Strengthening health services to fight HIV/AIDS

POST-EXPOSURE PROPHYLAXIS TO PREVENT HIV INFECTION

Joint WHO/ILO guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection

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International Labour Organization

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CONTENTS

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immunodeficiency syndrome
ARVs	Antiretroviral (medicines)
ART	Antiretroviral therapy
AZT	Zidovudine (also known as ZDV)
HCW	Health-care worker
HIV	Human immunodeficiency virus
PEP	Post exposure prophylaxis for HIV
ILO	International Labour Organization
IDU	Injection drug use(r)
NGO	Nongovernmental organization
NRTI	Nucleoside reverse transcriptase inhibitor
NNRTI	Non-nucleoside reverse transcriptase inhibitor
PEP	Post-exposure prophylaxis
PI	Protease inhibitor
PITC	Provider initiated testing and counselling
PMTCT	Prevention of mother-to-child transmission
PLWHA	People living with HIV/AIDS
SOP	Standard operating procedure
STI	Sexually transmitted infection
UNHCR	Office of the United Nations High Commissioner for Human Rights
VCT	Voluntary counselling and testing
WHO	World Health Organization

1. INTRODUCTION

1.1 Background

Since the early 1990s, in many countries antiretroviral medicines have been prescribed for post-exposure prophylaxis (PEP) following occupational exposure to the human immunodeficiency virus (HIV). This practice has since been extended to non-occupational situations, primarily for cases of sexual assault.

Increasingly, however, both policy-makers and health care providers have been raising questions about certain aspects of the use of HIV PEP: in particular, about the indications for post-exposure prophylaxis, the most suitable antiretroviral medicines to use and various issues relating to prescribing protocols and clinical management. Awareness of these areas of uncertainty has been further heightened by the expanding availability of antiretroviral therapy in more resource-constrained settings and has led to calls for clear operational guidance on providing PEP.

In September 2005, a Joint WHO/ILO Expert Consultation for the Development of Policy and Guidelines on Occupational and Non-occupational HIV Post-exposure Prophylaxis was held in Geneva. The objectives of this Consultation were (1) to review scientific evidence and programmatic experience in relation to providing PEP in occupational and non-occupational settings and (2) to recommend a consensus approach to formulating policy and operational guidelines for HIV PEP. Although the needs of workers and people who have been sexually assaulted provided the focus of the Consultation, consideration was given to other types of non-occupational exposure for which PEP might be indicated: specifically, those arising from isolated or episodic injecting drug use and consensual sexual exposure. The Consultation recommendations, which are based on current understanding of the efficacy of PEP and available data for comparing different PEP strategies, represent the collective opinion of experts working in this field and form the basis of the present policy guidelines and service delivery recommendations.

1.2 Definitions

The term *post-exposure prophylaxis* is generally understood to mean the medical response given to prevent the transmission of blood-borne pathogens following a potential exposure to HIV.[i] In the context of HIV, post-exposure prophylaxis refers to the set of services that are provided to manage the specific aspects of exposure to HIV and to help prevent HIV infection in a person exposed to the risk of getting infected by HIV. These services might comprise first aid, counselling including the assessment of risk of exposure to the infection, HIV testing, and depending on the outcome of the exposure assessment, the prescription of a 28-day course of antiretroviral drugs, with appropriate support and follow-up.

For the purposes of these guidelines on providing PEP, individuals sustain potential *occupational exposure* to HIV in the course of their work. However, the term *occupational post-exposure prophylaxis* should not be assumed to be solely related to health care. Other workers, such as

i Post-exposure prophylaxis may be administered to prevent infection after potential exposure to other viruses (such as hepatitis B with the injection of immunoglobulin and vaccine). In this document, by default, post-exposure prophylaxis means prophylaxis for preventing HIV infection.

emergency rescue staff, waste-disposal workers, law enforcement personnel and fire-fighters, may be exposed to blood and other potentially infectious body fluids while performing their work duties.

Individuals can also face potential *non-occupational exposure* to HIV outside the work setting. In these guidelines, this term predominantly refers to potential exposure through sexual assault. Other forms of potential non-occupational exposure include those arising from needle-sharing among injecting drug users and potential exposure through consensual sex.

The *exposed person* is the person who has been potentially at risk of acquiring HIV infection through exposure to blood or body fluids in his or her occupation or in another non-occupational situation.

The *source person* is the person who is (either identified or not identified as) the possible source of contamination through potentially infectious blood or body fluid. If the serostatus of the source person is unknown, he or she may be asked to provide informed consent to HIV testing. The source person may be a patient if a health care worker is exposed or the perpetrator in sexual assault.

1.3 Rationale for using post-exposure prophylaxis

Worldwide, in 2007, an estimated 33.2 million people were infected with HIV. Post-exposure prophylaxis, which by definition includes the prevention of mother-to-child transmission, is currently the only way of reducing the risk of development of HIV infection in an individual who has been exposed to the virus, and as such, is widely considered to be an integral part of the overall strategy for preventing the transmission of HIV.

Strong ethical arguments support providing PEP for HIV infection. Each day, thousands of people around the world experience accidental exposure to blood and other body fluids or tissues while performing their work duties. Health care workers are especially vulnerable[1]. Moreover, in many parts of the world, the potential for workplace accidents that may expose workers to HIV-infected blood and other body fluids is increasing. Several factors are contributing to the increased risk of occupational HIV exposure. First, more people are living with HIV infection. At the same time, antiretroviral medicines are becoming increasingly available for treating AIDS, including in many resource-constrained settings, with the result that more people with HIV are coming into contact with health care services. Second, as people receiving antiretroviral therapy accrue its benefits and live longer, they are more likely to survive, and the numbers of people living with HIV in contact with health services is increasing, both as health care providers and as people receiving treatment.

