analysis are summarized below, with details included on the following slides.

- PLANNING & BUDGETING
- SUPPLY CHAIN MANAGEMENT
- DELIVERY PLATFORMS
- UPTAKE & EFFECTIVE USE
- MONITORING, EVALUATION, & LEARNING

opportunities for introduction

- Finding 1
- Finding 2
- Finding 3
- Finding 4
- Finding 5

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Analysis & Synthesis

Detailed CAB PrEP Introduction Framework

Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning and private sector providers/pharmacies

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	UPTAKE & EFFECTIVE USE	MONITORING, EVALUATION, & LEARNING
<p>Convene new or existing subcommittee or task team within HIV prevention or PrEP technical working groups.</p> <p>Identify focus populations and set targets to inform CAB PrEP planning.</p> <p>Engage community stakeholders to inform planning for CAB PrEP rollout.</p> <p>Include CAB PrEP in national HIV prevention and other relevant plans and policies (e.g., HIV testing, FP).</p> <p>Issue standard clinical guidelines for delivery and use of CAB PrEP.</p> <p>Develop an implementation plan and budget to guide initial introduction and scale-up of CAB PrEP.</p>	<p>Register CAB PrEP and include it on the national essential medicines list, if needed.</p> <p>Update supply chain guidelines and logistics systems to include CAB PrEP.</p> <p>Conduct forecasting and/or quantification to inform procurement of CAB PrEP.</p> <p>Establish procurement, commodity monitoring, and distribution for CAB PrEP and associated materials.</p> <p>Establish storage and distribution systems that maintain temperature controls for CAB PrEP.</p>	<p>Dedicate resources to conduct regular HIV tests, initiate PrEP, and support ongoing CAB PrEP use.</p> <p>Develop trainings and materials for health care workers on CAB PrEP.</p> <p>Establish referral systems to link clients from other channels to sites providing CAB PrEP.</p> <p>Integrate support for partner communication and services for intimate partner violence response.</p>	<p>Develop and implement demand generation strategies that include CAB PrEP promotion.</p> <p>Address social norms/stigma to build community and partner acceptance of CAB PrEP use.</p> <p>Develop information and tools for clients to support product choice.</p> <p>Support effective use of CAB PrEP.</p>	<p>Update or establish integrated monitoring tools to support data collection and analysis on PrEP use across multiple products.</p> <p>Establish systems for pharmacovigilance and to monitor drug resistance.</p> <p>Conduct implementation science research to inform policy and scale-up.</p>

private sector providers/pharmacies

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Planning & budgeting

Key steps and considerations



PLANNING &
BUDGETING

	Current situation of oral PrEP	What is needed to introduce CAB PrEP and other considerations
Convene new or existing subcommittee or task team within HIV prevention or PrEP technical working group.		<p>Refer to P1 in the Question Bank and include details on:</p> <ul style="list-style-type: none"> Plans for a task force or technical work groups (TWGs) to lead CAB PrEP introduction Timelines and/or milestones for key decisions Plan for participation of stakeholders from other relevant areas (e.g., FP, maternal and child health [MCH])
Identify focus populations and set targets to inform CAB PrEP planning.		<p>Refer to P2 in the Question Bank and include details on:</p> <ul style="list-style-type: none"> Plans for end-user population (e.g., etc.)
Engage community stakeholders to inform planning for CAB PrEP rollout.		<p>Refer to P3 in the Question Bank and include details on:</p> <ul style="list-style-type: none"> Key lessons on community engagement (to authentically engage community members and hear their perspectives) Plans for engaging community stakeholders on CAB PrEP introduction
Include CAB PrEP in national HIV prevention and other relevant plans and policies (e.g., HIV testing, family planning, private sector).		<p>Refer to P5 in the Question Bank and include details on:</p> <ul style="list-style-type: none"> Key HIV prevention strategies/plans that will need to incorporate CAB PrEP; how these strategies/plans currently incorporate oral PrEP Other strategies/plans that could include CAB PrEP (e.g., plans for SRH, adolescent health, or private sector delivery)
Issue standard clinical guidelines for delivery and use of CAB PrEP.		<p>Refer to P6 in the Question Bank and include details on:</p> <ul style="list-style-type: none"> Current state of and lessons learned from clinical guidelines for oral PrEP Plans/timelines for clinical guidelines for CAB PrEP
Develop an implementation plan and budget to guide initial introduction and scale-up of CAB PrEP.		<p>Refer to P7 in the Question Bank and include details on:</p> <ul style="list-style-type: none"> Plans/timelines for introduction and scale-up of CAB PrEP Integration of CAB PrEP in HIV prevention budgets and donor requests Sources of financial resources to support CAB PrEP procurement and introduction activities

Text in pink indicates key steps related to diverse delivery channels (e.g., non-HIV channels)

TEMPLATE

CAB PrEP introduction situation analysis summary

PLANNING & BUDGETING

SUPPLY CHAIN MANAGEMENT

DELIVERY PLATFORMS

UPTAKE & EFFECTIVE USE

MONITORING, EVALUATION, & LEARNING

Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning and private sector providers/pharmacies

Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working groups**.

Identify **focus populations and set targets** to inform CAB PrEP planning.

Engage **community stakeholders** to inform planning for CAB PrEP rollout.

Include CAB PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, family planning).

Issue standard **clinical guidelines** for delivery and use of CAB PrEP.

Develop an **implementation plan and budget** to guide initial introduction and scale-up of CAB PrEP.

Register CAB PrEP and include it on the national essential medicines list, if needed.

Update **supply chain guidelines and logistics systems** to include CAB PrEP.

Conduct **forecasting and/or quantification** to inform procurement of CAB PrEP.

Establish **procurement, commodity monitoring, and distribution** for CAB PrEP and associated materials.

Establish **storage and distribution systems** that maintain temperature controls for CAB PrEP.

Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing CAB PrEP use**.

Develop training and materials for **health care workers** on CAB PrEP.

Establish **referral systems** to link clients from other channels to sites providing CAB PrEP.

Integrate support for **partner communication** and services for intimate partner violence response.

Develop and implement **demand generation strategies** that include CAB PrEP promotion.

Address social norms/stigma to build **community and partner acceptance** of CAB PrEP use.

Develop **information and tools for clients** to support product choice.

Support **effective use** of CAB PrEP.

Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.

Establish systems for **pharmacovigilance** and to monitor drug resistance.

Conduct **implementation science** research to inform policy and scale-up.

COLOR KEY

Opportunity to easily build on oral PrEP rollout

Will require new effort, but no anticipated challenges

Requires significant consideration specifically for CAB PrEP

TEMPLATE

Remaining key questions



PLANNING & BUDGETING

- Question 1
- Question 2
- Question 3



SUPPLY CHAIN MANAGEMENT



DELIVERY PLATFORMS



UPTAKE & EFFECTIVE USE



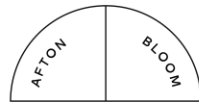
MONITORING

GOAL: To identify the remaining key questions about CAB PrEP and its introduction along the PrEP Introduction Framework.

INSTRUCTIONS: List the key outstanding concerns, information gaps, and unknowns for each stage of the framework that arise from your research and/or stakeholder interviews.

ACKNOWLEDGMENTS

Thank you to Afton Bloom for the development of this tool. For questions about the tool, please contact the MOSAIC Consortium at info@prepnetwork.org



