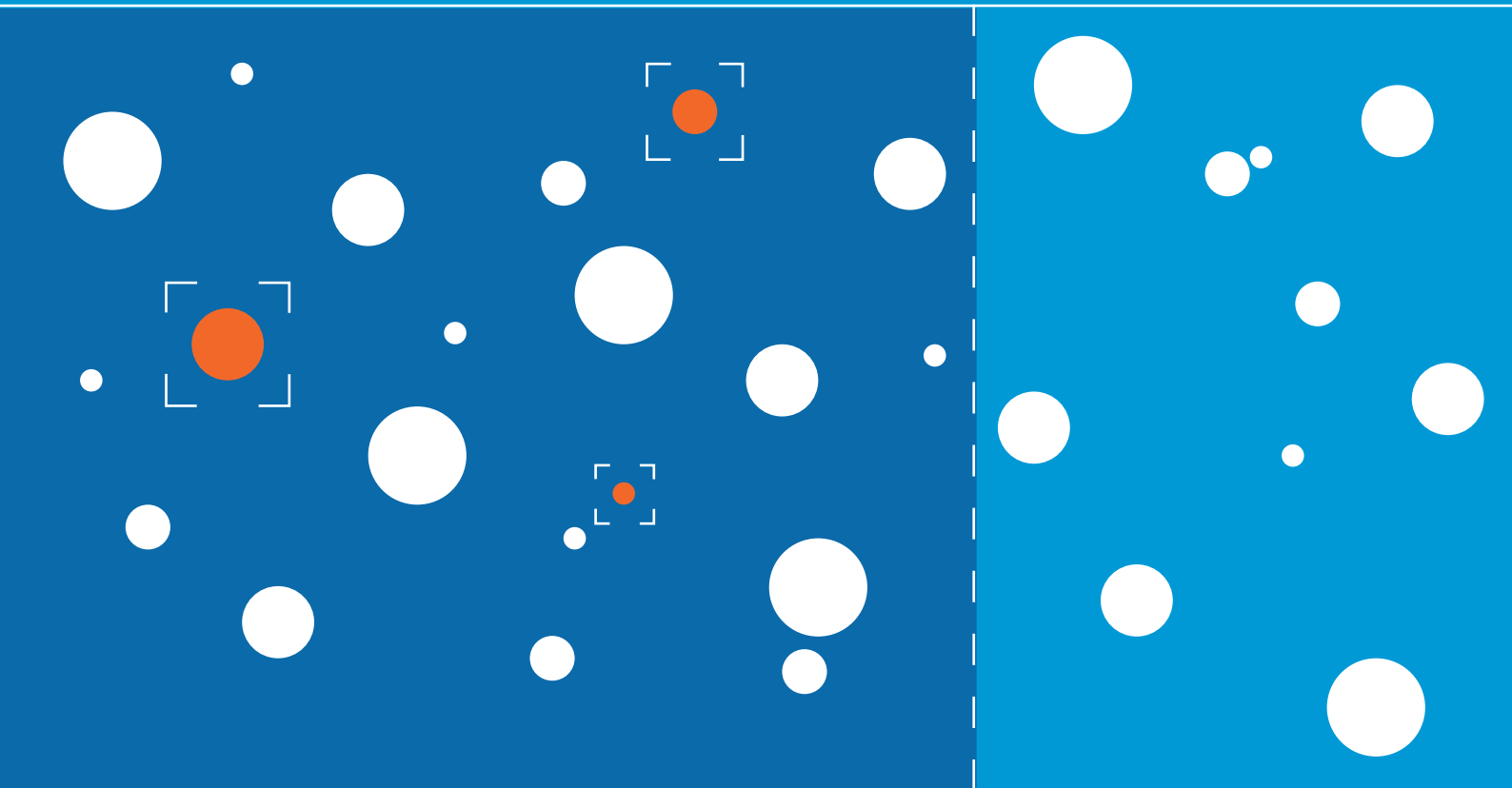


# Guidelines for HIV post-exposure prophylaxis





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# Abbreviations and acronyms

<b>3TC</b>	lamivudine
<b>ABC</b>	abacavir
<b>ART</b>	antiretroviral therapy
<b>ARV</b>	antiretroviral (drug)
<b>ATV</b>	atazanavir
<b>AZT</b>	zidovudine
<b>CAB-LA</b>	long-acting injectable cabotegravir
<b>CRE</b>	Office of Compliance, Risk Management and Ethics
<b>DRV</b>	darunavir
<b>DTG</b>	dolutegravir
<b>DVR</b>	dapivirine vaginal ring
<b>ERG</b>	External Review Group
<b>FTC</b>	emtricitabine
<b>GAM</b>	Global AIDS Monitoring System
<b>GDG</b>	Guidelines Development Group
<b>GSG</b>	Guidelines Steering Group
<b>GRADE</b>	Grading of Recommendations Assessment, Development and Evaluation
<b>HBV</b>	hepatitis B virus
<b>LPV</b>	lopinavir
<b>LPV/r</b>	lopinavir/ritonavir
<b>PICO</b>	population, intervention, comparator, outcome
<b>PEP</b>	post-exposure prophylaxis
<b>PrEP</b>	pre-exposure prophylaxis
<b>RAL</b>	raltegravir
<b>RTC</b>	randomized controlled trial
<b>TDF</b>	tenofovir disoproxil fumarate
<b>TLD</b>	tenofovir disoproxil, lamivudine, dolutegravir
<b>UN</b>	United Nations
<b>WHO</b>	World Health Organization

# Acknowledgements

## Contributors to the guidelines

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 Sexually Transmitted Infections Programmes), and Heather-Marie Schmidt (Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes and UNAIDS) under the leadership of Rachel Baggaley (Unit Head, Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes). The development process involved the formation of five main groups to guide and implement the process:

**WHO Guideline Steering Group (GSG).** The Testing, Prevention and Population Unit within the department of Global HIV, Hepatitis and STI Programmes led this group and served as the WHO secretariat. Participants included WHO staff from other units within the Programme, as well as from the Department of Sexual and Reproductive Health and Research. The GSG also included WHO technical staff from two WHO regions, the Region of the Americas and the South-East Asia Region.

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**Guideline Development Group (GDG).** This group consisted of 17 members, with a balanced representation of geographic regions, gender and perspectives, including academia and research, programme implementation and policy, and community organizations and networks. The group members were selected in coordination with the GSG and WHO country and regional offices. This group was responsible for the formulation of the new and updated WHO recommendations.

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**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. All observers are potential donors and implementers of the proposed guideline, with a long history of collaboration with WHO's department of Global HIV, Hepatitis and STI Programmes. We would like to acknowledge in particular Heather-Marie Schmidt from UNAIDS headquarters.

