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 anaylsis

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

PLANNING & BUDGETING

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

SUPPLY CHAIN MANAGEMENT

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

DELIVERY PLATFORMS

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

UPTAKE & EFFECTIVE USE

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

MONITORING, EVALUATION & LEARNING

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

COLOR KEY

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

- O Oral PrEP
- C CAB PrEP
- R PrEP ring

Process Overview

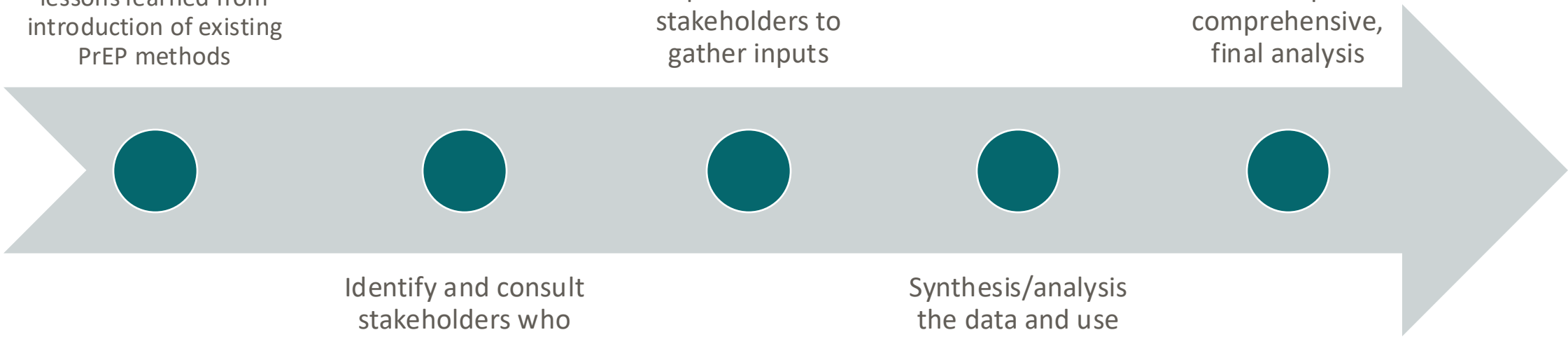
Share/review relevant documents and secondary research that capture the current state of the HIV epidemic and the PrEP program, as well as lessons learned from introduction of existing PrEP methods

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

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

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

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



Step 1: HIV in [Country]

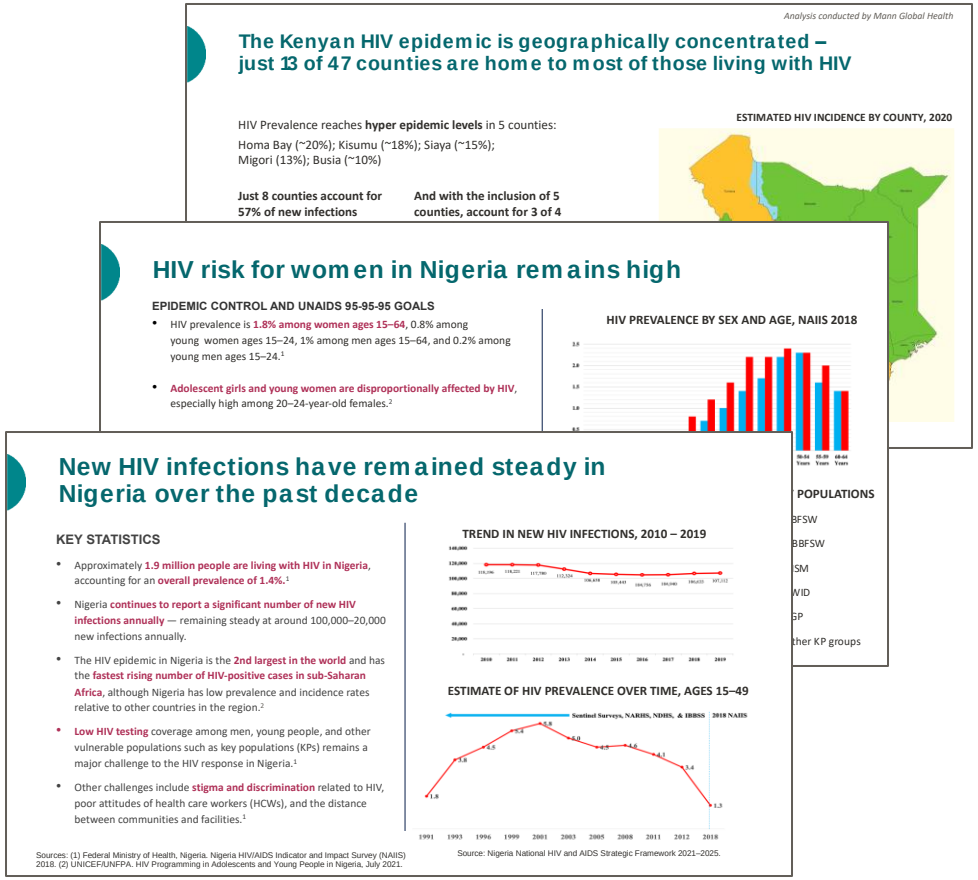
Step 1A: HIV prevention context

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



Completed situation analyses from other countries can be found on PrEPWatch.

Step 1: HIV in [Country]