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

Photo Credit: MOSAIC Consortium



OVERVIEW OF PrEP AND PEP POLICIES

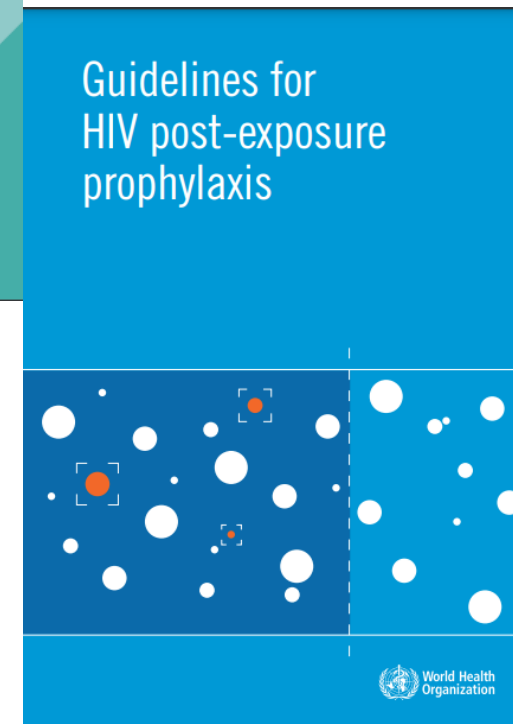
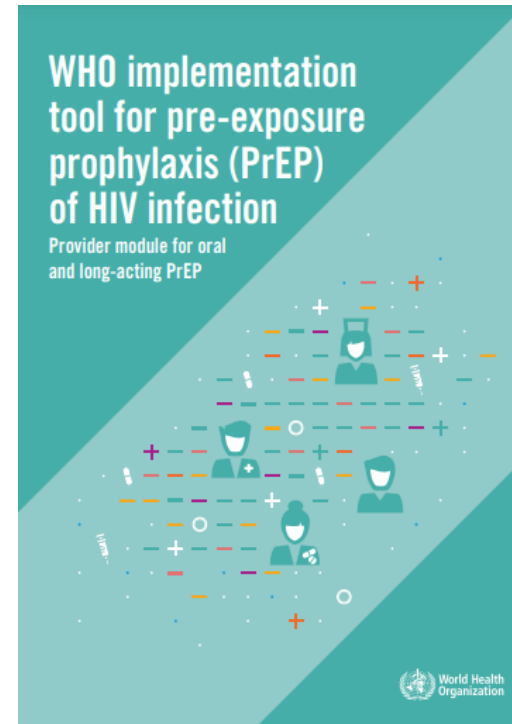
PRESENTED AT THE AFRICA REGIONAL PREP WORKSHOP
9TH SEPTEMBER 2024

NJAMBI NJUGUNA, FHI 360, MOSAIC



Background

- Many countries rely heavily on WHO guidance and policies to formulate their own.
- WHO has recently released two guideline documents for PrEP and PEP.
- Countries adopt different approaches to policy documents- updates to existing guidelines, addendum guidelines, draft guidelines for pilot studies
- Multiple documents at country level – implementation plans, PrEP guidelines, PrEP framework, PEP policy





1

PREP POLICY ANALYSIS



PrEP policy overview

- We reviewed content of PrEP guidelines across 10 African countries
 - Products and regimens included
 - Populations
 - Age or weight considerations
- Challenges/gaps in PrEP guidelines
- How to make policies more inclusive – things to consider so PrEP is available to anyone who needs it (value of offering choice)

PrEP guideline overview

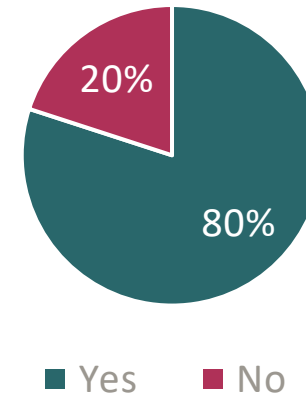
Country	Policy name	Date
Botswana	2023 Botswana Integrated Clinical Care Guidelines	2023
Eswatini	Eswatini PrEP Implementation Guidance	2024
Kenya	Kenya HIV Prevention and Treatment Guidelines	2022
Lesotho	National Guidelines on the Use of Antiretroviral Therapy for HIV Prevention and Treatment (Sixth Edition)	2021
Namibia	National Guidelines for Antiretroviral Therapy	2021
Nigeria	National Guidelines for HIV Prevention, Treatment and Care	2020
South Africa	Updated Guidelines for the Provision of Oral Pre-Exposure Prophylaxis (PrEP) to Persons at Substantial Risk of HIV Infection; National Dapivirine Vaginal Ring Implementation Guidelines; Long Acting Injectable Cabotegravir (CAB-LA) National Implementation Guidelines	2021, 2022, 2023
Uganda	Technical Guidance on PrEP for Persons at Substantial Risk of HIV Infection in Uganda	2022
Zambia	HIV Pre & Post-Exposure Prophylaxis Guidelines	2023
Zimbabwe	Guidelines for HIV Prevention, Testing, and Treatment of HIV In Zimbabwe	2022

Oral PrEP guidelines

Oral PrEP guidelines



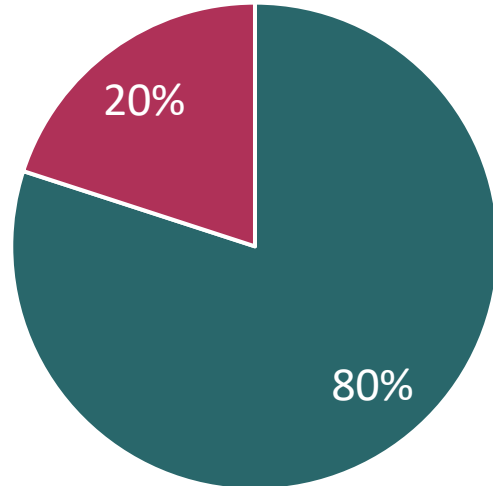
ED-PrEP/Infrequent dosing regimen



- All 10 countries have detailed oral PrEP guidelines, but only 8 allow for infrequent dosing regimen (previously known as ED-PrEP)

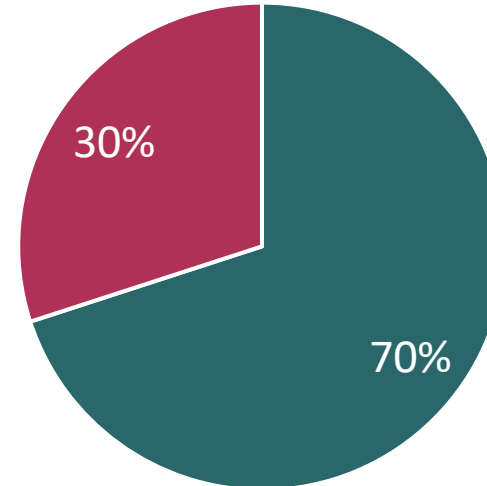
PrEP ring guidelines

PrEP ring mentioned in guideline



■ Yes ■ No

Detailed PrEP ring guidance

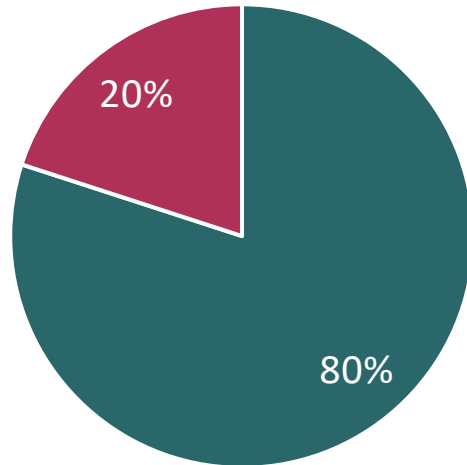


■ Yes ■ No

- Eight out of 10 countries mention PrEP ring in guidance, and 7 of these have comprehensive guidelines for PrEP ring use

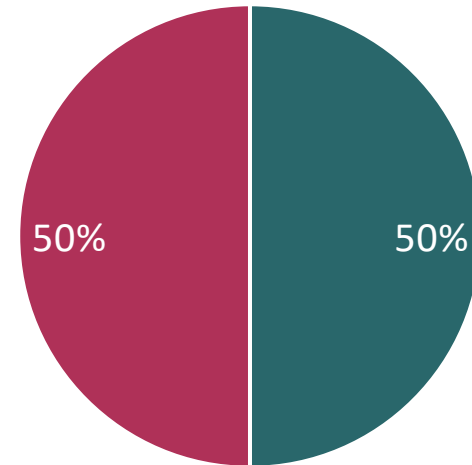
CAB PrEP guidelines

CAB PrEP mentioned in guideline



■ Yes ■ No

Detailed CAB PrEP guidance



■ Yes ■ No

- Eight countries have mentioned CAB PrEP in their guidelines, with 5 of these having comprehensive CAB PrEP guidance.

PrEP guideline overview (1)



General access

WHO recommends PrEP methods as additional combination prevention methods for people at substantial risk of HIV. Also recommend access for all who request PrEP.

- ✓ All countries allowed access for people at substantial risk of HIV
- ✓ Some guidelines described particular groups of people who may be at substantial risk eg key populations
 - ✓ However, not all guidelines explicitly mentioned allowing access for all people who requested PrEP

PrEP guideline overview (2)

Age/Weight

-  **PrEP ring:** studies initially only included people 18+ so many guidelines using this cutoff. This may change in the future based on new AGYW safety and acceptability data from the REACH study.
 -  **CAB PrEP:** studies used a weight minimum (35kg) instead of age.
- ✓ Age – generally the age cutoff was lower for oral PrEP than ring or CAB PrEP.
 - ✓ Weight – some countries described a weight cutoff for oral PrEP and CAB PrEP, in addition to age

PrEP guideline overview (3)

Pregnancy & Breastfeeding



PrEP ring: recent data from DELIVER and B-PROTECTED studies demonstrated safety in pregnant and breastfeeding people.



