

Synthesis of Post-Exposure Prophylaxis (PEP) Policies in MOSAIC Countries

BRIEF
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Background

Guidelines from the World Health Organization (WHO) recommend the use of post-exposure prophylaxis (PEP) by individuals potentially exposed to HIV for the prevention of HIV¹. 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 pre-exposure prophylaxis (PrEP).

Through MOSAIC (Maximizing Options to Advance Informed Choice for HIV Prevention), FHI 360 and its partners will expedite access to a range of biomedical HIV prevention products, including ARV drugs for PEP, that are affordable, acceptable, safe, and effective. The MOSAIC consortium is led by FHI 360 along with core partners Wits Reproductive Health and HIV Institute (Wits RHI), Pangaea Zimbabwe AIDS Trust (PZAT), LVCT Health, Jhpiego, and AVAC. MOSAIC currently operates in Eswatini (E), Kenya (K), Lesotho (L), Nigeria (N), South Africa (SA), Uganda (U), Zambia (ZA) and Zimbabwe (ZW).

This brief aims to summarize the PEP policy landscape, illustrate how to address policy and implementation barriers, and recommend ways to increase access to and uptake of PEP as part of HIV prevention. While it focuses on countries within the MOSAIC consortium, the findings are applicable across the HIV prevention landscape and can be used by ministries of health, implementing partners, providers, and potential PEP users alike to better inform and expand access to PEP and aptly elevate this underutilized prevention method.²

Methods

To start, nineteen potentially relevant policies were collected from all MOSAIC countries to inform this brief. MOSAIC consortium members helped identify these policies and offered insights on the relevant PEP-related content in each document. After further review, 17 policies (Table 1) were selected for data extraction and analysis, which focused on the following policy elements considered to have the greatest impact on PEP access: eligibility requirements, time frame for PEP provision, recommended drug regimen for adults, and linkages between PEP and PrEP. While there are specific policy elements related to children under the age of 10, this analysis focuses on adults and adolescents, in alignment with WHO recommendations for that same group.

¹ World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. WHO. 2021 July. <https://www.who.int/publications/i/item/9789240031593>.

² Ayieko J, Petersen ML, Kamya MR, Havlir DV. PEP for HIV prevention: are we missing opportunities to reduce new infections? J Int AIDS Soc. 2022 May 28;25(5): e25942.

Table 1. Policies included in analysis

Country	Policy Name	Date Issued
Eswatini	DRAFT PEP Section Guidelines	2022 (not public)
	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

When multiple policies were available for the same country, the most recent policy was used. To complement the analysis, extracted data were shared with MOSAIC consortium members from all eight countries for contextualization using a set of guiding questions about how the policies are operationalized in practice. The following questions were posed to guide the reflection conversations:

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

Reflections were received from MOSAIC consortium members in all eight countries.

Findings and Discussion

MOSAIC consortium members in eight countries shared reflections in response to the proposed guiding questions. MOSAIC consortium members from six countries agreed that the policies extracted for this analysis are generally reflective of the reality of PEP access and service delivery in their countries.^{E,L,N,U,ZA, ZI} Members from two countries said either the policies are not optimally reflected in practice^K or they provide insufficient guidance for implementation, specifically of PEP and PrEP together.^{SA}

PEP Eligibility

WHO recommends that PEP be offered to “all individuals with exposure that has the potential for HIV transmission.” All national policies allow 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 policies explicitly mention the use of PEP by survivors of sexual assault and mention use by individuals who may be occupationally exposed to HIV; most^{K,L,U,ZA} mention PEP use by those with other potential sexual exposures. However, South Africa’s policy is the only one to include recreational intravenous drug use as a type of exposure, qualifying it as an “inadvertent exposure.” No other policies specifically address PEP access for people who may be exposed through injection-related practices outside of occupational settings. **Given the likelihood of HIV acquisition when someone is exposed through nonoccupational injection-related practices, explicitly including people with injection-related potential exposures in policies may raise awareness and increase access to and uptake of PEP among these individuals.**

Four policies outline differentiated services for individuals based on type of exposure,^{E,K,L,N} which can be valuable in providing different clients with appropriate services; **including individuals with nonoccupational injection-related potential exposures would be beneficial.** Differentiating types of exposures in policy can be clarifying, but when not done holistically, it can contribute to provider and client bias about who should access PEP and for what reasons. If a potential user arrives with no occupational or post-sexual assault criteria, which are featured heavily in all policies, they may not be counseled on or given access to PEP.