Step 1B: Oral PrEP rollout

GOAL

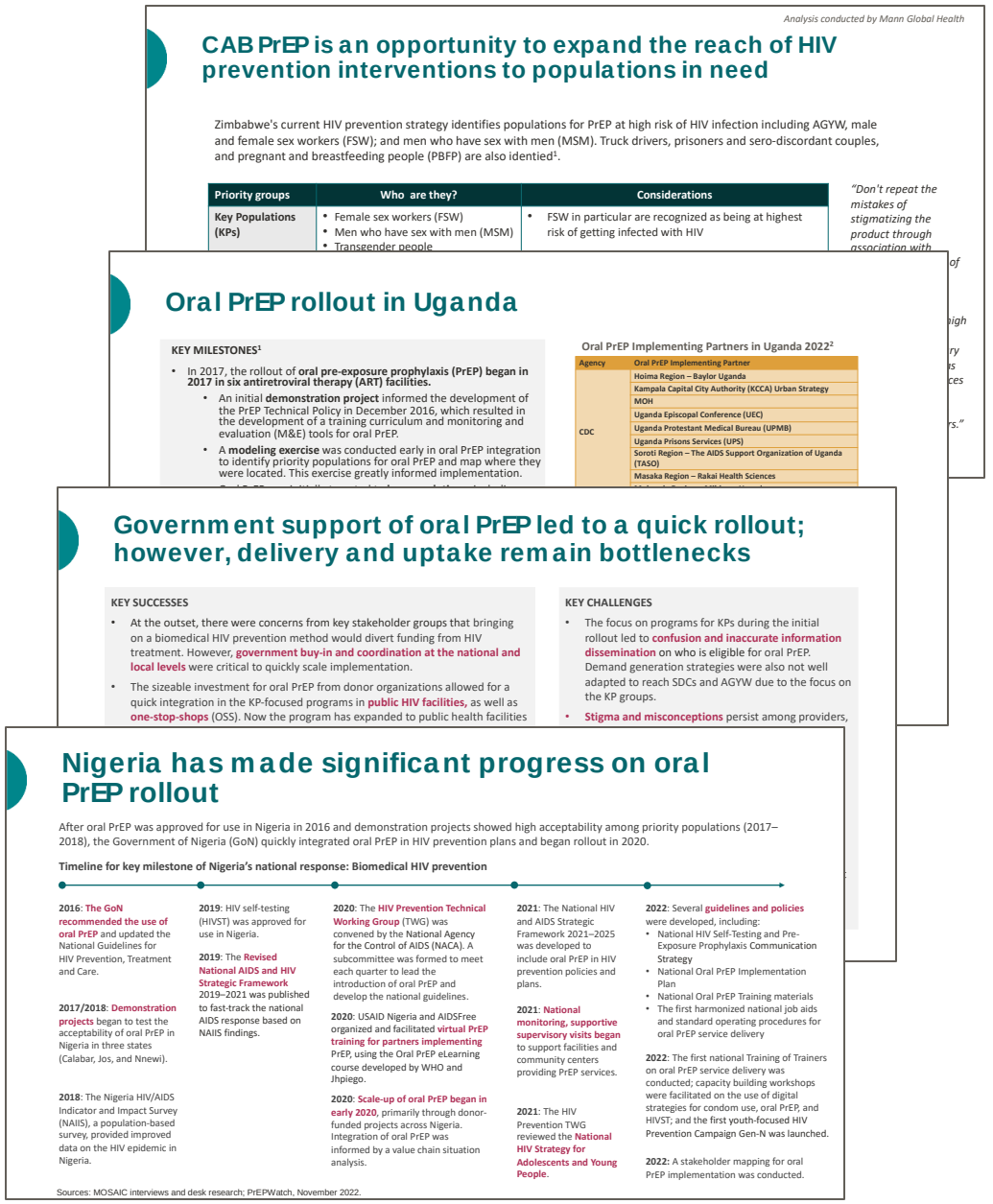
Understand the current situation for existing PrEP product (oral PrEP) rollout in country.

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.



Step 2

Stakeholder Interviews

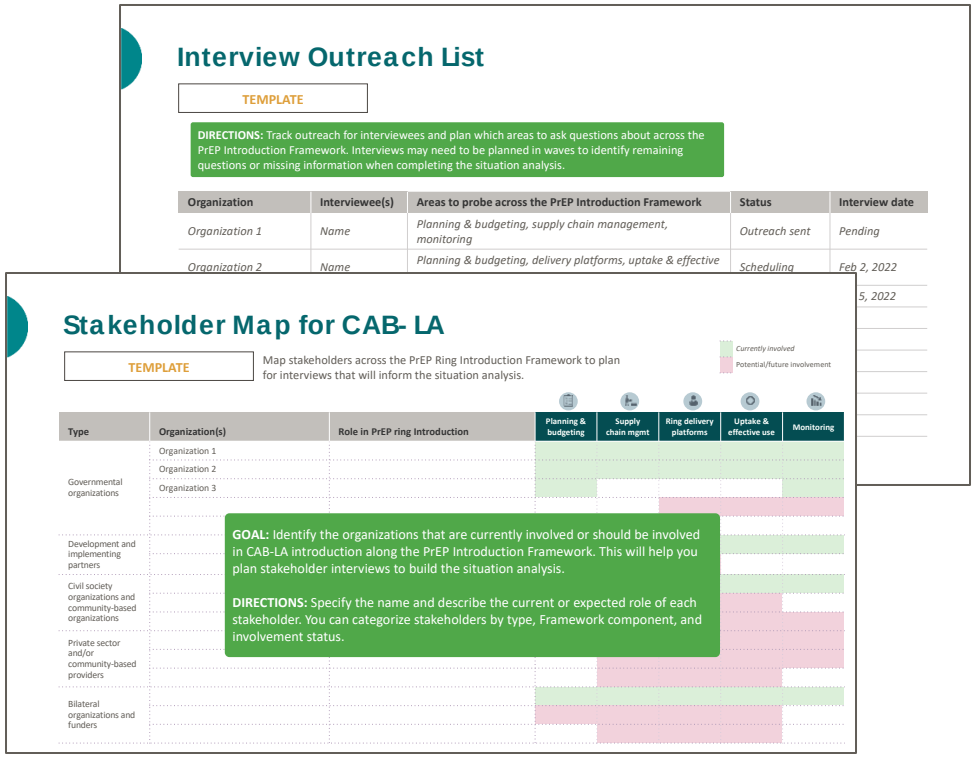
GOAL: Gather input from key stakeholders to inform an assessment of the current situation for new PrEP product (CAB PrEP, etc) rollout in your country along a structured framework.

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.