CAB PrEP: HPTN 084 open label extension presented at the AIDS 2024 meeting in July 2024 reported no difference in pregnancy outcomes for women taking CAB; waiting for data on breastfeeding.

- ✓ Countries have varying recommendations on use in PBFP. Three countries allow use during pregnancy and breastfeeding, while one allows use during breastfeeding only.
- ✓ For CAB, country guidance varies – all 5 countries with guidance do not currently allow people to start CAB while pregnant or breastfeeding but three allow continued use if clients get pregnant.

PrEP guidelines – Challenges

- ✓ Countries often wait for WHO guidance to base their policies/guidelines
 - ✓ Review of existing data to help inform in-country guidance is useful, even as WHO formulates guidelines
- ✓ Evidence matters – some MoH would prefer to use data generated in-country
 - ✓ Consider available data as studies/implementation in similar countries are conducted
- ✓ Misalignment of age of access of various HIV prevention services - age cutoffs for HIV testing vary from PrEP access and sometimes even by PrEP method
- ✓ Rapidly evolving evidence is creating a challenge in updating policy documents
 - ✓ Consider not being too prescriptive in main guideline to allow for changes
 - ✓ Templates help!
 - ✓ [PrEP product implementation plan template](#)
 - ✓ [PrEP guideline template](#)

Considerations for inclusive PrEP guidelines

- Populations , including PBFP
 - ✓ Access by all who request it
 - ✓ Allow PBFP to choose - WHO recommends oral PrEP in PBFP, highlights that PrEP ring has evidence for safety, and highlights that though there are limited data for CAB PrEP in PBFP, there has been no safety signal and it is not contraindicated.
- Product choice – availability alone is not choice. Allow for change as appropriate or desired by clients in various stages of their lives
- Age and weight – consider aligning age of access for products and HIV testing.
- Regimens – allow easier regimens for men not taking gender affirming hormones
- Differentiated service delivery – allow focus on person-centered services
 - ✓ Multimonth access including access to HIV self-testing where feasible
 - ✓ Community delivery



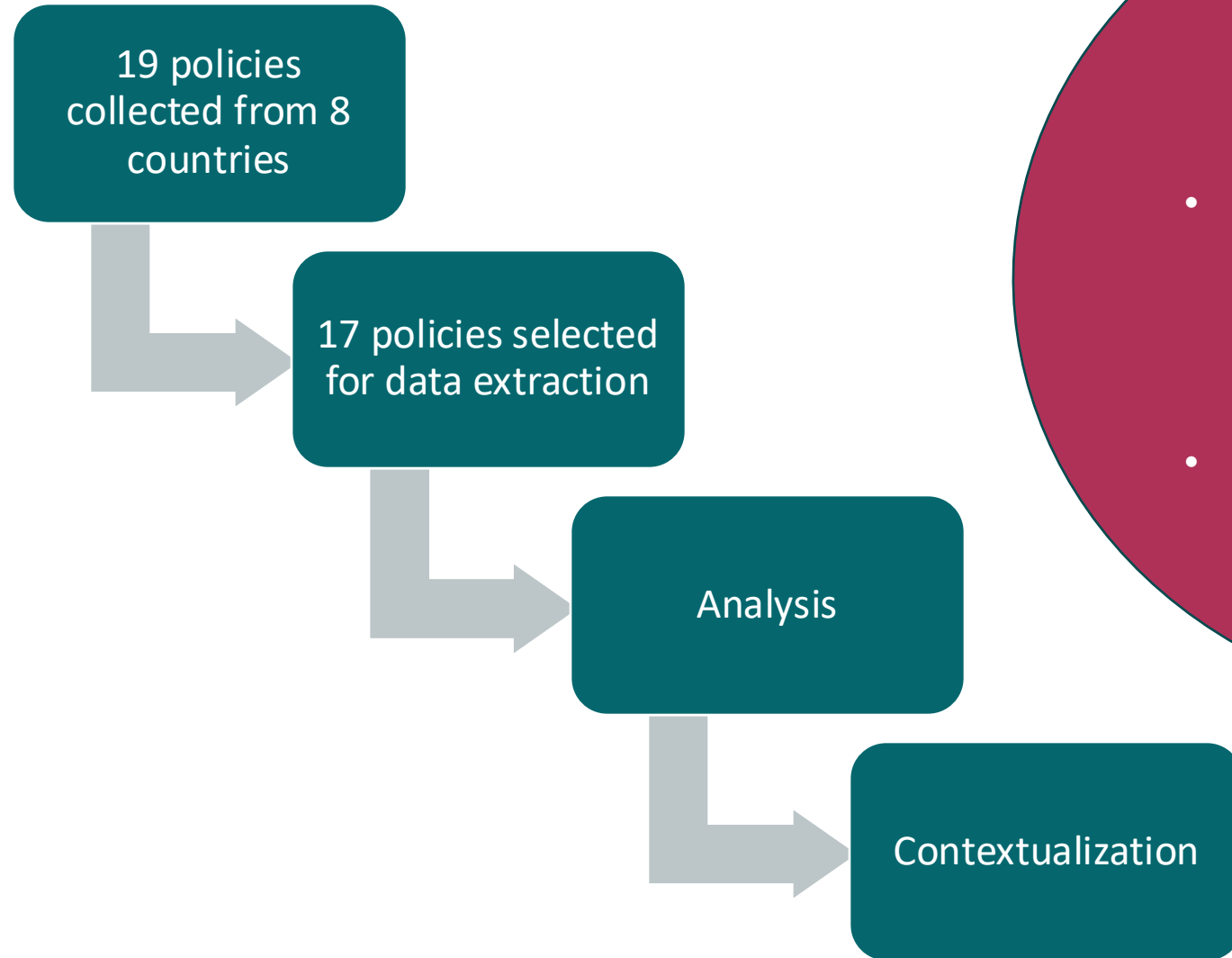
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PEP POLICY ANALYSIS

Background

- Guidelines from WHO recommend the use of post-exposure prophylaxis (PEP) by individuals potentially exposed to HIV for the prevention of HIV.
- Evidence supporting the use of antiretrovirals (ARVs) for HIV PEP dates to 1990, but it remains an underutilized part of HIV combination prevention.
- In addition to playing a vital role in HIV prevention on its own, PEP can act as bridge from potential exposure to uptake of other HIV prevention strategies, including PrEP.
- The PEP policy analysis, synthesized in this [PEP policy brief](#), aimed to:
 - Summarize the PEP policy landscape in 8 countries
 - Illustrate how to address policy and implementation barriers
 - Recommend ways to increase access to and uptake of PEP as part of HIV prevention

Methods



- Do these policies reflect what you know to be the reality of PEP access and service delivery?
- What are the barriers to PEP access generally? For adolescent girls and young women (AGYW) specifically?
- Where do you see opportunities to strengthen PEP access generally? For AGYW specifically?

Policies included in analysis

Country	Policy Name	Date Issued
Eswatini	DRAFT PEP Section Guidelines	2022 (launched February 2023)
	Clinical Implementation Guide for PrEP Provision in Eswatini	2019
	Swaziland Integrated HIV Management Guidelines	2018
Kenya	Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV in Kenya	2018
	Pre-exposure Prophylaxis for the Prevention of HIV Infection: A Toolkit for Providers	2017
Lesotho	National Guidelines on the Use of Antiretroviral Therapy for HIV Prevention and Treatment, Sixth Edition	2021
Nigeria	National Guidelines for HIV Prevention, Treatment and Care	2020
	Guidelines for Providing Post Exposure Prophylaxis	2020
South Africa	National Clinical Guidelines of Post-Exposure Prophylaxis (PEP) in Occupational and Non-occupational Exposures	2020
	Guideline on the Management of Occupational and Non-occupational Exposure to HIV and Recommendations for PEP (2015 update)	2015
	Corrigendum PEP Guidelines	2015
Uganda	Consolidated Guidelines for the Prevention and Treatment of HIV and AIDS in Uganda	2020
Zambia	Consolidated Guidelines for HIV Care & Treatment	2020
	Implementation Framework & Guidance for Pre-Exposure Prophylaxis Of HIV Infection	2018
Zimbabwe	Zimbabwe National HIV & AIDS Strategic Plan 2021–2025	2021
	Addendum to the Guidelines for the Antiretroviral Therapy for the Prevention & Treatment of HIV in Zimbabwe	2020
	Guidelines for ART for the Prevention & Treatment of HIV in Zimbabwe	2016

PEP Eligibility

- WHO recommends that PEP be offered to “all individuals with exposure that has the potential for HIV transmission.”