Stigma remains a driving force in lack of access to and uptake of HIV prevention options overall, but potential PEP users also face nuanced stigma based on the nature of their exposure. When that exposure is due to sexual assault or rape,^{L,N,ZA,ZW} for example, they may be reluctant to disclose their potential exposures. The quotation in the sidebar elucidates the limitations that exposure-based eligibility has on PEP access: a female sex worker (FSW) in Zambia explains how she falsified her exposures to access PEP. In this example, the stigma around PEP access converges with eligibility requirements, as the woman believes she would not be considered eligible for PEP because she was not assaulted. This insight points to potential misalignments in policy on paper and in practice. **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.**

"What we do sometimes, we go straight to the hospital, and you can't say that I am a prostitute, they will look down on you. So, what you can say is that I was drinking beer and there is this man who has raped me. You can't say I did it without a condom so that I get enough money — no, you can't say that. Then they will refer you to the police so that the VSU will write it as a rape case. Then you go to the doctor, and he does the lab necessities until you are given PEP without them knowing that you are a prostitute."

– Female sex worker,
Zambia

Sometimes it is possible to test the source of the potential exposure for HIV. In these cases, WHO says the client does not require PEP if the source is “established to be HIV negative.” In assessment for eligibility, all policies mention the HIV status of the potential source. Six policies^{E,K,L,SA,U,ZW} indicate that PEP should not be offered to individuals if the HIV status of the potential source is established to be negative. Three of these policies^{E,K,SA} clarify that if the potential source has had recent exposure to HIV or may be in the window period, PEP could be considered for the client. South Africa’s policy further specifies that a laboratory ELISA test should be used when the potential source can be tested for HIV. The other two policies^{L,U} provide no guidance about the window period or testing type and do not allow for PEP if the potential source is HIV negative. Zambia’s policy says that PEP can be offered if the potential source is known to be living with HIV or their HIV status is unknown. Since the dependability of HIV tests varies and it may not always be possible to obtain reliable information about the possible HIV exposures of a potential source, the current HIV status of a potential source often cannot be established. **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

WHO recommends that PEP be accessed “ideally within 72 hours” of potential HIV exposure. All but one national policy^N require that eligible individuals access PEP within 72 hours of potential exposure. Nigeria has two slightly different policies — one states that PEP needs to be accessed within 72 hours; another issued the same year says it should be accessed “ideally within 2–72 hours.” Uganda’s policy clarifies that PEP would ideally be accessed within the first two hours of potential exposure. The most recent policy from South Africa indicates PEP must be accessed within 72 hours of potential exposure, but previous guidelines state that it would be accessed “ideally within 72 hours but could be considered up to 7 days after potential exposure.”

Multiple MOSAIC consortium members named lack of awareness about PEP among potential PEP users, including not knowing when it may be appropriate,^{E,N,SA,U,ZW} as a major barrier to access — including timely access— for AGYW,^{E,L,N,SA,ZA,ZW} FSWs,^E and providers.^U Further, late reporting of exposures for those who have experienced intimate partner- or gender-based violence leads to confusion among clinicians about appropriate initiation on PEP.^L **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 appropriate 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. Policies in seven countries^{E,K,L,N,SA,U,ZW} recommend TDF/3TC/DTG as the preferred drug regimen for PEP. Zambia’s policy identifies TDF (or TAF) + FTC (or 3TC) + DTG as the preferred regimen. **As national policies are updated, policies that align with WHO guidelines may improve PEP completion and effectiveness.** Despite the effectiveness of the two-drug regimens, none of the policies reviewed allow for their use, potentially over concerns of promoting HIV drug resistance. As two-drug oral PrEP becomes more available, it may be

beneficial for national programs to consider allowing TDF + FTC or TDF + 3TC to be used for PEP in situations where a three-drug regimen is not available.