Step 3

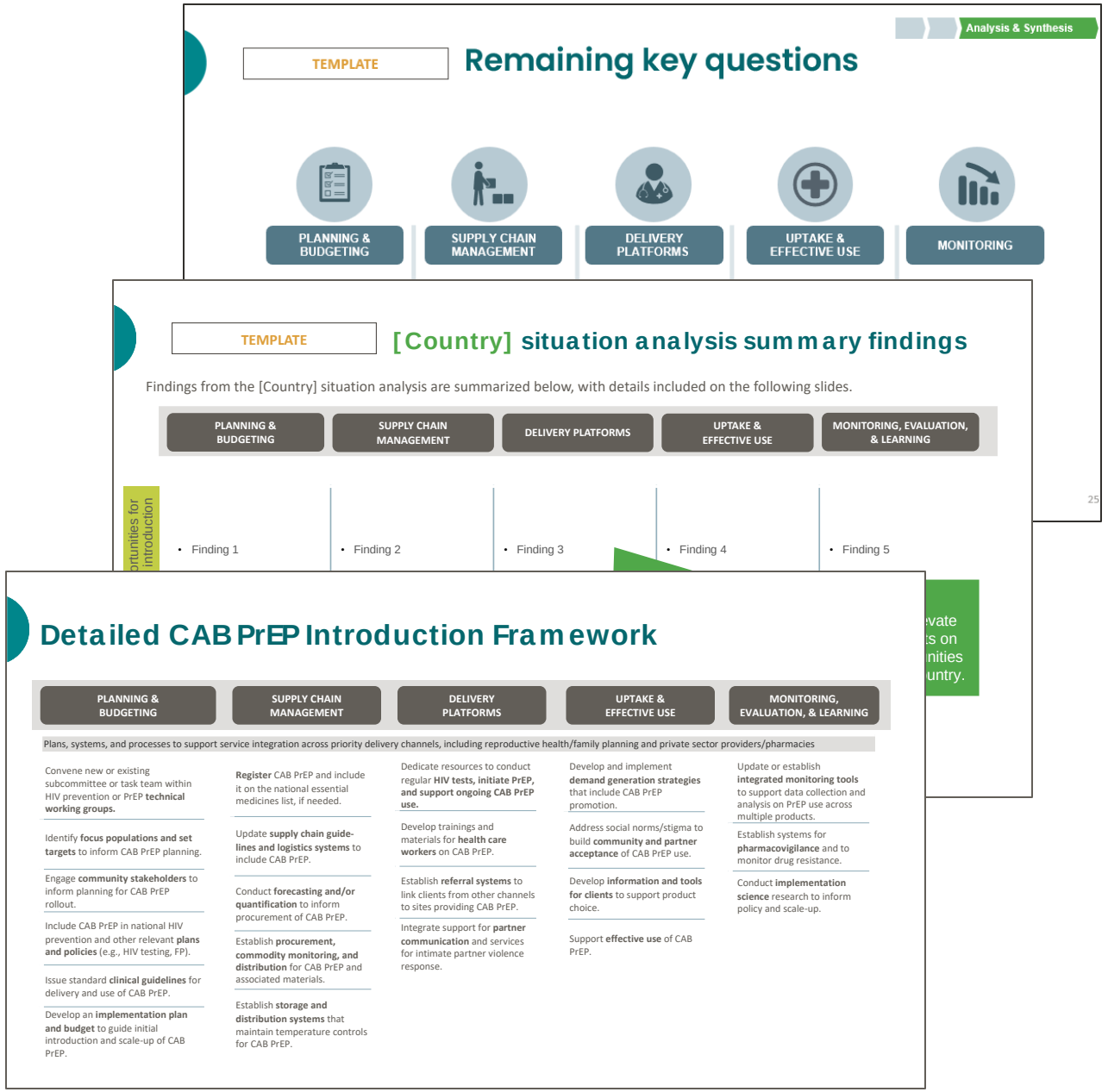
Analysis and synthesis

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.



Planning & budgeting

PLANNING & BUDGETING

Key steps and considerations

	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.**		**Refer to P1 in the Question Bank and include details on:** • 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.		**Refer to P2 in the Question Bank and in ils on:** • Plans for end-user popula etc.)
Engage **community stakeholders** to inform planning for CAB PrEP rollout.		**Refer to P3 in the Question B** • Key lessons on communit 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).		**Refer to P5 in the Question Bank and include details on:** • 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.		**Refer to P6 in the Question Bank and include details on:** • 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.		**Refer to P7 in the Question Bank and include details on:** • 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.**	**Register** CAB PrEP and include it on the national essential medicines list, if needed.	Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing CAB PrEP use.**	Develop and implement **demand generation strategies** that include CAB PrEP promotion.	Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.
Identify **focus populations and set targets** to inform CAB PrEP planning.	Update **supply chain guidelines and logistics systems** to include CAB PrEP.	Develop training and materials for **health care workers** on CAB PrEP.	Address social norms/stigma to build **community and partner acceptance** of CAB PrEP use.	Establish systems for **pharmacovigilance** and to monitor drug resistance.
Engage **community stakeholders** to inform planning for CAB PrEP rollout.	Conduct **forecasting and/or quantification** to inform procurement of CAB PrEP.	Establish **referral systems** to link clients from other channels to sites providing CAB PrEP.	Develop **information and tools for clients** to support product choice.	Conduct **implementation science** research to inform policy and scale-up.
Include CAB PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, family planning).	Establish **procurement, commodity monitoring, and distribution** for CAB PrEP and associated materials.	Integrate support for **partner communication** and services for intimate partner violence response.	Support **effective use** of CAB PrEP.	
Issue standard **clinical guidelines** for delivery and use of CAB PrEP.	Establish **storage and distribution systems** that maintain temperature controls for CAB PrEP.			
Develop an **implementation plan and budget** to guide initial introduction and scale-up of CAB PrEP.				

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.

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OVERVIEW OF PrEP AND PEP POLICIES

PRESENTED AT THE AFRICA REGIONAL PREP WORKSHOP
9TH SEPTEMBER 2024

NJAMBI NJUGUNA, FHI 360, MOSAIC

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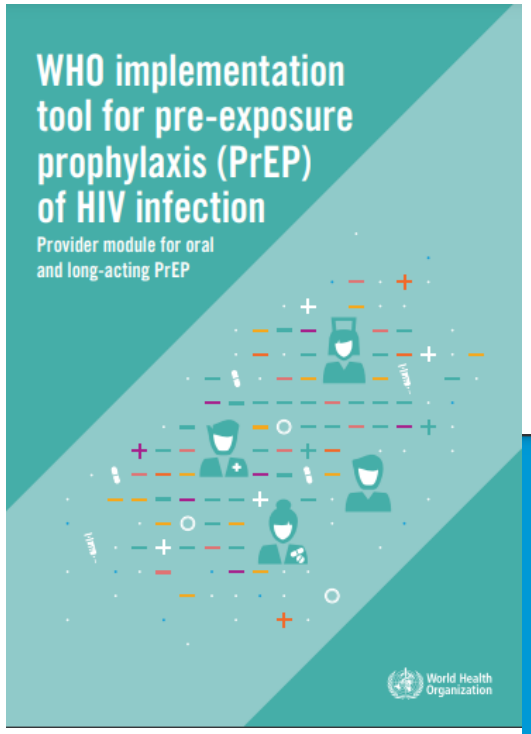
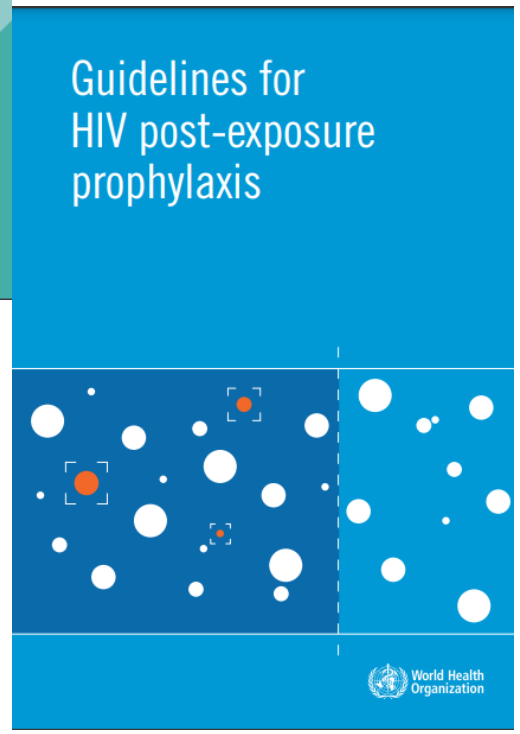
Background