Policy element	Country
PEP access to anyone who has a potential exposure to HIV, with no restrictions on PEP eligibility by age and no mention of required parental consent	ALL
Use of PEP by survivors of sexual assault	ALL
Use of PEP by individuals who may be occupationally exposed	ALL
Use of PEP by those with other potential sexual exposures	Kenya, Lesotho, Uganda, Zambia
Use of PEP by those who may be exposed through injection-related practices outside of occupational settings	South Africa
Differentiated services for individuals based on type of exposure	Eswatini, Kenya, Lesotho, Nigeria
PEP should not be offered to individuals if the HIV status of the potential source is established to be negative*	Eswatini, Kenya, Lesotho, South Africa, Uganda, Zimbabwe

*Three policies clarified that if the potential source has had recent exposure or may be in the window period, PEP can be considered (Eswatini, Kenya, South Africa). One policy recommends laboratory ELISA test if the potential source can be tested (South Africa).

PEP Eligibility – Key Recommendations

- Explicitly including people with injection-related potential exposures in policies may raise awareness and increase access to and uptake of PEP among these individuals.
- Including individuals with nonoccupational injection-related potential exposures would be beneficial.
- Policies that are comprehensive and cover differentiated services for different types of exposure, as well as making PEP available to those seeking PEP, may expand access.
- National policies and global recommendations may best serve people with recent HIV exposures by explicitly allowing for PEP access regardless of the HIV status of a potential source.

Time Frame of Provision

- Current WHO guideline recommends that PEP be accessed “as early as possible, ideally within 24 hours but not later than 72 hours” of potential HIV exposure and that “Starting as soon as possible after exposure is the most important consideration when taking PEP”.

Policy element	Country
Eligible individuals are required to access PEP within 72 hours of potential exposure* ^β	ALL

* Nigeria had two policies with both recommending access within 72 hours, and one specifying within 2-72 hours

^β Uganda’s policies clarify that PEP would ideally be accessed within the first two hours of potential exposure

Time Frame of Provision – Key Recommendation

- Potential PEP users may benefit from adoption of national policies that align with WHO recommendations and **allow PEP access immediately after a potential exposure**, without delay and with flexibility around the latest someone can access PEP, provided with clear information about the time frame in which PEP can be provided.

Recommended Drug Regimen for Adults and Adolescents

- WHO acknowledges that a PEP regimen with two ARV drugs is effective, but three drugs are preferred. For adults and adolescents taking PEP, WHO recommends tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) or emtricitabine (FTC) as the preferred backbone regimen, with dolutegravir (DTG) as the preferred third drug.

Policy element	Country
TDF/3TC/DTG as the preferred drug regimen for PEP	Eswatini, Kenya, Lesotho, Nigeria, South Africa, Uganda, Zimbabwe
TDF (or TAF) + FTC (or 3TC) + DTG	Zambia
Two-drug regimen	NONE

Recommended Drug Regimen for Adults and Adolescents – **Key Recommendations**

- As national policies are updated, policies that **provide flexibility for application as per WHO guidelines for two-drug regimen where necessary** may improve PEP completion and effectiveness
- Procurement of drugs for PEP needs to be included in **national procurement plans and long-term support for PEP procurements** must be established, with one-month supply supported by donors.

Linkages between PEP and PrEP

- WHO recommends offering PrEP to individuals after the completion of PEP if they are HIV negative and potential exposure to HIV is expected to continue after PEP completion

Policy element	Country
Recommendations for connecting PEP user to PrEP	Eswatini, Lesotho, Kenya, Zambia
“PEP to PrEP” mentioned in PEP-specific section	Eswatini, Kenya
“PEP to PrEP” mentioned in PrEP-specific section	Lesotho, Zambia
PrEP recommended for repeat PEP users	Eswatini, Kenya, Zambia

Linkages between PEP and PrEP – Key Recommendations

- Establishing **stronger “PEP to PrEP” policies** that support bidirectional referrals in service delivery settings may better enable informed choice and increase access to comprehensive HIV prevention.
- **Repeated PEP use** can be an indication that a client may benefit from PrEP, but offering PrEP only to those repeatedly returning for PEP may prevent the offer of PrEP to some potential users and contribute to limited access more broadly.



Additional findings: Non-policy barriers

Barriers to PEP Access

- For adolescent girls and young women (AGYW) specifically:
 - Traditional cultural norms and existing stigma shape and limit discussions with parents or other adults about sexual encounters or ways to seek sexual health
 - Lack of AGYW-responsive centers
 - Negative provider attitudes towards AGYW exposure
 - Clinic and school hours do not align
- Limited provider knowledge and training
- Confusion about PEP and PrEP
- Required prescription for pharmacy provision
- Testing requirements or diagnostic elements
- Parental or guardian consent
- Limited monitoring systems for PEP use, distribution and follow-up
- Stigma, especially when the exposure is due to sexual assault or rape
- Late reporting of exposures by those experiencing intimate partner or gender-based violence

Barriers to PEP Use

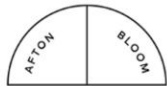
- Fear of side effects
- Lack of integrated sexual and reproductive health and HIV prevention services
- Gaps in follow-up for PEP adherence
- Lack of information on when PEP is appropriate to take (limiting timely access)
- PEPFAR had stopped procuring TDF/3TC/DTG in bottle sizes appropriate for the 28-day course of PEP, opting for 90-day count bottles as it focuses on supporting multi-month dispensation of ARVs for people living with HIV, leaving the responsibility of procurement of PEP-appropriate bottles to national programs and other donors
- No inclusion of provision of PEP proactively (sometimes called PEP in Pocket)



Additional findings (non-policy barriers): **Key Recommendations**

- Supporting **sensitization, training, and mentorship efforts** to familiarize both users and providers with PEP as part of the comprehensive HIV prevention package may address these barriers.
- Developing, testing, and codifying models for **community-based distribution** may elevate PEP awareness and elucidate opportunities for expanding differentiated service delivery.
- As other policy elements are strengthened to better support access to PEP, complementary efforts could be made to **standardize monitoring and evaluation** of PEP effective use and dispensation.

ACKNOWLEDGMENTS

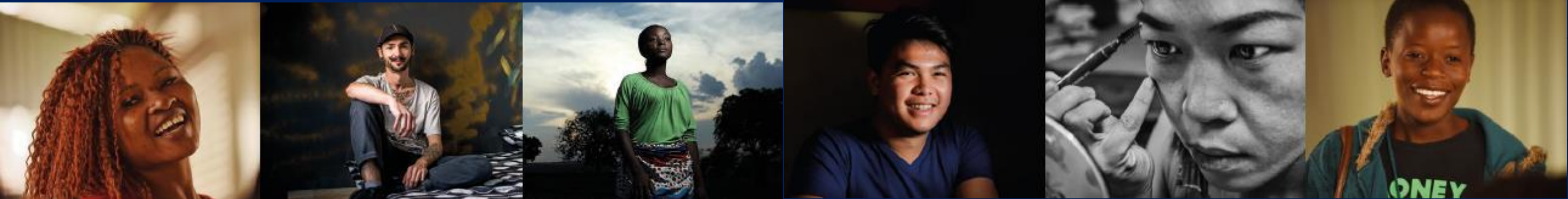


MOSAIC is made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID) cooperative agreement 7200AA21CA00011. The contents of this presentation are the responsibility of MOSAIC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

Photo Credit: MOSAIC Consortium



Scaling-up PEP for impact: increasing access via community delivery & task shifting