**Observers:** Lao-Tzu Allan-Blitz (Brigham and Women's Hospital, USA), Ramona Bhatia (CDC, USA), Isaac Bogoch (University of Toronto, Canada), Bidia Deperthes (UNFPA, USA), Emily Dorward (USAID, USA), Robyn Eakle (USAID, USA), Chris Obermeyer (Global Fund, Switzerland), Jason Reed (Jhpiego, USA), Carlos Toledo (CDC, USA).

# Executive summary

Persistent numbers of new HIV infections, particularly among key populations, demonstrate the need for enhanced prevention efforts. Despite advancements in testing and treatment, achieving epidemic control remains elusive, necessitating a renewed focus on preventive measures such as HIV post-exposure prophylaxis (PEP). WHO's updated guidelines prioritize broader access to PEP, including community-based delivery and task sharing to mitigate barriers such as stigma and to ensure timely access post exposure.

PEP involves administering antiretroviral (ARV) medication after potential HIV exposure to prevent infection. **Timely access to PEP is the most crucial factor in PEP effectiveness.** PEP is most effective when initiated as soon as possible, ideally within 24 hours and no later than 72 hours after exposure. While a PEP regimen of two drugs can be effective, three drugs are preferred. It is recommended that people be given a 28-day prescription for PEP. This guideline includes recommended drug regimens for adults, adolescents and children.

Comprehensive HIV prevention strategies are important. Linking HIV pre-exposure prophylaxis (PrEP) and PEP can enhance HIV prevention efforts, with PEP serving as a bridge to PrEP for individuals with repeated exposures to HIV. Conversely, individuals on PrEP who experience lapses in adherence or who discontinue use may benefit from PEP to prevent HIV acquisition.

This guideline includes two new recommendations related to increasing access to PEP through community delivery and task sharing. Following a systematic review and assessment of the evidence, the WHO Guidelines Development Group decided that PEP can be effectively provided in community settings; providing PEP closer to where individuals live and work will help to ensure timely access after HIV exposure. Evidence suggests that offering PEP in community settings is feasible. Successful implementation has been demonstrated in various locations such as private pharmacies, police stations and online platforms. Task sharing for PEP, involving non-specialist health workers such as pharmacists and community health workers, also has been shown to be effective and acceptable, with potential cost savings and increased equity in access.

## Key Points:

- **Timely access to PEP is the most crucial factor in PEP effectiveness.**
- Ideally, PEP should be started within 24 hours after HIV exposure and no later than 72 hours.
- While two ARV drugs are effective for PEP, three drugs are preferred.
- New recommendations endorse delivery of PEP in communities and through task sharing.

## Summary of HIV PEP recommendations and guidance statements

**Post-exposure prophylaxis 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.**

**An HIV PEP regimen with two ARV drugs is effective, but three drugs are preferred**

*(conditional recommendation, low-certainty evidence).*

### Recommended drug regimens

#### Adults and adolescents

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

#### Children

- ABC + 3TC is recommended as the preferred backbone regimen for HIV PEP for children <30 kg. AZT + 3TC or TDF + 3TC (or FTC) can be considered as alternative regimens (*strong recommendation, low-certainty evidence*).
- DTG is recommended as the preferred third drug for HIV PEP with approved DTG dosing (*strong recommendation, low-certainty evidence*).
- When available, ATV/r, DRV/r, LPV/r and RAL may be considered as alternative third drug options for PEP (*conditional recommendation, low-certainty evidence*).

**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*).

**In addition to existing WHO guidance for provision of PEP, this guideline includes two new recommendations:**

- **HIV PEP should be delivered in community settings** (*strong recommendation, very low-certainty evidence*).
- **Task sharing should be employed to dispense, distribute, provide and monitor PEP** (*strong recommendation, very low-certainty evidence*).



# Introduction

## Background

In 2022 it was estimated that 1.3 million people acquired HIV. That number indicates that much progress is needed to reach the 2025 target of fewer than 370 000 new infections annually (1). In all settings key populations (men who have sex with men, trans and gender-diverse people, sex workers, people who inject drugs and people in prisons) are disproportionately affected by HIV due to structural barriers such as criminalization, incarceration, stigma and discrimination (2). Other populations who are disproportionately affected and need increased attention in the HIV response include adolescent cis-girls and young cis-women<sup>1</sup> in East and Southern Africa, although there is considerable variation in risk and vulnerability across the region. While HIV incidence and prevalence are lower in cis-men than in cis-women, access to HIV services is often more difficult for cis-men than cis-women in this region. Poverty, geographic isolation, lack of educational opportunities, disability, race, religion and gender also intersect to increase vulnerability to HIV.

Access to testing, linkage to antiretroviral therapy (ART) and ART adherence to maintain an undetectable viral load have been critical to reducing new HIV infections. However, even when countries have reached, or nearly reached, the United Nations (UN) 95–95–95 goals,<sup>2</sup> this high testing and treatment coverage has not been sufficient to reach the low levels of new infections necessary for epidemic control. Wider use of effective prevention options is needed. WHO recommends a number of interventions to prevent HIV. These include use of condoms and lubricant, harm reduction for people who inject drugs (needle/syringe programmes, opioid agonist maintenance therapy and naloxone for overdose management), voluntary medical male circumcision, PrEP, provision of HIV treatment during pregnancy to prevent mother-to-child transmission and post-exposure prophylaxis (PEP). However, in many settings uptake of these options is low (3).

HIV PEP is a prevention intervention that involves taking ARV medications shortly after a potential exposure to HIV in order to reduce the risk of HIV acquisition. PEP can be effective regardless of the route of exposure – whether through unprotected sexual intercourse, sexual assault including rape, sharing needles for drug use or occupational exposure in health care settings. WHO published guidelines on HIV PEP in 2014 (4) and updated these guidelines in 2018 (5).

## Rationale for guidelines update

While HIV PEP is an effective HIV prevention intervention that has been recommended by WHO for all potential HIV exposures, access to and uptake of PEP is still sub-optimal, leading to missed opportunities to prevent new HIV transmissions. There has been huge interest and increased programming and uptake of pre-exposure prophylaxis (PrEP) over the past 10 years. In contrast PEP, which also has been recommended for a decade, has received little attention and limited use, even though, with expanded PrEP access, PEP has important additional prevention benefits. Expanding access to PEP after all potential exposures through sexual and injecting drug use is needed.

The lack of attention to PEP over the past decade, particularly to its use outside clinical settings, may help to explain limited access and use. Outdated and restrictive policies may limit use to those with occupational exposure or sexual assault (including rape) and may not support approaches to providing PEP in communities. Providers lack knowledge and some, particularly providers working in community settings, lack access. In communities and among people who might benefit, awareness of PEP is poor. These interrelated factors have contributed to low PEP availability, use and impact of PEP programmes.

Stigma and discrimination can deter people from accessing health services, including services for PEP, and this is particularly true for key populations (6). Many people prefer community-based health care services and the involvement of community health workers and peers over clinic and hospital care because community services models can mitigate stigma and discrimination. However, PEP is often not available in community settings and the health care providers who can provide HIV PEP services are limited.