- 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

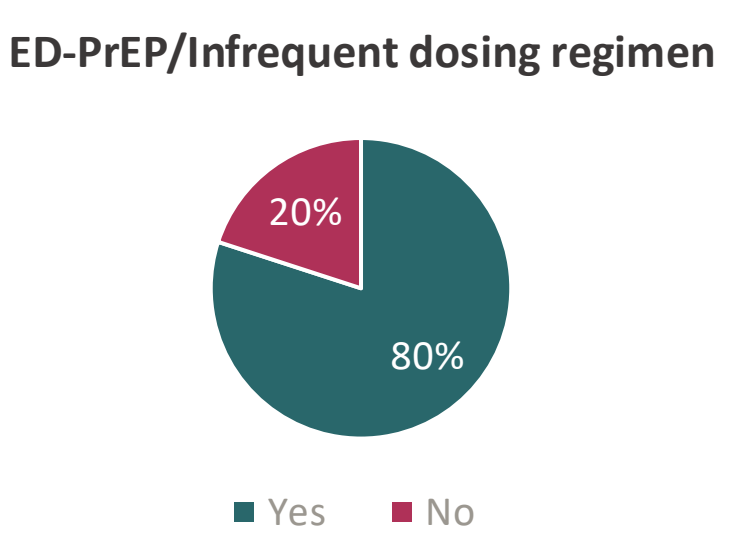
PrEP policy overview

- 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

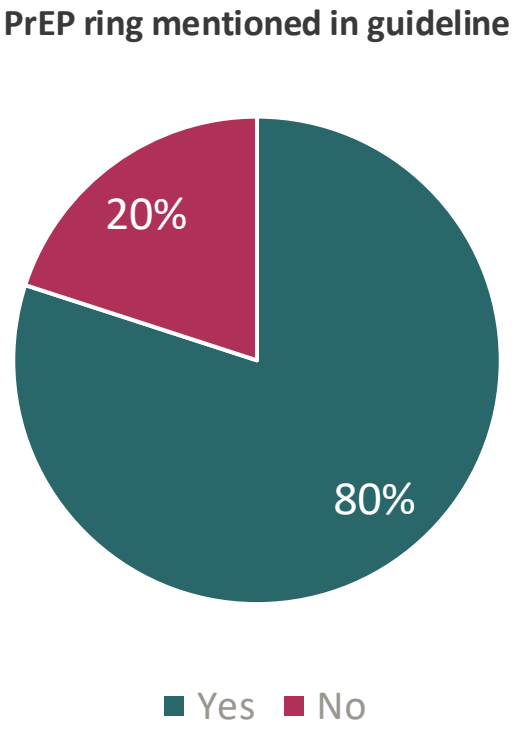
Country	Policy name	Date
Botswana	2023 Botswana Integrated Clinical Care Guidelines	2023
Eswatini	Eswatini PrEP Implementation Guidance	2024
Kenya	Kenya HIV Prevention and Treatment Guidelines	2022
Lesotho	National Guidelines on the Use of Antiretroviral Therapy for HIV Prevention and Treatment (Sixth 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

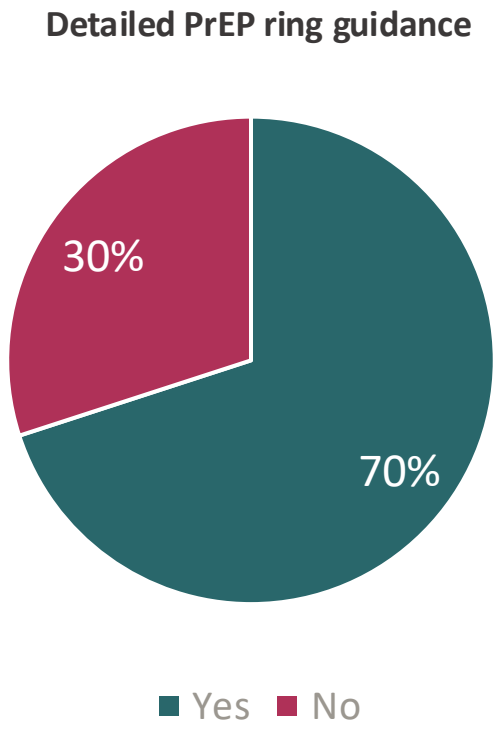
Oral PrEP guidelines



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

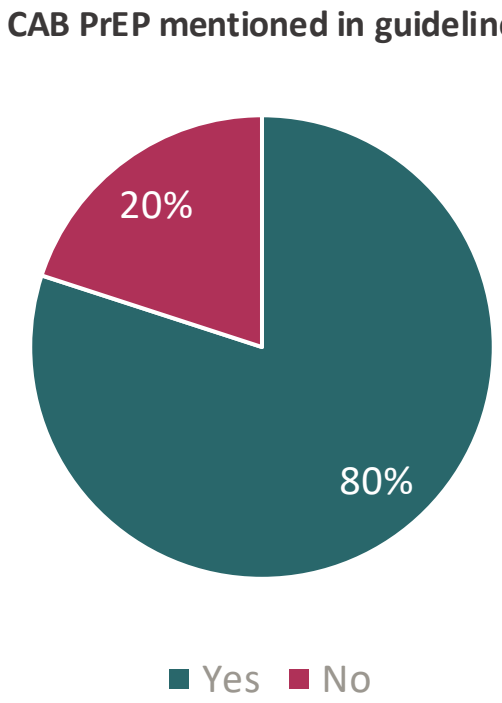
PrEP ring guidelines

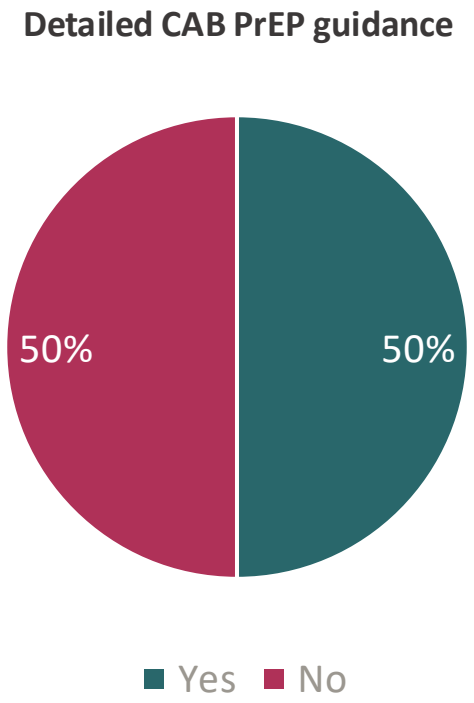




- Eight out of 10 countries mention PrEP ring in guidance, and 7 of these have comprehensive guidelines for PrEP ring use