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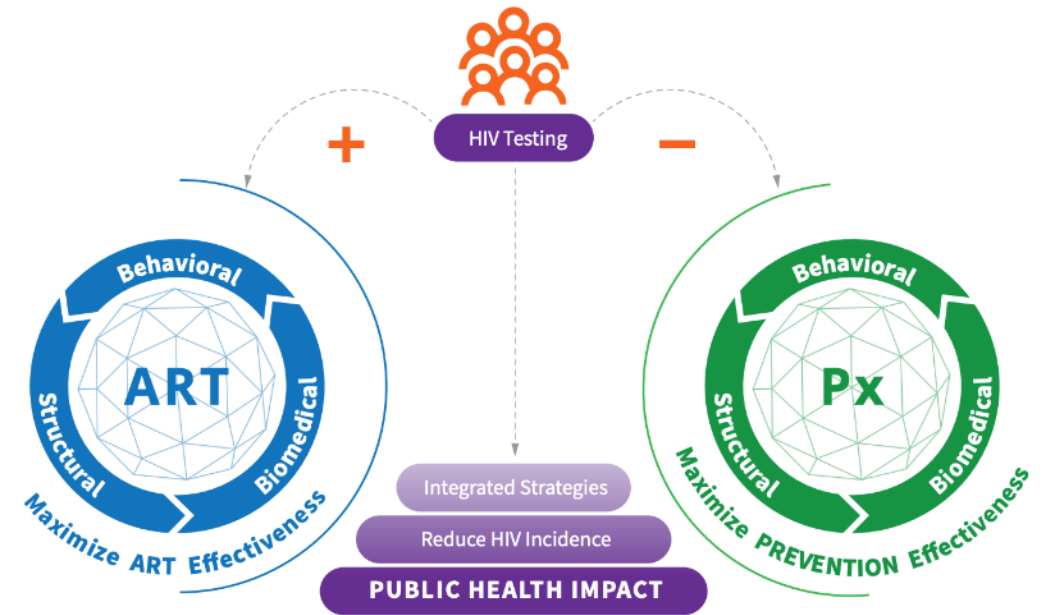
*On behalf of the WHO PrEP and PEP team: Michelle Rodolph, Mateo Prochazka Nuñez, Heather Ingold,
and Sushena Reza-Paul*

PEP is a key part of combination HIV prevention

Combination HIV prevention seeks to maximise the impact of HIV prevention by combining human rights-based and evidence-informed behavioural, biomedical and structural strategies

(adapted from UNAIDS 2015)

- PEP is an effective and under-utilized ARV-based HIV prevention option for HIV-negative people
 - PrEP is started prior to a potential exposure (pre-)
 - **PEP is started after a potential exposure (post-)**
 - ART is used by people living with HIV as treatment
- Complement other HIV prevention options, with strong synergies with PrEP



**Adapted from Wafaa El-Sadr*

Existing WHO PEP guidance and recommendations

PEP drug regimens and timing

Start early - PEP should be offered, and as early as possible, to individuals with suspected or known exposure to HIV, ideally within 24 hours but not later than 72 hours.

Starting PEP as soon as possible after exposure is the most important consideration when taking PEP.

ARV drug regimens for HIV post-exposure prophylaxis

An HIV post-exposure prophylaxis regimen with two ARV drugs is effective, but three drugs are preferred (*conditional recommendation, low-certainty evidence*)^a

Adults and adolescents

TDF + 3TC (or FTC) is recommended as the preferred backbone regimen for HIV post-exposure prophylaxis (*strong recommendation, low-certainty evidence*)^a

▶ DTG is recommended as the preferred third drug for HIV post-exposure prophylaxis for children for whom an approved DTG dosing is available (*strong recommendation, low-certainty evidence*)^b

▶ When available, ATV/r, DRV/r, LPV/r and RAL may be considered as alternative third drug options for post-exposure prophylaxis (*conditional recommendation, low-certainty evidence*)

Children^c

AZT + 3TC is recommended as the preferred backbone regimen for HIV post-exposure prophylaxis for children. ABC + 3TC or TDF + 3TC (or FTC) can be considered as alternative regimens (*strong recommendation, low-certainty evidence*)^a

▶ DTG is recommended as the preferred third drug for HIV post-exposure prophylaxis for children for whom an approved DTG dosing is available (*strong recommendation, low-certainty evidence*)

▶ When available, ATV/r, DRV/r, LPV/r and RAL may be considered as alternative third drug options for post-exposure prophylaxis (*conditional recommendation, low-certainty evidence*)

TLD, a fixed-dose combination of TDF, 3TC and DTG recommended by WHO for HIV treatment, may be preferable for HIV PEP as it reduces pill burden.

Existing WHO PEP guidance and recommendations

PEP duration and adherence

A 28-day prescription of antiretroviral drugs should be provided for HIV post-exposure prophylaxis following initial risk assessment. *(Strong recommendation, low-quality evidence)*

Enhanced adherence counselling is suggested for individuals initiating HIV post-exposure prophylaxis *(conditional recommendation, moderate-quality evidence)*

Rethinking post-exposure prophylaxis (PEP)

Issues with current PEP implementation

- Low knowledge of PEP by health care workers
- Low knowledge of PEP among communities at risk of HIV
- PEP availability often restricted to HCWs with workplace exposure and sexual exposures from sexual violence
- Limited PEP delivery points
- High cost in private sector
- Complexities for access, including strict eligibility check lists, stigma and discrimination

Implications

- Low access and uptake outside HCW services
- Late start for PEP
- Low completion/follow up, including return for HIV testing

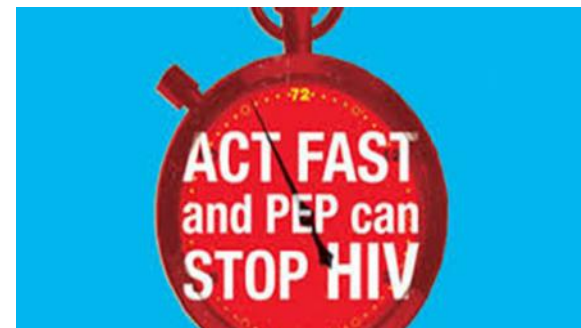
Guidance gaps

- Differentiated service delivery options for PEP
- Transitioning from PEP to PrEP for longer term prevention AND use of PEP for people stopping PrEP

Low completion of PEP course

- 56.6% [95% (CI 50.9-62.2%) people considered eligible for PEP completed 28-day course
- PEP completion rates highest for nonoccupational exposures (65.6%, 95% CI 55.6-75.6%)
- lowest for sexual assault (40.2%, 95% CI 31.2-49.2%)
- higher rates of PEP completion reported for MSM (67.2%, 95% CI 59.5-74.9%).

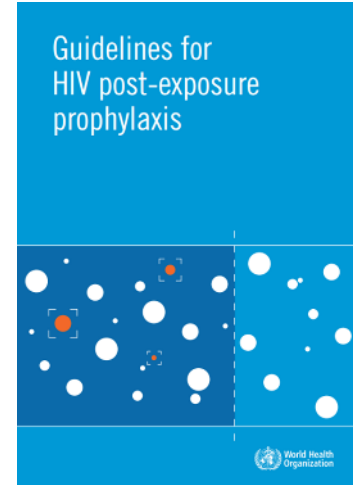
Ford N, Irvine C, Shubber Z, Baggaley R Adherence to HIV postexposure prophylaxis: a systematic review and meta-analysis. *AIDS*, 2014



New WHO PEP guidance and recommendations (July 2024)

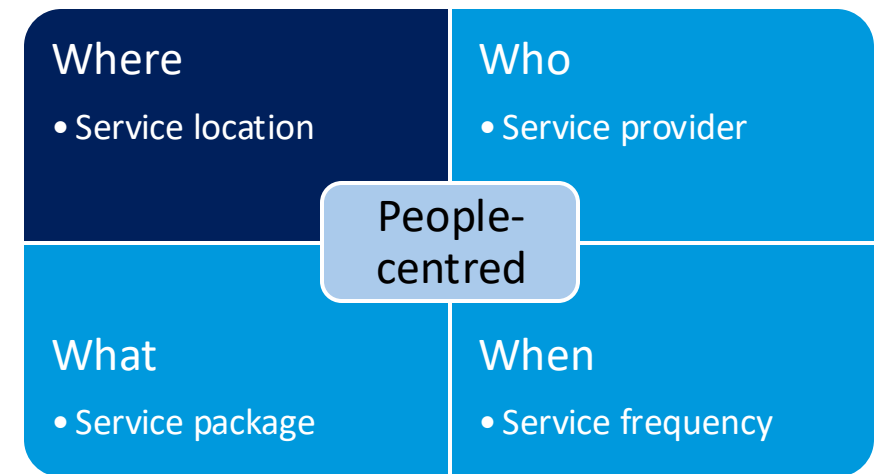
(I) Community delivery

HIV PEP should be delivered in community settings
(strong recommendation, very low certainty of evidence)