Timely access to PEP is fundamental to effectiveness. The shorter the gap between HIV exposure and PEP initiation, the less likely that HIV will establish a persistent infection. Therefore, PEP services need to be close at hand when needed.

Given the existing challenges to access to and uptake of PEP, there is a need to rethink how PEP is offered to people most at risk for HIV and how to provide it as soon as possible after exposure (7). This updated guideline aims to address these issues by providing guidance on simplifying and improving PEP service delivery, including making new recommendations on:

- 1) expanding access to PEP through integrated community health care facilities and other, non-health care facilities and services;
- 2) expanding who can be involved in the prescription and distribution of PEP to include community-based providers.

<sup>1</sup> Cis-gender means a person whose gender identity corresponds to the sex they were assigned at birth.

<sup>2</sup> The UN 95–95–95 goals call for diagnosing 95% of all HIV-positive individuals, providing ART for 95% of those diagnosed and achieving viral suppression in 95% of those treated by 2030.

The two new PEP recommendations in this guideline were developed by a GDG in 2023. For these two recommendations, a summary of evidence, GRADE tables and evidence-to-decision making tables appear in [web annexes to this guideline](#).

This guideline summarizes other recommendations from previous WHO PEP guidelines (4, 5). The evidence supporting them can be found in the previous guidelines.

## Target audience

This guideline is intended to promote increased attention to and use of PEP among policy makers, donors, programme managers, health care providers, communities, potential PEP users and others.

The recommendations in this guideline will be useful for programme managers involved in the implementation and adaptation of WHO guidelines into national HIV and STI programmes, particularly those in low- and middle-income countries.

## Guiding principles

The following principles guided the development of these guidelines:

### Human rights

The development of these guidelines is based on human rights principles set forth in a number of international agreements (8, 9). These include the right to the highest attainable standard of physical and mental health for all, without discrimination, and accessible, acceptable, available and quality health facilities, goods and services, including medicines for the prevention and treatment of HIV, on an equal basis, without discrimination. It also includes the right to self-determination, the right to privacy and the right to confidentiality, which are equally important in this context.

### Gender equality

The promotion of gender equality, which affects both cis-women and trans and gender-diverse individuals, is central to the achievement of HIV prevention, diagnosis and treatment goals. This means recognizing and taking into account how unequal power in intimate relationships, harmful gender norms and lack of access to resources and control over them affects exposure to risks related to unprotected or unsafe sex and access to, and experiences with, health services.

### Equity and inclusion

Recognizing and addressing the social determinants of health and promoting equity and inclusion are central to achieving health for all.

### Medical ethics

Health care providers and institutions must serve people, based on the principles of medical ethics, regardless of personal philosophy, politics, religion, moral theory or opinion (10). Particularly relevant are ethical principles related to provider–patient/client relationships: patient or client autonomy; confidentiality; informed consent and voluntary involvement in health services.

### Universal health coverage

Universal health coverage (UHC) means that all individuals and communities receive the health services they need without suffering financial hardship. This includes the full spectrum of essential health services, from health promotion to prevention, treatment, ongoing recovery and palliative care across the life course, which should be made available through an integrated, people-centred, primary care approach to health.

### Evidence-based public health

Recommendations in this guideline are based on an impartial synthesis of evidence and guided by an independent group of experts, the GDG.

### Community-led response

This guideline upholds the principle of the greater involvement of people living with HIV (the GIPA principle) (11) and commits to support the meaningful engagement of communities, including communities of key populations, in the response to HIV.

# Methods

## Overview

The WHO Department of Global HIV, Hepatitis and STI Programmes led the development of these consolidated guidelines, following procedures and reporting standards laid out in the *WHO handbook for guideline development* (12). The recommendations in the guidelines are based on the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation) (13) to reviewing evidence and formulating recommendations.

These guidelines are an update of PEP guidelines published in 2014 and 2018 (4, 5).

## Competing interests

All external contributors to the development of the guidelines, including members of the GDG and the ERG, completed WHO declaration of interests forms. All declaration of interests forms are on electronic file at the WHO Department of Global HIV, Hepatitis and STI Programmes and will be maintained there for 10 years.

Participation of each contributor was reviewed with regard to the interests declared. To assess competing interests of the GDG members, the WHO responsible technical officers reviewed declarations of interests forms and curricula vitae and performed online searches. Before finalization, the proposed membership list was posted for public review and comment 14 days prior to the GDG meeting. A management plan for each declared conflict was agreed on and recorded at the time of the meeting. Two potential conflicts were identified and reviewed by the WHO Office of Compliance, Risk Management and Ethics (CRE). One was considered not relevant. The other related to a GDG member's involvement in one of the studies included in the systematic review. The CRE advised that the GDG member should not participate in the decision-making process concerning PICO 2 (see [Web Annex A](#)).

## Developing recommendations

To support the development of these guidelines, WHO commissioned a systematic review of effectiveness, case examples, values and preferences, and cost data related to the provision of HIV PEP in community settings and through task sharing.

The evidence review covered two complementary questions framed using the PICO approach (population, intervention, comparator, outcomes):

1. Should PEP be offered in community settings?
2. Should PEP be offered through task sharing?

The same search strategy used for the effectiveness review was also used for values and preferences, case examples and cost. [Web Annex B](#) presents details of the search strategy. Other evidence used to develop the recommendations included details of existing WHO recommendations related to decentralization and task shifting.

For each outcome of the PICO questions, the GDG members were asked to rate the importance of the outcomes on a scale from "limited importance" to "critical" for making a decision, and the average ranking was calculated. [Annex B](#) presents GRADE tables, which include the importance to each outcome.

GRADE specifies four levels of certainty that can be applied to the outcome of the effectiveness review (see [Annex B](#)):

1. High – the GDG is very confident that the true effect lies close to the estimate of effect.
2. Moderate – The GDG is moderately confident in the estimate of effect. The true effect is likely to be close to the estimate of effect, but it could be substantially different.
3. Low – The GDG's confidence in the estimate of effect is limited. The true effect may be substantially different from the estimate of effect.
4. Very low – The GDG has very little confidence in the estimate of effect. Any estimate of effect is very uncertain.

In order to use this evidence to reach a decision about making a recommendation, the GDG used an evidence-to-decision framework to consider and make judgements on different questions, as described in Table 1.