CAB PrEP guidelines





- 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

2 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

19 policies collected from 8 countries

17 policies selected for data extraction

Analysis

Contextualization

- 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

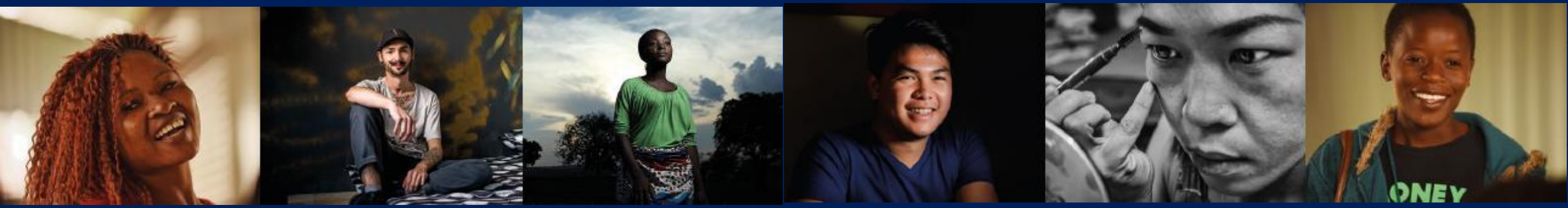
- Supporting **sensitization, training, and mentorship efforts** to familiarize both users and providers with PEP as part of the comprehensive HIV prevention package may address these barriers.
- Developing, testing, and codifying models for **community-based distribution** may elevate PEP awareness 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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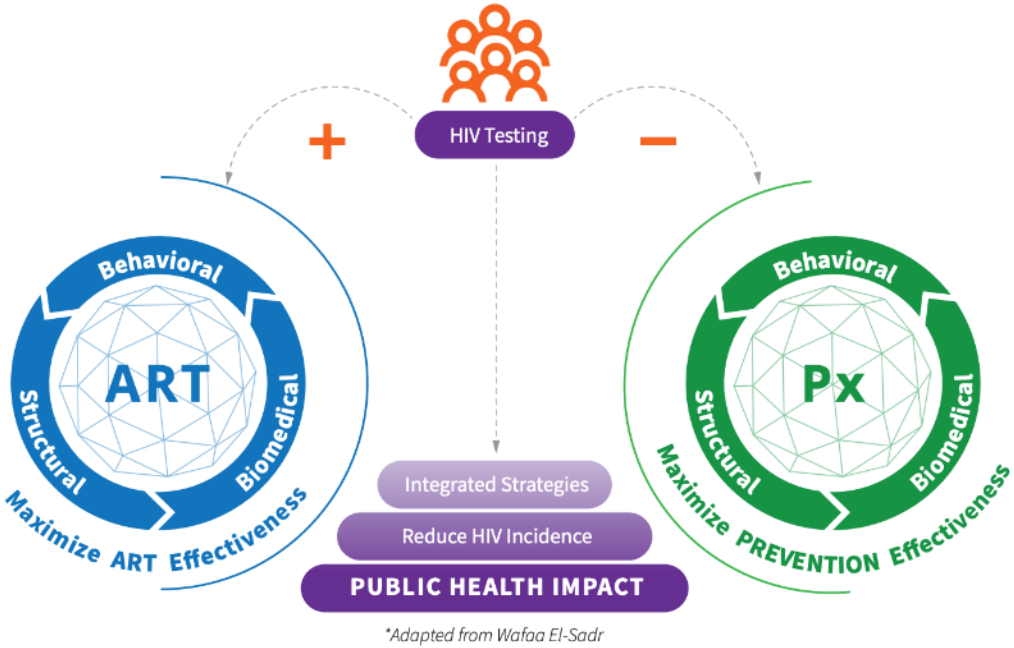
PEP is a key part of combination HIV prevention

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



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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.

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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)*

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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

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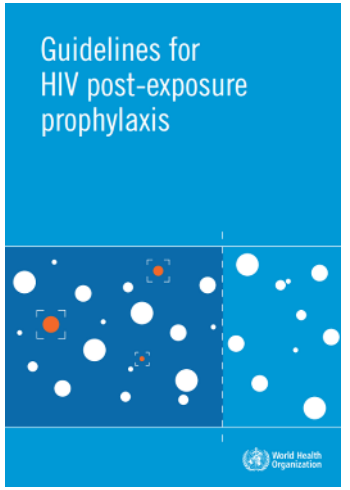
New WHO PEP guidance and recommendations (July 2024)

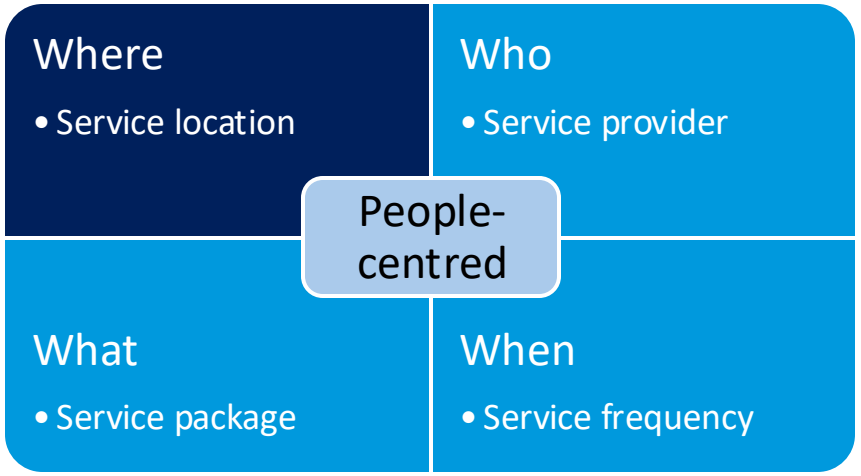
(I) Community delivery



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



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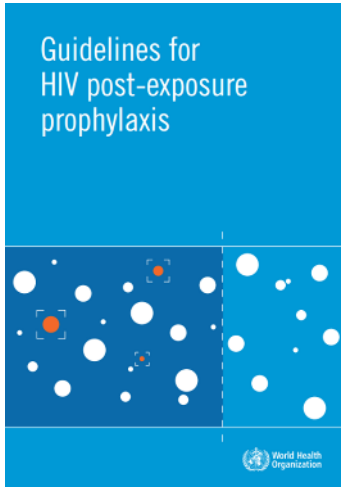
New WHO PEP guidance and recommendations (July 2024)