Remarks:

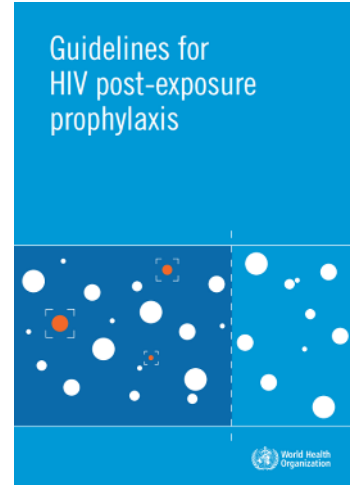
- Community delivery of PEP should **complement delivery** in other settings with strong linkages and referral pathways
- Community settings can include a **wide range of options**, including but not limited to pharmacies, community-based organizations, drop-in centres, mobile clinics, online delivery



New WHO PEP guidance and recommendations (July 2024)

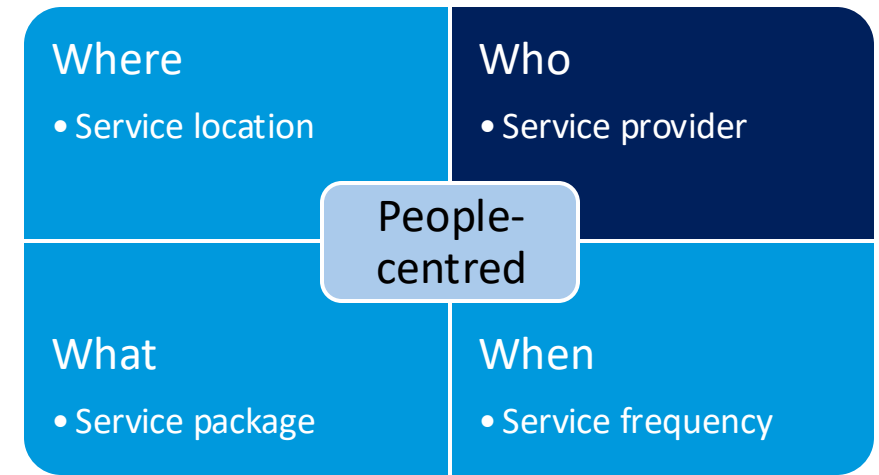
(II) Task sharing

Task sharing should be employed to dispense, distribute, provide and monitor PEP
(strong recommendation, very low certainty of evidence)



Remarks

- This is an additional approach to providing PEP
- **Training, support and supervision** for all health workers is essential, including sensitization on stigma and discrimination and key populations
- Adequate and equitable **remuneration** is required for community and other health providers
- Providers should offer first-line support and offer post-rape care for survivors of sexual assault at the first point of contact in line with WHO guidelines and refer to additional support services as needed.
- Tasks can be shared with a range of health workforce teams, including **pharmacists, nurses, doctors and trained lay and peer health workers**



New WHO guidance on HIV self-testing (HIVST) for PEP (July 2023)

HIVST can be considered as part of post-exposure prophylaxis (PEP) implementation.

- HIVST is empowering, acceptable and a low-cost way of increasing access to testing for people who have not tested before or who could benefit from regular opportunities to test.
- HIVST is an important tool for supporting PEP (and PrEP) delivery.
 - HIVST can be delivered in health facilities and communities, offered to partners and social contacts and made available through virtual platforms.
- HIVST can be also performed with HIV/syphilis dual self-tests as well, beneficial in cases of potential sexual exposures

Consolidated guidelines
on differentiated
HIV testing services

World Health
Organization

Where

- Service location

Who

- Service provider

People-
centred

What

- Service package

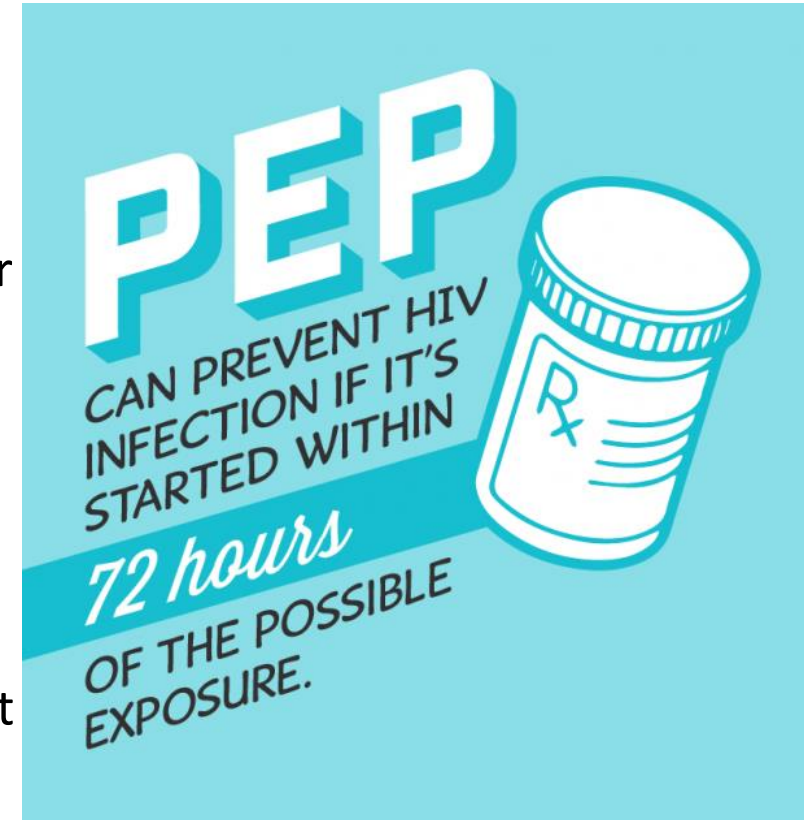
When

- Service frequency

PEP ↔ PrEP: enhancing HIV prevention

PEP to PrEP: PEP as an entry point for HIV PrEP

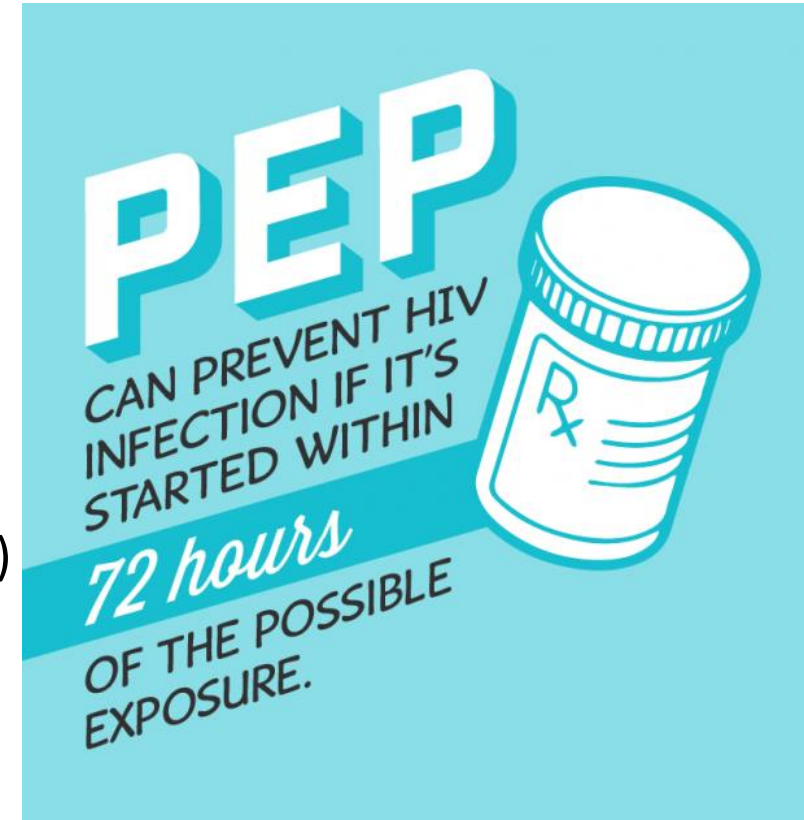
- PEP use can be an entry point to promote awareness, access and use of PrEP.
 - Some people may prefer not to take PrEP and may want to use other methods of HIV prevention.
- Inform PEP clients about PrEP where there may be ongoing or periodic HIV exposure
- Immediate transition: Individuals who complete the 28-day PEP regimen can start PrEP without a gap if they have a negative HIV test on completion of PEP and do not have contraindications to the PrEP product (e.g. oral PrEP, DVR or CAB-LA).
- Eligibility and management the same as any other PrEP client.