**Table 1. Judgements used in evidence-to-decision making framework**

Question	Possible judgements
1. Is the problem a priority?	No, Yes, Varies, Uncertain
2. How substantial are the potential benefits?	Large, Moderate, Small, Trivial, Varies, Uncertain
3. How substantial are the potential harms?	Large, Moderate, Small, Trivial, Varies, Uncertain
4. What is the overall certainty of the evidence?	High, Moderate, Low, Very Low
5. What is the balance between benefits and harms?	Favours intervention, Against intervention
6. Do people value the intervention?	Degree of variability or uncertainty
7. How large are the resource requirements (costs)?	Large, Moderate, Negligible costs or savings
8. Is the intervention cost-effective?	Favours intervention, Against intervention
9. What would be the impact on health equity?	Reduced, Increased, Varies, Uncertain
10. Is the intervention acceptable to all stakeholders?	No, Yes, Varies, Uncertain
11. Is the intervention feasible to implement?	No, Yes, Varies, Uncertain

Finally, the GDG decided whether to make a recommendation for or against the intervention and the strength of the recommendation. A recommendation can be:

- 1) **Strong** – The GDG is **confident** that the desirable effects of adherence to the recommendation outweigh the undesirable effects; or
- 2) **Conditional** – The GDG concludes that the desirable effects of adherence to the recommendation **probably** outweigh the undesirable effects (or vice versa).

## Funding

Financial contributions from the Bill & Melinda Gates Foundation and USAID supported development of these guidelines.

## Plans for dissemination and updating

These guidelines will be updated based on regular scoping exercises of available evidence and of experience with country implementation, which will guide and trigger the need for new guidance. As the evidence base grows or users' needs change, consideration will be given to producing technical updates on specific subjects.

The guidelines will be disseminated electronically on the WHO Global HIV, Hepatitis and STI Programmes website and as a print publication available on demand. Dissemination will be supported by publication of selected systematic reviews and evidence in peer-reviewed journals, as well as policy briefs and web- and mobile phone-based apps. Also, the guidelines will be presented at international conferences and through webinars, as appropriate.

Working with partners such as the United Nations Joint Programme on HIV/AIDS (UNAIDS) and its Global AIDS Monitoring System (GAM), donors and others, WHO will ensure that the uptake of PEP is continually monitored and that additional indicators related to community PEP and task sharing will be included in indicator lists.

# Providing PEP

## What is post-exposure prophylaxis of HIV?

HIV PEP is the use of ARV medication to prevent acquisition of HIV after a possible exposure. PEP works by halting viral replication and preventing establishment of a persistent infection during the brief interval after the virus has entered the body but before it becomes an established infection. There have been no randomized controlled trials (RCTs) assessing the efficacy HIV PEP. Evidence of PEP efficacy comes from one case-control study (14) and several animal studies and other types of observational studies (15, 16). These studies show that HIV PEP can reduce the risk of infection if taken quickly after exposure and for a long enough period.

## When to prescribe PEP

**Post-exposure prophylaxis should be offered to individuals with suspected or known exposure to HIV, and as soon as possible, ideally within 24 hours and not later than 72 hours.**

There are serious methodological and ethical challenges to conducting trials on PEP efficacy in humans. At the same time, while data from animal studies and models are important and can yield results that indicate the time after exposure during which PEP is efficacious, they have limitations.

Nonetheless, data from animal and modelling studies make clear that the efficacy of HIV PEP in preventing transmission is time-dependent. For example, modelling data of HIV PEP pharmacokinetics suggests that, without any HIV PEP drugs, HIV infection becomes irreversible two to five days after exposure. With a combination of two drugs, HIV PEP will probably be effective only if taken within 24 hours of exposure. With a combination of three drugs, HIV PEP will almost certainly prevent HIV infection if taken within 48 hours after exposure. However, efficacy will decrease steeply after this time. If taken between 48 and 72 hours after exposure, regardless of the number of drugs, PEP is much less likely to be effective (7, 17–20). Given limited evidence, it is not possible to state definitively at which time point PEP will no longer be effective with either a two- or three-drug combination.

**The crucial factor that influences PEP efficacy is the time between exposure and starting PEP drugs. Starting as soon as possible after exposure is the most important consideration when taking PEP.**

## Who should receive PEP?

**Anyone with a known or suspected exposure to HIV should be offered PEP.**

Known or suspected exposures that warrant PEP include parenteral exposure (through occupational exposure, other needle-stick injuries or use of contaminated needle/syringes during illicit or licit injecting drug use) or mucous membrane exposure (through sexual exposure including that involving sexual assault and rape and splashes to the eye, nose or oral cavity).

Known exposures are those where:

- the source is a person confirmed to be living with HIV;
- the fluid involved in the exposure has potential for HIV transmission; and
- the exposure event was parenteral or, if sexual, the source has detectable levels of virus.

Suspected exposures are those where the HIV status of the source is not known.

The following fluids pose a risk of HIV infection: blood, blood-stained saliva, breast milk, genital secretions and cerebrospinal, amniotic, rectal, peritoneal, synovial, pericardial or pleural fluids. Various factors may influence the risk of sexual transmission, including: presence of other STIs in either the source or exposed individual, the plasma viral load of the source if HIV-positive and penile circumcision status (4). For parenteral exposures deep injury, hollow-bore needles, needles placed in arteries or veins or visible blood in the needle are factors that increase the risk of HIV transmission (21, 22).

Exposures that do not require PEP include:

- when the exposed individual is already living with HIV;
- exposure to bodily fluids that do not pose a significant risk: tears, non-blood-stained saliva, urine, sweat, sputum and diarrhoea/faeces;
- when the source is established to be HIV-negative or if the exposure was sexual and the source has an undetectable viral load.

**Note:** Where exposure is suspected, provision of PEP should not be delayed by trying to identify or find out the HIV status or viral load of the source of exposure.

In low-prevalence settings the likelihood of exposure to HIV may be low for many people. When discussing with clients whether or not to take PEP, providers should consider the local epidemiology, the reported exposure and the client's risk and context in evaluating the individual benefit of PEP.

## How many drugs should be prescribed for PEP?

### Recommendation (2014)

**An HIV PEP regimen with two ARV drugs is effective, but three drugs are preferred** (conditional recommendation, low-certainty evidence).

Providing three drugs for post-exposure prophylaxis is consistent with recommendations for ART, the standard for which is triple-drug combination therapy (4). Further, as noted, animal studies and pharmacokinetic modelling studies suggest that, with just two drugs, PEP is unlikely to be effective if taken 24 hours or more after exposure, but, if a third drug is added, then PEP may be effective when taken as late as 48 to 72 hours after exposure (7).

Where only two drugs are available to someone who has been exposed to HIV, a two-drug combination should be taken as soon as possible after exposure. If a third drug becomes available, this should be immediately included in the PEP regimen.

## Which drugs should be used for HIV PEP?

### Recommendations (2018)

#### Adults and adolescents

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

#### Children

- ABC + 3TC is recommended as the preferred backbone regimen for HIV PEP for children weighing less than 30 kg. AZT + 3TC or TDF + 3TC (or FTC) can be considered as alternative regimens (*strong recommendation, low-certainty evidence*).
- DTG is recommended as the preferred third drug for HIV PEP with approved DTG dosing (*strong recommendation, low-certainty evidence*).
- When available, ATV/r, DRV/r, LPV/r and RAL may be considered as alternative third drug options for PEP (*conditional recommendation, low-certainty evidence*).

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

WHO regularly updates the recommended ARVs as new drugs become available. Other drugs for PEP are in use in high-income settings but are not yet recommended by WHO, mainly due to limited access in low- and middle-income settings.