PEPFAR recently 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 multimonth dispensation of ARVs for people living with HIV, leaving the responsibility of procurement of PEP-appropriate bottles to national programs and other donors. **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. Four countries' policies include a recommendation for connecting PEP users to PrEP,^{E,L,K,ZA} and four do not.^{N,SA,U,ZW} For the countries with no clear "PEP to PrEP" recommendation, PEP is included elsewhere in the policy, but usually only by name as part of a recommended combination prevention package.

From a policy perspective, there are notable inconsistencies in where the policies mention any "PEP to PrEP" recommendation. In some policies,^{E,K} it is listed in PEP-specific sections, and in others,^{L,ZA,ZW} it is included in PrEP-specific sections. PrEP and PEP are both elements of a comprehensive combination prevention package, but siloed information regarding how the two can and should coexist limits the potential reach of both methods. Collectively, this is a missed opportunity for the comprehensive prevention approach. **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.**

WHO also identifies that PEP use an indicator that a client may benefit from PrEP. Three policies^{E,K,ZA} recommend the use of PrEP to PEP users, but specify that is for repeat PEP users. **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.** Requiring repeat PEP use may also mean that some PEP users are not being offered PrEP despite having ongoing potential exposure to HIV.

Furthermore, current policies do not allow for the provision of PEP proactively (sometimes called PEP in Pocket) in situations where potential exposures may be anticipated but longer use of oral PrEP is not desired or feasible. AGYW in South Africa sometimes come to clinics to initiate PrEP but request PEP as a back-up option in situations where they may have challenges adjusting to daily oral PrEP use. Providing PEP in this way may support users who struggle early on with adherence, further illustrating how strong linkages between PEP and PrEP could help clients use biomedical prevention options effectively. With the imminent introduction of the PrEP ring in many countries, PEP could play a role for ring users whose primary exposure to HIV is through receptive vaginal sex but may also occasionally be potentially exposed to HIV through anal sex or injection-related practices, when the ring would be ineffective. **Expanding PEP policies to allow for the preemptive provision of PEP in special situations may fill key gaps in HIV biomedical prevention and support more effective use of other prevention products.**

Additional Findings

In their contributions to the policy analysis, MOSAIC consortium partner identified other non-policy barriers to PEP access. For AGYW, traditional cultural norms and existing stigma shape, and often limit, discussions with parents or other adults about sexual encounters or ways to seek sexual health guidance.^{K,N,U,ZA,ZW} Their experiences are further marred by a lack of AGYW-responsive centers^{K,L,U} and by negative health care provider attitudes about PEP for AGYW, based largely on stigma around AGYW exposure,^{K,SA} or by discomfort with provision of PEP, based on limited provider knowledge and training.^{U,ZW} There also tends to be a layered confusion around PEP and PrEP, sometimes bolstered by the stigma toward people living with HIV, when potential users think PrEP and HIV treatment are the same because they are both distributed at HIV or TB clinics^{ZA,K} or private facilities.^U For some AGYW, school and clinic hours do not align, hampering timely access to PEP and other prevention interventions.^K In Zimbabwe, provision of PEP at pharmacies requires a prescription, which many AGYW struggle to obtain as a result of stigma from providers and the cost of private facility visits to providers with the ability to write a prescription. **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.**

PEP policies that require HIV testing or other diagnostic elements prior to the provision of PEP or that allow only a trained health care provider to prescribe or dispense PEP preclude community-based distribution, which could expand access to PE and other biomedical prevention options. While this analysis focuses on adults and adolescents, considerations for parental/guardian consent for testing is also important to understand in expanding PEP dispensation. Only one policy from South Africa referenced a separate policy on required consent. **Developing, testing, and codifying models for community-based distribution may elevate PEP awareness and elucidate opportunities for expanding differentiated service delivery.**