PEP ↔ PrEP: enhancing HIV prevention

PrEP to PEP: when should this be considered?

- People using PrEP as directed would not normally need PEP
 - But if PrEP is not used as directed or is stopped, there may be a risk of acquiring HIV if exposure occurs.
- All individuals taking PrEP should be informed about PEP
- To decide whether PEP is needed, providers should consider:
 - the PrEP product used (oral PrEP containing TDF, the DVR or CAB-LA)
 - the type of exposure to HIV (e.g. anal sex, vaginal sex or parenteral/injecting)
 - the networks in which the person is in and has had sex in
 - the time elapsed since PrEP was last used
 - individual characteristics that may affect PrEP efficacy



PrEP product	Doses taken in the 7 days before exposure*	Exposure	Consider PEP
Oral PrEP containing TDF/XTC	4-7 (cisgender men**)	Sexual exposure	No, continue oral PrEP
	6-7 (all other groups)	All exposures	
	0-3 (cisgender men)	Sexual exposure	Yes
	0-5 (all other groups)	All exposures	
DVR	DVR placement		
	DVR in place	Vaginal sex from 24 hours after insertion	No, continue using the DVR
		Exposures other than vaginal sex e.g. anal sex, parenteral	Yes
		Vaginal sex within 24 hours of insertion	Yes
	DVR not in place	Vaginal sex within 24 hours of removal	Yes
CAB-LA***	Delayed injection / time since stopping CAB-LA		
	Scheduled follow-up injection delayed ≤7 days	Any exposure	No, continue CAB-LA
	Scheduled follow-up injection delayed > 7 days OR >2 months since stopping CAB-LA		Yes

*Simplified depiction for oral PrEP, additional considerations include post-exposure PrEP use. Those taking PrEP as directed do not need PEP.

**Transgender women not taking gender affirming hormones should also follow this approach

***There is a 7-day window for receiving follow-up CAB-LA injections, i.e. 7 days earlier or 7 days later. Individuals presenting for their scheduled CAB-LA injection within this window would not need PEP.

How to provide PEP: Essential elements

Task sharing and community delivery of PEP: bringing services closer to people

- Promote **task sharing** to make the best use of available human resources e.g. physicians, nurses, pharmacists, clinical officers, and trained and supervised peer and community health workers
- Address **legal and regulatory issues** for different cadres of providers able to provide PEP (and PrEP) (incl. accreditation, remuneration)
- Provide **training, support and supervision** for all PrEP/PEP providers
- Develop **quality assurance** measures, protocols for community delivery, and establish linkage to facilities
- Develop partnerships for **community led monitoring** (CLM) to insure services are effective and acceptable



VIEWPOINT | VOLUME 9, ISSUE 5, E363-E366, MAY 01, 2022

Scaling up access to HIV pre-exposure prophylaxis (PrEP): should nurses do the job?

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Michelle Rodolph, MPH • et al. [Show all authors](#)

Open Access • Published: March 28, 2022 •
DOI: [https://doi.org/10.1016/S2352-3018\(22\)00006-6](https://doi.org/10.1016/S2352-3018(22)00006-6)



International Journal of STD & AIDS
OnlineFirst
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<https://doi.org/10.1177/09564624231215151>

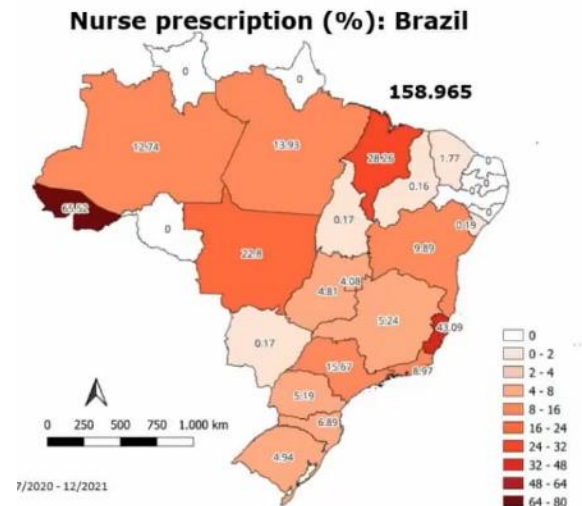
Sage Journals

Original Research Article

Appropriate usage of post-exposure prophylaxis-in-pocket for HIV prevention by individuals with low-frequency exposures

Matthew Clifford Rashotte¹, Deborah Young², Mark Naccarato³, Oscar J Pico Espinosa⁴, Karla Fisher⁵, Isaac I Bogoch^{5,6}, and Darrell HS Tan ^{4,6,7}

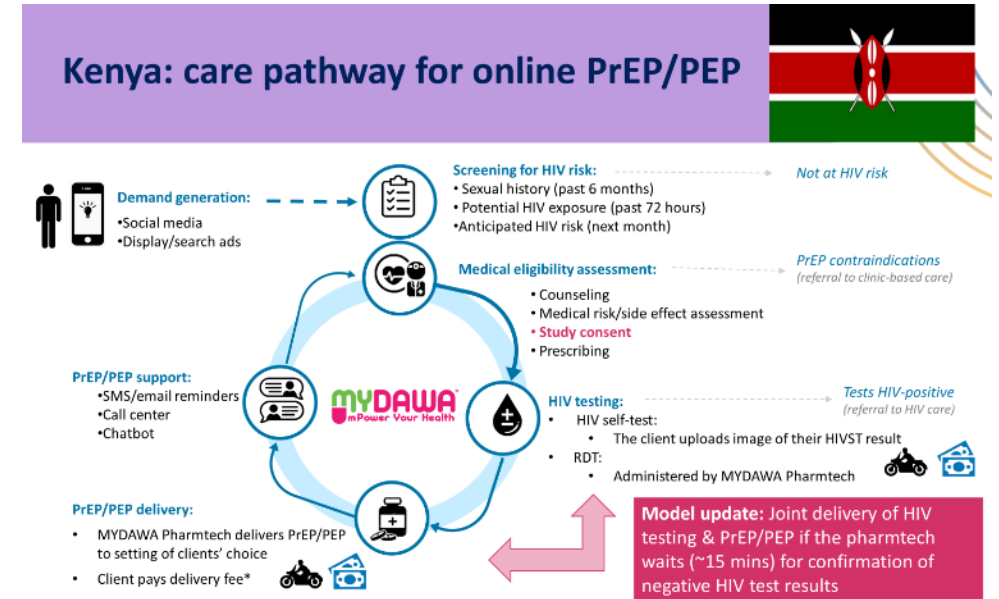
Abstract
PEP-In-Pocket (Post-Exposure Prophylaxis-In-Pocket, or "PIP") is a biobehavioural HIV prevention strategy wherein patients are proactively identified and given a prescription for HIV post-exposure prophylaxis (PEP) medications to self-initiate in case of high-risk exposures. We evaluated this strategy in a prospective observational study at two hospital-based clinics in Toronto, Canada. HIV-negative adults using PIP underwent chart review and completed quarterly electronic questionnaires over 12 months. The primary objective was to quantify appropriate PIP initiation, defined as starting PIP



Differentiated service delivery (DSD) options for PEP

To ensure PEP is available, quickly accessible and acceptable ASAP after exposure, DSD models are needed

- Availability and accessibility important to provide PEP as quickly as possible after an exposure and to increase use for non-healthcare exposures, e.g.
 - Home or starter packs of PEP (e.g. Toronto PEP in Pocket (PIP), PEPSE trial in England)
 - Self-start, attend clinic on a non-urgent basis
 - Reduced time to start
 - Decreased cost vs daily PrEP for infrequent exposures
 - Autonomy and agency
 - Online and pharmacy delivered PEP (e.g. China online PEP service, Kenya MyDawa project, 14+ States in the USA allow pharmacy PEP, PIMART in South Africa)
 - Safe, effective, reasonable cost
 - Acceptable and high uptake
 - Policy and guidance adoption (e.g. South Africa)



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- <https://www.dph.ncdhhs.gov/docs/PEP-StandingOrder-March2022.pdf>

South Africa: new guidelines and tools focusing on PEP for all exposures



Post Exposure Prophylaxis (PEP) FACT SHEET

What is PEP? Post Exposure Prophylaxis or PEP is an emergency treatment that is given to a person exposed to HIV to prevent HIV.