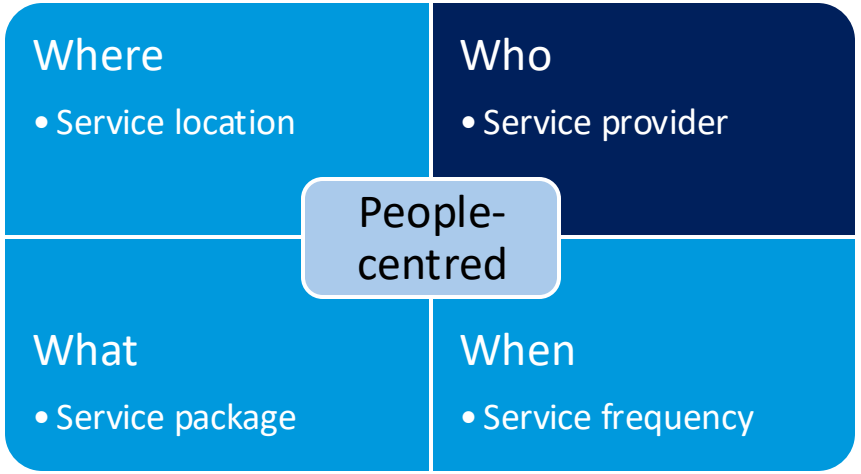
(II) Task sharing

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**



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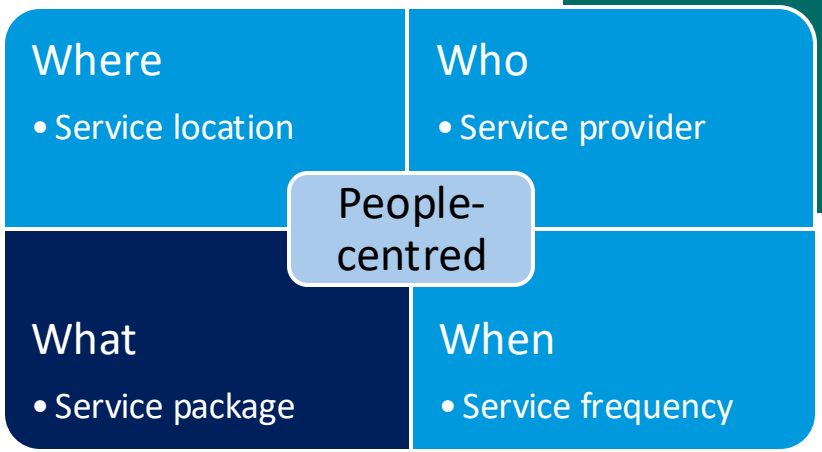
New WHO guidance on HIV self-testing (HIVST) for PEP (July 2023)

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



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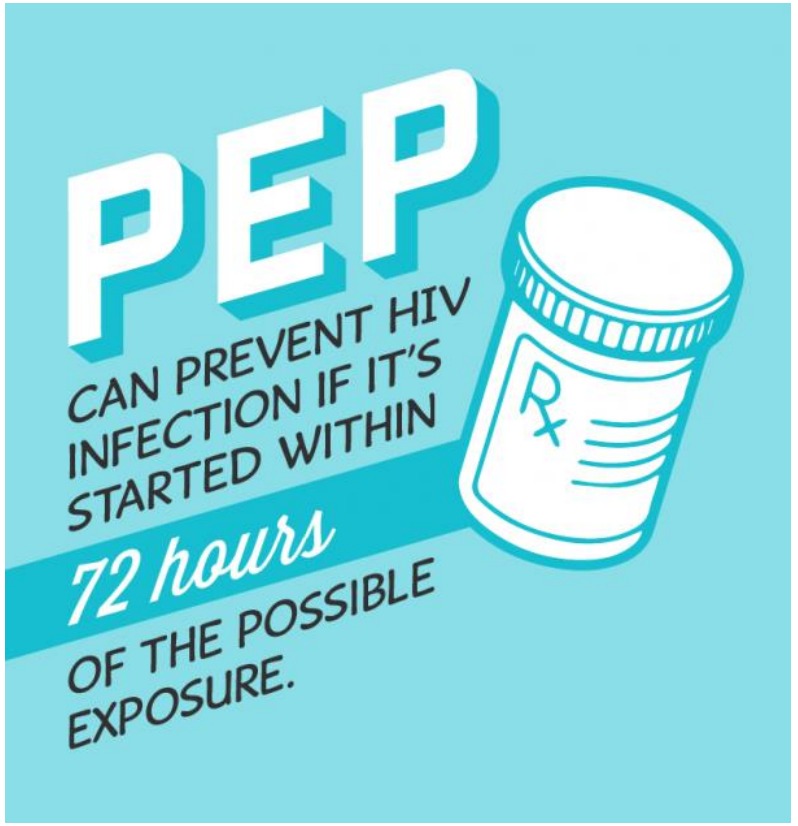
PEP ↔ PrEP: enhancing HIV prevention

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.



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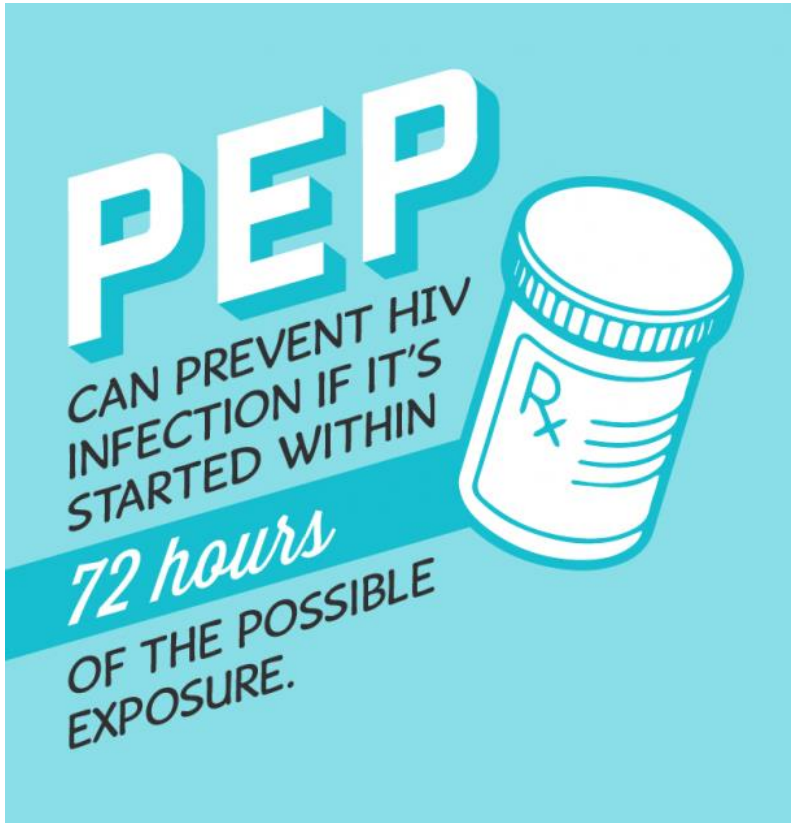
PEP ↔ PrEP: enhancing HIV prevention

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



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PrEP product	Doses taken in the 7 days before exposure*	Exposure	Consider PEP
Oral PrEP containing TDF/XTC	4-7 (cisgender men**) 6-7 (all other groups)	Sexual exposure All exposures	No, continue oral PrEP
	0-3 (cisgender men) 0-5 (all other groups)	Sexual exposure All exposures	Yes
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.