Annex C lists ARV dosages for use in HIV PEP for adult, adolescent and child. Details of interactions among ARV drugs can be found at <https://hiv-druginteractions.org/>.

## Prescribing frequency and how long to take PEP

### Recommendation (2018)

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

The evidence used to make this recommendation was drawn from observational studies showing that adherence is better if all 28 days of medication is given at once: the proportion of individuals completing a 28-day course of PEP was higher among those receiving the full 28-day prescription of ARV drugs at their initial assessment than among those receiving partial prescriptions (that is, starter packs) (5). WHO does not recommend distributing starter packs to people using PEP. In some settings people who are at increased risk of HIV are given 28 days of PEP ARVs to take home, which they can take if they have a potential HIV exposure. This approach means people do not need to visit a clinic for PEP, which increases access and an earlier start to PEP (23).

Giving the full 28-day dose at once leads to the best adherence.

While there may be concerns about frequent PEP use, an HIV prevention strategy that includes periodic/frequent PEP is effective and safe, provided the person is using PEP as recommended.

Animal studies of HIV PEP suggest that a 28-day course of PEP may not be needed and that PEP can be effective if taken for shorter durations, particularly if taken very soon after exposure and with certain classes of ARVs (7). Shorter PEP durations may be preferable, as uptake and adherence may improve, and adverse drug reactions could be less likely. However, at this stage WHO does not have enough evidence available to recommend a shorter PEP course.



## Considerations related to PEP regimens

Currently recommended regimens for PEP are safe and have limited side-effects. Hepatitis B is not a contraindication for offering PEP regimens that include TDF, FTC or 3TC, and so assessing for and ruling out hepatitis B infection should not be a precondition for offering PEP. Hepatitis B virus tests are not available everywhere and particularly scarce in community settings. However, if the test is available and particularly in settings where hepatitis B is hyperendemic, people started on PEP should be tested for hepatitis B to detect active infection and the need for treatment. Results of hepatitis B testing have no relevance to PEP prescribing decisions.

People with active HBV infection should be monitored for a flare of hepatitis after discontinuation of TDF-, 3TC- or FTC-based PEP if these drugs are not continued for the treatment of HBV. This may require referral to a hepatologist. Hepatitis flares are extremely rare.

Choice of an HIV PEP regimen should consider the ARV drugs already being procured within national HIV programmes. Additional considerations include the availability of heat-stable formulations, daily dosing, availability and affordability.

## How to provide PEP

Wherever people are provided PEP, there are basic steps, accompanying interventions or referrals that should be provided (Fig. 1).

### A note on testing for PEP

Before starting PEP, people should be tested for HIV, using the relevant national guidelines. WHO recommends a testing strategy that includes a professional-use rapid test or an HIV self-test (24). If the HIV test is non-reactive (negative), PEP can be started immediately. **If HIV tests are unavailable but the person is suspected to have been exposed to HIV, PEP should be started regardless.** If the HIV test is reactive, the person should seek further testing following the WHO three test strategy and be linked to ART if confirmed to have HIV. No other test is needed for people taking PEP. After a person completes the 28-day PEP course, follow up HIV testing should be done. Again, this can be done with a professional-use rapid test or an HIV self-test. If the result is reactive, the person should seek further testing. HIV self-testing has been shown to facilitate PrEP initiation and improve adherence and continuation and, therefore, may also increase access to and uptake of PEP.

## PEP and PrEP: linking ARV-based HIV prevention

Pre-exposure prophylaxis (PrEP) is a highly effective HIV prevention option that involves the use of ARV medication *before, during and after* a potential exposure to reduce the risk of HIV acquisition. WHO recommends HIV PrEP for people at substantial risk of HIV (25). PrEP can be taken as an oral medication using two of the drugs also recommended for PEP – TDF/FTC or TDF/3TC – or in long-acting single-drug formulations such as long-acting injectable cabotegravir

(CAB-LA) (26) or the dapivirine vaginal ring (DVR) (25). Linking PEP and PrEP can maximize their combined effectiveness and reduce missed opportunities for sustained HIV prevention.

### Transitioning from PEP to PrEP

Some people needing PEP will have repeated or ongoing exposures to HIV. Health care providers should discuss with people presenting for PEP whether they may benefit from and be interested in

PEP use can be an entry point to promote awareness, access and use of PrEP.

transitioning to PrEP after completing the PEP course. In this way PEP use can be an entry point to promote awareness, access and use of PrEP.

PrEP may not be wanted or needed in every instance of PEP use, however. Some people at continuing risk of exposure may prefer not to take PrEP and may want to use other methods of HIV prevention. And some exposures may be isolated events that do not require continuing prevention, such as a health care-associated exposure (for example, needlestick injury) or some cases of sexual exposure, such as sexual assault.

Immediate transition to PrEP is preferable for individuals with ongoing exposure to HIV. People who complete the 28-day PEP regimen and wish to use PrEP can start PrEP without a gap if they have a negative HIV test result on completion of PEP and do not have any contraindications to the chosen PrEP product (that is, oral PrEP, DVR or CAB-LA). WHO recommends that this testing can include the use of an HIV self-test as well as a dual HIV/syphilis self-test.