- PEP is using ARV medication to prevent HIV.
- PEP must be started within 72 hours of possible exposure to HIV.
- The sooner PEP is started after a possible exposure, the more effective it is.
- PEP can only be taken by HIV-negative individuals.
- PEP is taken for 28 days after possible exposure to HIV to prevent an HIV infection.

Who should take PEP?

- Anyone who may have been exposed to HIV through contact with blood or during sex, or through their work.
- It's only recommended for people who are HIV negative or don't know their status.

Is PEP safe?

- It is safe to take PEP to prevent you from getting HIV.
- PEP can be taken when pregnant and breast-feeding, and will not hurt you or your baby.

How are ARVs used differently for HIV prevention and treatment?

ARVs can be used to prevent HIV:

- When ARVs are taken before someone is exposed to HIV to protect them from HIV it is called Pre-Exposure Prophylaxis (PrEP).
- When ARVs are taken within 72 hours after exposure to HIV to prevent HIV it is called PEP.

ARVs can be used as treatment:

- ARV are used to treat HIV-positive people to reduce the levels of HIV in the body, this is called ART.

health
Department of Health
REPUBLIC OF SOUTH AFRICA

Clinical Algorithm JOB AID

for Initiation of Post Exposure Prophylaxis (PEP) for HIV prevention

Did potential exposure to HIV occur in the past 72 hours?

YES (within 72 hours): Immediately provide PEP STAT dose, for children <18 months initiate PEP. Conduct HIV rapid test, for children <18 months conduct PCR test. If HIV positive, initiate ART. If HIV negative, PCR negative for children <18 months, continue PEP.

NO (more than 72 hours): PEP not required. NO in any/all of these.

Confirm if the person was exposed to HIV through:

- Exposures via (including condom, condom, diaphragm/bag, sexual contact)
- Shared needles (including drug use)
- Contact with blood, semen, or vaginal fluids
- Injected breast milk from a woman of unknown HIV status or HIV positive
- Contact with contaminated medical waste

YES to any of the above: Continue 28-day PEP. DO NOT WAIT FOR LABORATORY BLOOD TEST RESULTS.

PEP Drug Regimen	Tests for source person	Tests for exposed person
Adults and children <18 years If weight is <30kg: DTG 30mg + 3TC 150mg + DTG 30mg, once daily as TLD. If weight is >30kg: DTG 30mg + 3TC 150mg, once daily as TLD. If weight is <20kg: DTG 15mg + 3TC 75mg, once daily as TLD. If weight is >20kg: DTG 15mg + 3TC 75mg, once daily as TLD.	HIV rapid test or ELISA if available If negative → Discontinue PEP or refer individual If positive → Continue PEP for 28 days Other baseline tests if available or required as per guidelines: Hepatitis B, Hepatitis C, Syphilis, STI screening, TB screening	HIV rapid test or ELISA if available If negative → Discontinue PEP or refer individual If positive → Continue PEP for 28 days Other baseline tests if available or required as per guidelines: Hepatitis B, Hepatitis C, Syphilis, STI screening, TB screening

Follow-up arrangements

For all exposed persons, offer the following:

- Initial drug services
- Referral for sexual assault, GBV and HIV support services
- Referral for substance use or mental health services
- Referral for HIV and/or PCR management
- Referral for substance use or mental health services

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PEP GUIDE TO OFFERING PEP

Post Exposure Prophylaxis

PEP is an emergency treatment

A person seeking PEP or exposed to HIV should be attended to immediately.

PEP must be offered to all persons that have been potentially exposed to HIV.

Make sure that you take the time to listen to the clients concerns and address these during your counselling.

When an individual reports exposure to HIV:

- Confirm that exposure to HIV occurred within the past 72 hours
- Explain to the client:
 - PEP is ARV medication given to an HIV-negative person after exposure to HIV to prevent them from being infected with HIV.
 - PEP should only be taken by HIV-negative individuals.
 - It is most effective if taken as soon as possible after the exposure to HIV.
 - Confirm that the client is agreeable to take the stat dose.
- Administer the first PEP dose immediately
- Conduct HIV (rapid) test
 - Provide pre-test counselling
 - Administer the HIV test
 - Provide the test result and post-test counselling
 - If test result is HIV-positive refer for or initiate ART
 - If test result is HIV-negative...

MOVE TO POINT 5 ON THE BACK OF THIS GUIDE TO CONFIRM THE EXPOSURE.

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NATIONAL CLINICAL GUIDELINES

OF POST-EXPOSURE PROPHYLAXIS (PEP) IN OCCUPATIONAL AND NON-OCCUPATIONAL EXPOSURES

Approved: 2019
Published: 2020

South African National Department of Health

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NDP

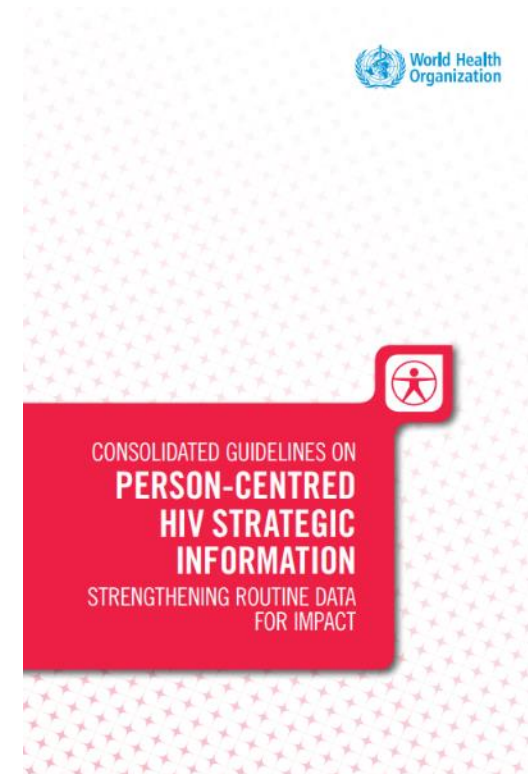
PEP Clinical Algorithm Provides guidance to the HCW on assessment for PEP initiation, and the clinical management of the client.

Guide to offering PEP Job aid providing practical guidance to the HCW on how to offer PEP.

PEP Guidelines NDOH National PEP guideline.

What next to strengthen access and uptake of PEP?

- **Dissemination of new normative guidance**
 - Support for adoption of new recommendations and guidance updates into country guidelines
- **Implementation support**
 - Expansion of differentiated service delivery options to include PEP within countries
 - Strengthening co-delivery of PrEP and PEP
 - Tools and training
 - Update the “PrEP / ARV-based prevention” prevention self-assessment tool (PSAT)
- **Evidence and data collection**
 - Strengthening monitoring and evaluation of PEP at national and international levels
 - Adoption of WHO priority indicators for PEP and minimum data set
 - More evidence from implementation / operational research needed to understand:
 - Feasibility, acceptability, effectiveness and costs for providing PEP in different settings for different pops and involving different providers
 - switching between PEP and PrEP
 - Where people prefer to receive PEP
 - Whether promoting and providing PEP influences uptake and use of PrEP
 - How to increase knowledge, demand and support people to access and adhere to PEP



Thank you to all of the guideline contributors!

The guidelines writing and review process was coordinated by **Virginia Macdonald** with **Michelle Rodolph**, **Nathan Ford**, **Mateo Prochazka Nunez** (Department of Global HIV, Hepatitis and STI Programmes), and **Heather-Marie Schmidt** (Department of Global HIV, Hepatitis and STI and UNAIDS) under the leadership of **Rachel Baggaley** (Unit Head, Department of Global HIV, Hepatitis STI Programmes).

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Thanks to the **WHO HHS Testing, Prevention, and Populations** team for contributions to this presentation.

WHO's global work on PrEP:

<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>

WHO Global PrEP Network webinars:

<https://www.who.int/groups/global-prep-network>

WHO technical brief on PrEP implementation guidance:

<https://www.who.int/publications/i/item/9789240053694>

WHO guidelines on CAB-LA:

<https://www.who.int/publications/i/item/9789240054097>

WHO consolidated key population guidelines:

<https://www.who.int/publications/i/item/9789240052390>

WHO consolidated HIV guidelines:

<https://www.who.int/publications/i/item/9789240096394>

WHO PrEP Implementation Tool:

<https://www.who.int/tools/prep-implementation-tool>

Updated PEP Guideline in 2024

<https://www.who.int/publications/i/item/9789240095137>

Thank you!