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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

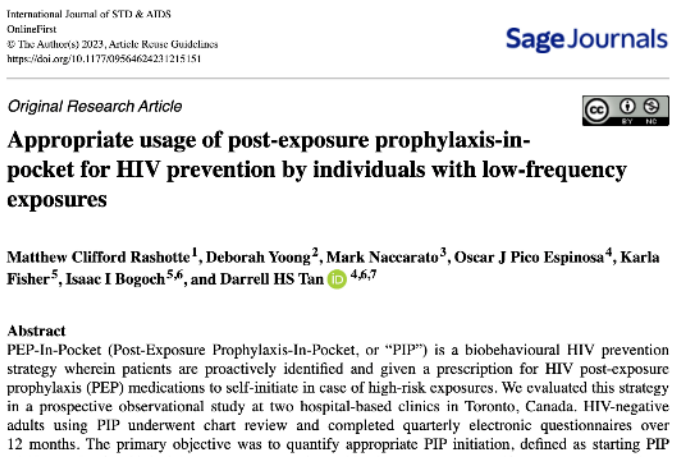

VIEWPOINT | VOLUME 9, ISSUE 5, E363-E366, MAY 01, 2022

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

Heather-Marie A Schmidt, PhD • Robin Schaefer, PhD • Van Thi Thuy Nguyen, PhD • Mopo Radebe, PhD • Omar Sued, PhD • 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 •


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

Sage Journals

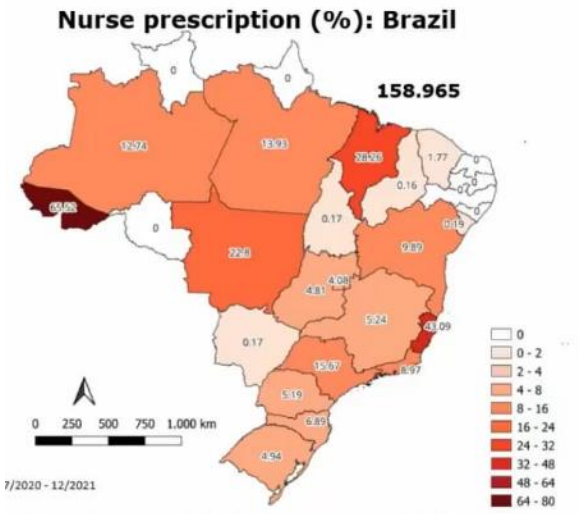
Original Research Article

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

Matthew Clifford Rashotte[1], Deborah Yoong[2], Mark Naccarato[3], Oscar J Pico Espinosa[4], Karla Fisher[5], 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



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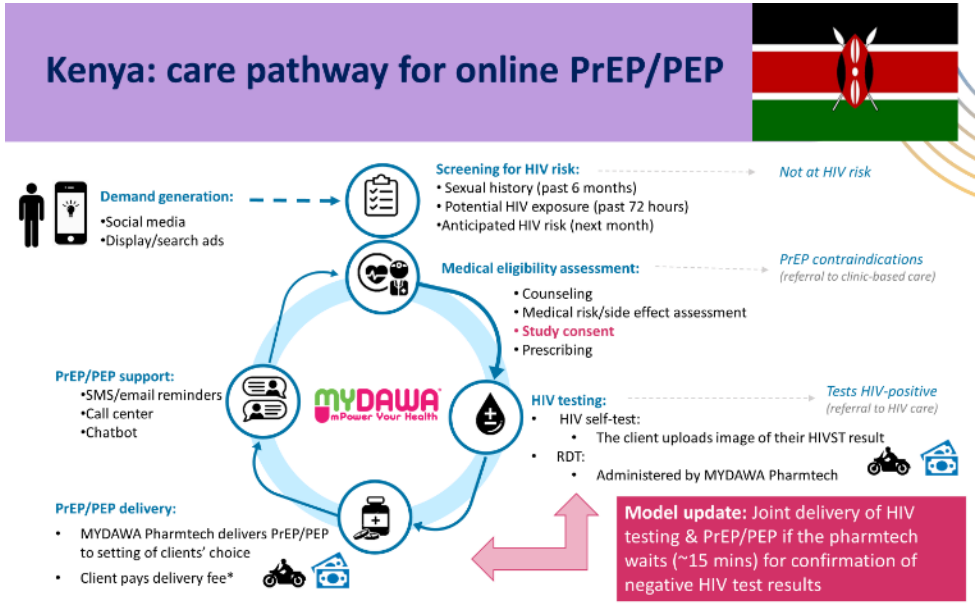
Differentiated service delivery (DSD) options for PEP

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)



- Fox JM, et al. Self-start HIV postexposure prophylaxis (PEPSE), to reduce time to first dose and increase efficacy. Sex Transm Infect. 2022 Dec 23:sextrans-2022-055622. doi: 10.1136/sextrans-2022-055622. Epub ahead of print. PMID: 36564186.
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- Shan D et al. Understanding the Uptake and Outcomes of Non-occupational Postexposure Prophylaxis Use Through an Online Medical Platform in China: Web-Based Cross-sectional Study. J Med Internet Res. 2023 May 19;25:e42729. doi: 10.2196/42729. PMID: 37204828; PMCID: PMC10238955.http://en.qstheory.cn/2022-02/16/c_707633.html
- https://nastad.org/resources/pharmacists-authority-engage-collaborative-practice-agreements-and-initiate-prep-pep-and
- https://getsfcba.org/wp-content/uploads/2022/07/California-SB159.pdf
- https://www.dph.ncdhhs.gov/docs/PEP-StandingOrder-March2022.pdf