### Transitioning from PrEP to PEP

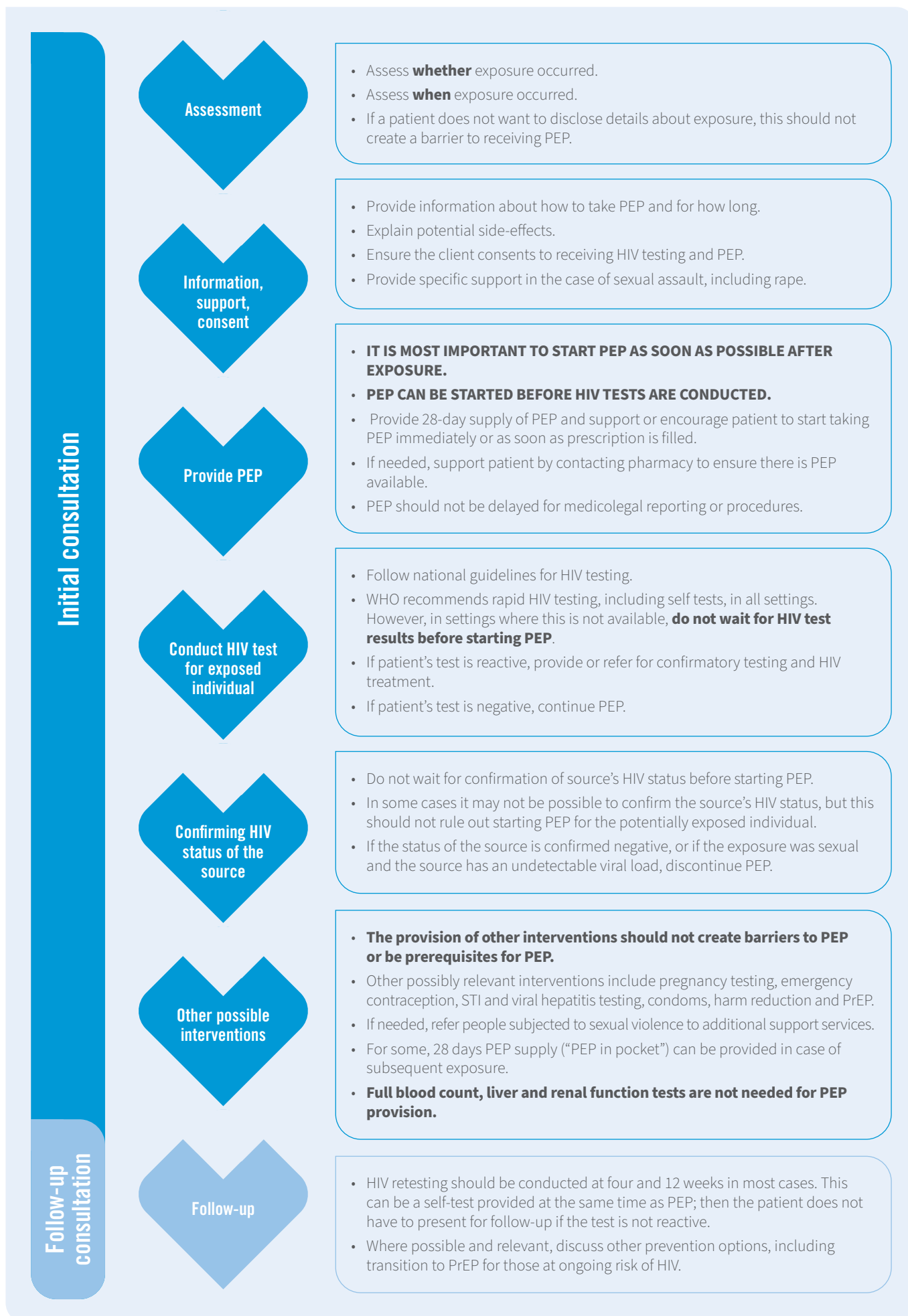
People using PrEP as directed would not usually need PEP. However, if PrEP is not used as directed or is stopped, there may be a risk of acquiring HIV if exposure occurs. PEP can be an important HIV prevention strategy during these periods. Table 2 outlines when PEP should be considered for someone who is taking or has recently stopped PrEP.

PEP providers should consider:

- the PrEP product used (oral PrEP containing TDF, the DVR or CAB-LA)
- the type of exposure to HIV (that is, anal sex, vaginal sex or parenteral/injecting)
- the person's sexual and/or drug-use networks
- the time since PrEP was last used
- individual characteristics that may affect PrEP efficacy.

PEP should be discussed with and available for people who stop CAB-LA to protect against HIV acquisition during the tail period (the period after stopping CAB-LA when cabotegravir remains within a person's system but at levels too low to protect against HIV acquisition). For people who have stopped CAB-LA, PEP should be considered when an exposure occurs more than two months after their last injection.

Fig. 1. Key steps in the provision of HIV PEP





Clinical trials and pharmacokinetic studies of oral TDF/FTC for PrEP have provided good evidence about the direct relationship between adherence and efficacy against HIV acquisition (27–31). This relationship has implications for how to combine PrEP and PEP. As Table 2 describes, the number of PrEP doses taken in the week before an HIV exposure indicates whether someone is protected against HIV if exposed and, therefore, does not need PEP, or if they are *not* protected and therefore *do* need PEP to prevent HIV acquisition. Further, as Table 2 describes, the relationship between PrEP adherence and efficacy and the subsequent need for PEP can differ, depending on individual characteristics and type of exposure (28, 30–32). The evidence is evolving on the relationship between PrEP adherence and efficacy for different routes of exposure and groups of users, including oral PrEP for cisgender women (29, 33, 34); WHO will continue to review the data as they become available.

**If someone is exposed to HIV and has stopped PrEP or missed doses (see Table 2 for detail) and already has oral PrEP (TDF/FTC or TDF/3TC) at home, they can begin PEP immediately by taking this two-drug combination and then should attend an appropriate service as soon as possible to add the third ARV drug. Clients without oral PrEP at home should attend an appropriate service for PEP immediately.**

**Table 2. PEP for people using PrEP or who have recently stopped PrEP**

PrEP product	Doses taken in the 7 days before exposure	Route of exposure	Consider PEP?
<b>Oral PrEP containing TDF</b> (27, 28, 30–32, 35)	4–5 (men <sup>a</sup> )	Sexual exposure	No, continue oral PrEP
	6–7 (all other groups)	Any exposure	
	0–3 (men)	Sexual exposure	Yes
	0–5 (all other groups)	Any exposure	
<b>DVR</b>	<b>DVR placement</b>		
	DVR in place	Vaginal sex from 24 hours after insertion	No, continue using the DVR
		Vaginal sex within 24 hours after insertion	Yes
		Exposures other than vaginal sex, that is, anal sex or parenteral exposure, at any time	Yes
DVR not in place	Vaginal sex within 24 hours after removal	Yes	
<b>CAB-LA</b>	<b>Delayed injection / time since stopping CAB-LA</b>		
	Scheduled follow-up injection delayed ≤7 days <sup>b</sup>	Any exposure	No, continue CAB-LA
	Scheduled follow-up injection delayed >7 days OR >2 months since stopping CAB-LA	Any exposure	Yes

<sup>a</sup> In this table “men” refers to individuals assigned male at birth who are not taking gender-affirming hormones.

<sup>b</sup> There is a seven-day window for receiving follow-up CAB-LA injections, that is, seven days earlier or seven days later. Individuals presenting for their scheduled CAB-LA injection within this window would not need PEP.

## Adherence strategies

### Recommendation (2014)

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

In many settings and among various populations, adherence to PEP (that is, completing a 28-day course and/or returning for a follow-up visit) has been reported to be poor (36–43). This is related to various factors. For example, people report not returning for a follow-up appointment because of inconvenience or lack of time (44) or because of structural barriers such as cost, lack of health insurance, stigma and discrimination (45, 46), as well as not being informed about the correct way to take PEP. Side-effects are commonly reported as a reason for discontinuation of PEP (46–48), although newer, currently recommended PEP regimens are better tolerated than older regimens and should help with adherence. For people who experience sexual assault, there are complex and different reasons for poor adherence to PEP, including those related to stigma and trauma (49, 50). Age-specific considerations for offering adherence counselling to children and adolescents who have been sexually abused are outlined in other WHO guidelines (51). Detailed guidance on clinical care and policy responses for those who have experienced sexual assault, including all women, adolescents and children can be found in other WHO guidelines (51–53).