Many consortium members also spoke of the limitations of monitoring systems for PEP use, distribution, and follow-up.^{E,N,SA} In some cases, only out dated hard copies of registers are available.^E In others, providers who qualify for PEP due to occupational exposure do not record themselves as PEP clients if they self-administer PEP in their own clinics.^N Elsewhere, standalone PEP indicators exist on certain platforms but are included in PrEP reports in the Ministry of Health register.^{ZA} **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.**

In addition to the barriers explained in this brief that are unique to PEP access, MOSAIC consortium members identified other barriers relevant to PEP use. These include fear of side effects^{SA,U,ZW} lack of integrated sexual and reproductive health (including family planning and screening for sexually transmitted infections [STIs]) and HIV prevention services,^{L,U} and gaps in follow-up systems for structured support of PEP adherence.^{K,SA,ZW} This analysis did not look at additional services provided with PEP, such as STI screening or emergency contraceptives; however, ensuring that policies advocate for integration of services will only strengthen access to PEP and comprehensive sexual and reproductive health care.³ These implementation barriers are created beyond policy and affect the broader success of the comprehensive HIV prevention package, and

³ Ayieko J, Petersen ML, Kamya MR, Havlir DV. PEP for HIV prevention: are we missing opportunities to reduce new infections? J Int AIDS Soc. 2022 May 28;25(5): e25942.

ministries of health, donors, and program implementers should explore, evaluate, and address them to more holistically expand access to PEP.

Conclusion

Key aspects of PEP access present rich opportunity for improvement. To strengthen PEP access as part of the comprehensive HIV prevention package, country policies should:

- Explicitly include in policies people with nonoccupational injection-related potential exposures to raise awareness and increase access and uptake of PEP among these individuals.
- Cover differentiated services for different types of exposure, as well as make PEP available to those seeking PEP.
- Explicitly allow for PEP access for those with recent HIV exposures regardless of the HIV status of a potential source.
- Allow PEP access immediately after a potential exposure, without delay and with some flexibility about the latest someone can access PEP, all provided with clear information on the time frame in which PEP may be provided.
- Align with WHO recommendations on PEP regimens, completion, and effective use.
- Allow TDF/FTC or TDF/3TC to be used for PEP in situations where a three-drug regimen is not available.
- Include procurement of drugs for PEP in national procurement plans and establish long-term support for PEP procurement.
- Establish stronger linkages between PEP and PrEP that support bidirectional referrals in service delivery settings.
- Recognize repeated PEP use as an indicator for PrEP but do not limit PEP provision or initiation to repeated PEP users.
- Allow for the preemptive provision of PEP in special situations to fill key gaps in HIV biomedical prevention and support more effective use of other prevention products.
- Support sensitization, training, and mentorship efforts to familiarize both users and providers with PEP as part of the comprehensive HIV prevention package.
- Develop, test, and enshrine a model for community-based provision of PEP.
- Standardize monitoring and evaluation of PEP effective use and dispensation.

PEP is a vital yet underutilized aspect of the comprehensive HIV prevention approach. There is ample opportunity to expand access and uptake of PEP in ways that recognize the dynamic nature of exposure and subsequent need for a prevention option that can be initiated after exposure without pre-planning and across a diversity of settings.⁴ By leveraging these concluding recommendations, actors in the HIV prevention space, including ministries of health, donors, and program implementers could be well positioned to support uptake and integration of these recommendations to facilitate strengthened and sustained access to and choice of PEP.

⁴ Ayieko J, Petersen ML, Kanya MR, Havlir DV. PEP for HIV prevention: are we missing opportunities to reduce new infections? *J Int AIDS Soc.* 2022 May 28;25(5): e25942.