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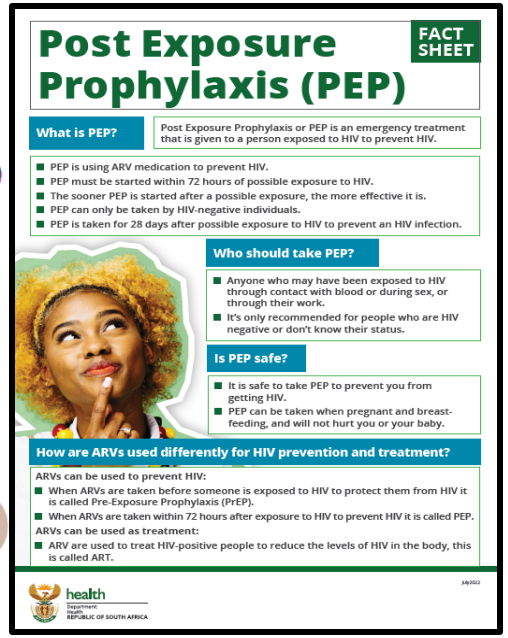
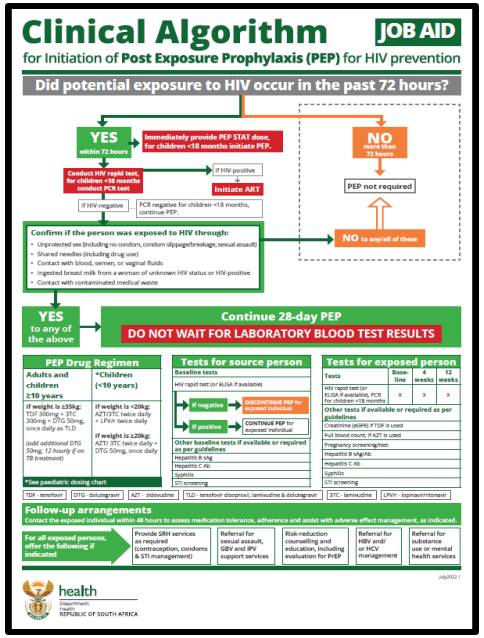
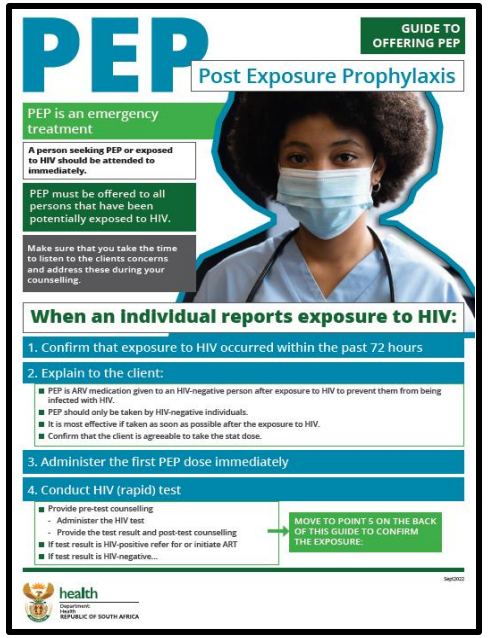
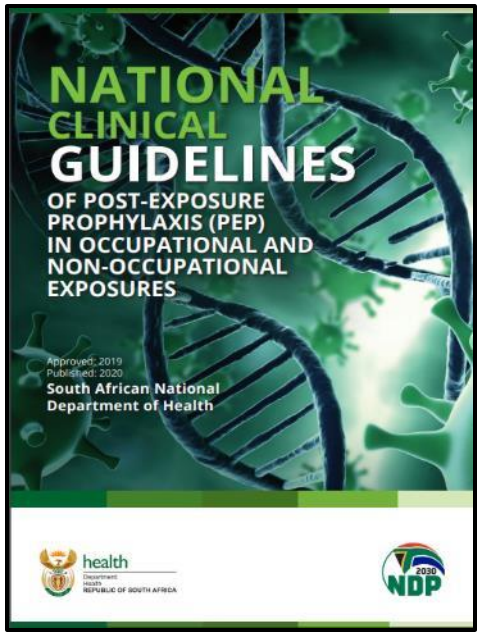
South Africa: new guidelines and tools focusing on PEP for all exposures









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.

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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

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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).

WHO technical staff: Avni Amin, Nancy Kidula; Tiara Nisa; Hortensia Peralta, Omar Sued. George Rutherford (methodologist). Evidence reviewers: Rahel Dawit, Caitlin Kennedy, Jason J. Ong, Teresa Yeh. GDG Co-chairs: Kenneth Mayer and Euphemia Sibanda. Members: Iskandar Azwa, Manisha Dhakal, Lina Digolo, LV Fan, Julie Fox, Kimberly Green, Beatriz Grinsztejn, Nathalie Kapp, Jules Kim, Kudzai Precious Maingire, Mohammed Majam, Njambi Njuguna, John Danvic T. Rosadiño, Hasna Salem, Darrell Tan. Peer Reviewers: Chris Akolo, Judy Auerbach, Teddy Cook, Frances Cowan, Rashida Ferrand, Morgan Garcia, Bridget Haire, Diane Havlir, Mehdi Karkouri, Colleen Kelley, Jeff Lucas, Sheena McCormack, Saiqa Mullick, Will Nutland, Nittaya Phanuphak, Andrew Phillips, Kristine Torjesen, Francois Venter. External partners and observers: Representatives of the United States Agency for International Development (USAID), the US Centers for Disease Control and Prevention (CDC), the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Bill & Melinda Gates Foundation and cosponsors of the Joint United Nations Programme on HIV/AIDS (UNAIDS) attended the GDG meeting as observers. We would like to acknowledge in particular Heather-Marie Schmidt from UNAIDS headquarters. Observers: Lao-Tzu Allan-Blitz, Ramona Bhatia, Isaac Bogoch, Bidia Deperthes, Emily Dorward, Robyn Eakle, Chris Obermeyer, Jason Reed, Carlos Toledo.

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Thank you!

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

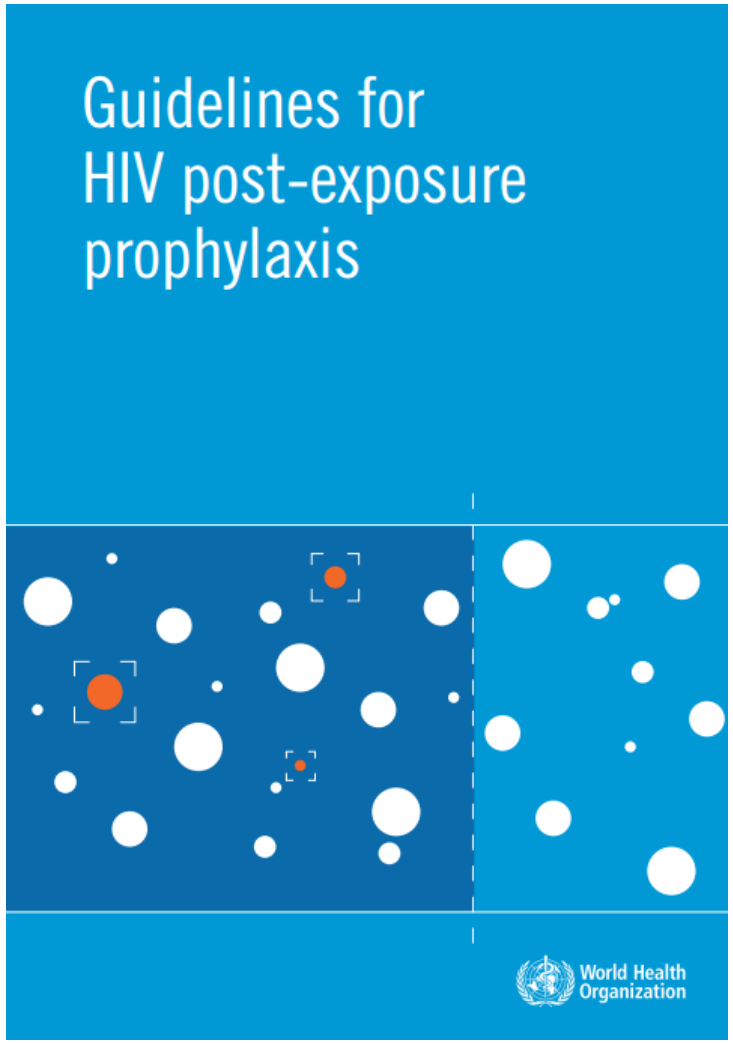
WHO guidelines on CAB-LA:
https://www.who.int/publications/i/item/9789240054097

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



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