Methods used to increase adherence to PEP include baseline individual needs assessment, counselling and education and follow-up telephone calls (4). A systematic review of three RCTs was not conclusive on whether these interventions are effective, although it showed a tendency towards improved adherence when enhanced counselling was provided (4).

## Where can PEP be provided?

### NEW recommendation

**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 and online delivery.

Since it is important to provide PEP as soon as possible after exposure to HIV, timely access is crucial. One way to increase access is to provide PEP in more settings, closer to where people live and work, at more times and with fewer other

barriers to access. For this reason, as part of the update of these guidelines, WHO and the GDG examined evidence related to community distribution of PEP. (Web Annex D provides details of the evidence to decision-making process.)

## Summary of evidence

A systematic review identified six studies assessing PEP in community settings: one effectiveness study (54), three case studies (55–57), one values and preferences study (58) and one cost study (59).

### Effectiveness

The effectiveness study, known as the SEARCH SAPHIRE study, took place in rural settings in Kenya and Uganda. It offered PEP as part of a “dynamic choice” model of HIV prevention options, which also included PrEP and condoms, in three different settings: in antenatal care settings and outpatient departments where PEP was offered by clinical officers and nurses and in community settings where PEP was offered by community health workers (54). At intervention visits during weeks 4, 12 and 24, participants were asked to select a choice of HIV prevention option (PrEP, PEP, condoms only or no selection), HIV testing modality and preferred setting for next visit. At week 24 PEP use and HIV risk for each of the prior six calendar months were assessed via a structured survey. The study measured uptake of PEP over 24 weeks of follow-up and found that the initial choice of PEP for HIV prevention was highest in the community setting – 46% – compared with 9% in the outpatient departments and 3% in the antenatal care settings. Selection of PEP over the follow-up study visits remained highest in the community setting (23% at week 24, for example). By comparison, in the outpatient departments and antenatal care settings, only 11% and 3%, respectively, ever selected PEP. No studies reported information regarding quality of PEP services offered, timeliness of PEP uptake, linkage to or uptake of appropriate additional services, or adverse events.

No studies of effectiveness reported on quality of PEP services offered, timeliness of PEP uptake, linkage to or uptake of appropriate additional services, or adverse events.

### Feasibility

The literature review identified three studies addressing feasibility. These described PEP as feasible in different settings – out-of-facility community sites (55), police stations (57) and online (56). The first study trained health workers from government clinics in Kenya and Uganda to deliver PEP in out-of-facility, community-based medication settings. The rate of PEP completion was high, and no serious adverse events or HIV seroconversions occurred among 124 participants (55). The second example involved training for police in Zambia on case management and initiation of PEP at police stations for sexual assault survivors (57). While police were able to provide PEP and make referrals, uptake was not high, partly because most women eligible for PEP presented outside of station opening hours. The third example is a web-based platform for delivering PEP in China. There 99% of people requesting PEP started within 72 hours of exposure, and there were no seroconversions among the 539 participants (56). Web Annex B presents full descriptions of case examples.

WHO has existing recommendations for delivery of ART and PrEP in community settings, which have been implemented in several countries and demonstrated as feasible (24).

### Values and preferences and acceptability

A cross-sectional survey of 342 sexual and gender minorities visiting collective sex venues (for example, bathhouses, sex clubs, private sex parties) in New York City, USA reported that respondents expressed interest in such venues providing a range of free HIV and STI prevention services, including PEP, and felt that services could be delivered in an acceptable way in these settings (58). Potential barriers included privacy concerns, an emphasis on personal responsibility, and negative reactions to the presence of service providers.

There was no evidence from the literature review that addressed questions of acceptability among other stakeholders.

### Resource needs

A modelling study examined a range of scenarios around wider PEP availability – that is, PEP freely available, with no prescription required – in community health care settings in West, East, Central, and southern Africa (59). This study estimated that three months of PEP use in Africa, including a 20% additional supply chain cost to cover distribution, would cost US\$ 16.20 per user. Overall costs were lower with community PEP than with no community PEP in 92% of setting scenarios. Community provision of PEP would save US\$ 18.0 million per year (14% of the current overall annual HIV budget of US\$ 127.8 million) over 50 years as a result of fewer people requiring ART and fewer ART-related clinic visits over the long-term. The model suggested that community PEP was cost-effective in 90% of setting scenarios and cost-saving (in terms of disability-adjusted life-years) in 58% of scenarios. In settings involving less uptake, community PEP was found to be cost-effective in 92%.

### Evidence to decision-making

Despite the very low certainty of evidence, the GDG unanimously decided that there were clear benefits to providing PEP in community settings in terms of earlier and increased access in a setting that potentially can reduce stigma. The GDG also agreed that, if PEP is expanded for use in community settings, the increased availability would help reduce overall inequities in HIV acquisition and outcomes. Indirect evidence, from experience with PrEP, suggests that people who access PrEP through community-based service delivery models are demographically different from people who access PrEP in health centres. If so, these models may reach some people who might not be reached through clinical services (60). The GDG considered that any potential harms were far outweighed by the harms incurred by limiting access to PEP (that is, an increased risk of HIV infection). It was agreed to make a strong recommendation for provision of PEP in community settings.

While the GDG agreed that most clients would value PEP in community settings, they noted that among other stakeholders there is likely more variability in the acceptability of PEP in community settings.

The GDG agreed that there would be moderate savings if community PEP was implemented, but that this would vary by setting and intervention type. They also agreed that cost-effectiveness would probably favour community PEP, but that this would vary, particularly in high income settings. The GDG unanimously agreed that community PEP would increase equity.

The GDG also noted that WHO strongly recommends that ARV drugs can be provided as part of ART in community settings, dispensed by community health workers (25). These recommendations have been implemented in several countries and their feasibility, demonstrated.

The GDG issued a strong recommendation, despite low-certainty evidence, in consideration of the strong evidence and programmatic experience supporting the feasibility and acceptability of providing ARV medicines across a range of community settings.

## Who can provide PEP?

### NEW recommendation

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

Remarks:

- This is an additional approach to providing PEP.
- Training, support and supervision for all health workers is essential, including sensitization to stigma and discrimination and key populations.
- Adequate and equitable remuneration is required for community and other health care providers.
- Providers should offer first-line support and post-rape care in line with WHO guidelines for survivors of sexual assault at the first point of contact 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.

Task shifting, or task sharing, is defined as the “rational redistribution of tasks among health workforce teams”, which can include nurses, pharmacists, community health workers and lay providers (61). Task sharing has the potential to make PEP more available.

## Summary of evidence

A systematic review identified 10 studies on PEP task sharing, including: three research studies (54, 62, 63), two case examples (64, 65), four values and preferences studies (65–68) and one costing study (62).

### Effectiveness

Overall, the certainty of the evidence was very low because of risk of bias, inconsistency and imprecision.

One of the studies identified was a retrospective chart review of PEP cases before and after implementation of a programme that allowed pharmacists in an infectious disease clinic to prescribe PEP following referral from an emergency department (62). (Previously, people requesting PEP were seen by doctors and nurses in the infectious disease clinic without pharmacist involvement.) After implementation of the programme, all 16 eligible clients left the clinic with PEP, compared with five of eight (62.5%) prior to implementation. Of those who left the clinic with PEP after being seen by a pharmacist, 42% completed the entire PEP course and came to a follow-up appointment, compared with 32% before implementation of the programme.

Another retrospective chart review which was also identified through the effectiveness review compared outcomes before and after implementation of a programme in an emergency department for responding to sexual assault. The programme involved pharmacists in dispensing free PEP, providing patient education prior to discharge and conducting a follow-up phone call after three months (63). With the pharmacist-delivered interventions, PEP completion was 19.8% (n=55), up from 4.3% (n=4) before the programme was implemented. There were two documented cases of HIV seroconversion before implementation of the programme and none afterwards.

The SEARCH SAPPHIRE study (54) described above was also included in the effectiveness review of task sharing for PEP.

### Feasibility

Two studies identified by the review described task sharing for PEP as feasible. In the first study, PEP was delivered in 12 private pharmacies in Kenya (65). The second study described training 14 nurse prescribers to offer PEP in nurse-delivered clinics in the United Kingdom, after which nurses became the second most frequent prescribers of PEP in these clinics (64).

### Values and preferences and acceptability

Four studies reported on values and preferences of users and the acceptability among health care workers of PEP offered through task-sharing. Two of these studies were online, cross-sectional surveys of PEP providers. The first study was an online survey of 214 nurses in Ontario, Canada to assess perspectives on allowing nurses to dispense PEP. Overall, 77% of participants indicated they would support nurse-led PEP under medical directives (68). The second study was a multi-country, mixed-methods study to examine values and preferences concerning PEP, conducted to inform prior WHO guidelines (66). The online survey was completed by 306 health care workers delivering PEP in five countries: Armenia (n=16), Kenya (n=15), Lesotho (n=16), South Africa (n=90) and the USA (n=51). Of these providers, 66% (n=110) disagreed that

28-day prescribing should be done only by HIV specialists, and 74% (n=126) agreed that non-HIV specialists could start PEP safely. The third study conducted semi-structured qualitative interviews with staff at PEP-prescribing pharmacies in the San Francisco Bay area, USA (67). Of seven interviewed participants, all felt the California state bill that allowed pharmacists to dispense PEP was a valuable expansion of pharmacists' offers, and two "indicated that furnishing PEP was a public health duty." Finally, the fourth study, also included in the case study review, evaluated a model of PEP delivery (along with PrEP and HIV testing) in private pharmacies in Kenya (65); PEP was not separated from PrEP in the analysis. Acceptability was generally high. The great majority of clients and providers reported that they liked getting/delivering PrEP/PEP at the pharmacy and that getting/delivering PrEP/PEP at the pharmacy was not hard.

There is also evidence from nurse-led delivery of ART that task sharing is acceptable to clients and providers, leading to feelings of emotional reward, accomplishment, prestige and improved morale among health care workers (69, 70). Clients have stated a preference for PrEP delivered by nurses due to improved accessibility, anonymity, autonomy and quality of counselling (71).

### Cost and resource needs

One study assessed cost savings for PEP offered by pharmacists in the United States (62). This study found clients' average out-of-pocket costs for PEP were US\$ 2.25–7.30 after the pharmacist intervention compared with US\$ 475–3733.40 before the pharmacist intervention.

### Evidence to decision-making

The GDG decided that there were large benefits and small or trivial harms associated with task sharing for PEP and agreed that the balance between benefit and harm favoured task sharing for PEP. GDG members were certain that clients would value task sharing for PEP but stated that training for health workers is needed, including on confidentiality and addressing sexual and gender-based violence and mental health, and that all health workers providing PEP needed to do so in a non-judgemental manner and provide stigma-free services.

The GDG decided that there were large benefits and small or trivial harms associated with task sharing for PEP.

The GDG decided that moderate savings may be associated with task sharing for PEP but that this would vary by type of intervention and setting. They agreed that there would be increased upfront costs but probably cost savings in the long run; they also agreed that task sharing for PEP was cost-effective or probably cost-effective.

The GDG agreed that, if PEP is expanded to be offered by non-specialist health workers, the increased availability may help reduce overall inequalities in HIV acquisition and outcomes and that equity would be increased. Further, they agreed that PEP is probably acceptable to all stakeholders, but this may vary by setting, and providers must be supported with adequate training and remuneration.

PEP is currently provided by non-specialist health workers and community health workers in some settings. For example, in the USA, laws have been changed to allow pharmacists to initiate or prescribe PEP in New York (as of 2017) (72) and California (as of 2019) (73), along with 10 other states (72). In 2023 new laws in South Africa were proposed to allow pharmacists to provide PEP. Finally, the GDG noted the existing strong WHO recommendations for task sharing for ART dispensing and distribution by non-specialist, community and lay health workers, which are implemented in many countries (25). Based on this experience, the GDG was confident that task sharing for PEP was generally feasible, noting, however, that feasibility will likely differ across settings and populations.

Because of the favourable balance of benefits and harms, potential savings, increased equity, acceptability and feasibility, the GDG agreed that a strong recommendation to implement task sharing for PEP should be made, despite very low quality of evidence. The decision to issue a strong recommendation was supported by the evidence and experience with the feasibility and acceptability of delivering ARV drugs for treatment and PrEP through task sharing.

The feasibility and acceptability of task sharing to deliver ARV treatment and PrEP supported the new PEP recommendation.

## Research gaps

Given the low quality of evidence available for the two new recommendations made in this guideline update, more research on delivering PEP in community settings and through task sharing is warranted.

The GDG identified the following research gaps:

1. **Research on timing and dosage** to investigate whether reducing the time between exposure and starting PEP and taking different combinations of ARVs can reduce the number of days PEP needs to be taken. There is currently insufficient information to definitively advise people that taking a shorter duration of PEP will be effective. Further data to support this could be helpful to encourage early PEP start, increased uptake and completion and to lower pill burden.
2. **Operational/implementation research** to understand:
  - the feasibility, acceptability, effectiveness and costs of providing PEP in different settings for different populations, including for key populations, and involving different health care providers;
  - how people can safely and effectively switch between PEP and PrEP;
  - where people prefer to receive PEP services (qualitative research);
  - whether promoting and providing PEP influences uptake of and effective use of PrEP;
  - how to increase knowledge, create demand, enhance health literacy and support people with access and adherence to PEP.
3. **Cost-effectiveness studies** on PEP in different settings.
4. **New PEP drug research/development.** Currently, all PEP regimes are a combination of oral ARVs that are recommended to be taken for 28 days. Long-acting products might increase acceptability if a “one-time option” were available, either an injection or long-acting oral formulations.



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# List of web annexes

- **Web Annex A.** Summaries of declarations of interest
- **Web Annex B.** Systematic review findings and GRADE tables
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