Given that sexual exposure is associated with the risk of HIV transmission, there are also ethical reasons to support providing PEP to people who have been sexually assaulted.

Although data on the efficacy of HIV PEP are fairly limited, good evidence suggests that a short course of antiretroviral therapy effectively reduces HIV transmission rates following needlestick exposure. This comes largely from a single case–control study involving health care workers

from France, the United Kingdom and the United States of America that revealed a strong inverse association between the likelihood of HIV infection following a needlestick injury and the post-exposure use of zidovudine[2].

Several case reports and cohort studies[3] document some failures of PEP to prevent HIV infection. However, the above-mentioned zidovudine study did much to focus attention on the possible application of HIV PEP to exposure in other settings (such as for sexual exposure and occupational exposure among non–health care workers) and to raise questions about the feasibility, safety and cost-effectiveness of providing PEP generally. Moreover, international interest in using antiretroviral therapy to prevent HIV transmission following sexual and other non-occupational exposure continues to grow, although there is no direct evidence of its efficacy in such contexts. Indirect evidence – that is, the results of animal studies and studies involving occupational exposure and mother-to-child transmission – nevertheless supports its biological plausibility.

Prospective, randomized studies to evaluate the efficacy of PEP in preventing HIV are unlikely to ever be conducted because the generally supportive data described above create difficulty in withholding PEP for ethical reasons. In addition, evaluating the efficacy of an intervention aimed at reducing the risk of single incidents of exposure associated with low-risk transmission would require an extremely large sample size.

PEP may never be considered 100% effective. It is therefore imperative that HIV post-exposure prophylaxis policies reinforce the importance of primary prevention and risk prevention counselling in all settings where HIV could be transmitted. PEP should never be provided in isolation, but should always form a part of a wider strategy for preventing exposure to HIV. It is also associated with measures to prevent other bloodborne diseases, such as hepatitis B and C.

1.4 Scope and structure of the guidelines

Although this publication aims to provide a unified framework to guide both PEP policy development and the implementation of services for situations of occupational and non-occupational exposure, it is recognized that service provision – both nationally and locally – needs to be context specific. The users of these guidelines are thus encouraged to adapt these guidelines to suit their own circumstances.

These guidelines focus on occupational exposure and exposure through sexual assault. Other non-occupational exposure situations for which PEP may be appropriate and is currently provided in some countries include injecting drug use and exposure through consensual sex. These guidelines do not provide detailed guidance relating to exposure of this type. Subsequent sections will be developed to provide specific guidance for such types of exposure and for selected population groups (such as children).

The content of these guidelines is organized as follows.

Chapter 2 discusses the general development of PEP policies and strategies for implementing programmes.

Chapter 3 addresses the overall management of HIV PEP in general terms.

Chapters 4 and 5 discuss specific policy development and clinical management of occupational exposure (Chapter 4) and exposure from sexual assault (Chapter 5). These two chapters should be used in conjunction with Chapter 3.

In addition to a list of further reading, which includes published guidelines on HIV testing and counselling, several other resources that users might find helpful are attached as annexes, such as: sample checklists, service provider scripts, patient information sheets and documentation templates, which can be adapted to suit users' specific needs.

2. POLICY DEVELOPMENT AND IMPLEMENTATION

2.1 National commitment to develop policy on post-exposure prophylaxis

National authorities are strongly urged to provide HIV post-exposure prophylaxis as part of their national HIV policy. This applies especially to countries that have a high HIV prevalence or concentrated epidemics with population subgroups affected by high HIV prevalence (see also section 2.3.1).

Although resource constraints may necessitate giving priority to other primary prevention interventions, strong ethical arguments support integrating PEP into national HIV and AIDS programmes. There are also benefits to be gained from developing PEP services. Post-exposure prophylaxis has been shown to be effective in occupational settings, not only in saving lives but also in avoiding life-long, costly treatment. These findings can be extrapolated, with some modifications, to non-occupational situations, particularly to people who have been sexually assaulted. In addition, providing occupational PEP can help to ensure the protection, well-being and retention of health care workers. This is likely to be especially significant in high-prevalence countries, where the health care workforce is already limited; here the availability of PEP services could be a critical factor for protecting and retaining professional staff.

Being able to offer PEP after occupational and/or non-occupational exposure to HIV requires a national multisectoral commitment to develop a policy on it and to provide sufficient resources to enable services to be implemented and evaluated.

2.2 Addressing legal and human rights issues

HIV PEP can preserve life and health. Providing post-exposure prophylaxis is an important component of compliance with protection obligations deriving from national and international human rights laws.

In the context of HIV PEP, the key human rights obligations are to ensure the right to the highest attainable standard of health, to protect against violence and its consequences and to protect rights to privacy and bodily integrity. In developing PEP policies, the goal is to strike a balance between protecting population health and protecting individual human rights.

2.2.1 Non-discrimination

A non-discriminatory approach to service accessibility, information provision and education is critical and must underpin any policy or operational guidelines on HIV PEP. The ILO code of practice on HIV/AIDS and the world of work[4] and several other international human rights instruments provide detailed guidance regarding consent, confidentiality and access to information and health care services on a non- discriminatory basis.

The policy for eligibility for PEP should always be founded on the principle of equity. Decisions about whether or not to offer post-exposure prophylaxis should be based purely on clinical considerations of risk and should not be tied in any way to a person's decision to file a police report or to pursue legal action. Individuals should be assessed for PEP regardless of their involvement in any activities considered to be illegal by national legislation, such as injecting

drug use, sex work or men having sex with men. Nor should there be any barriers to access for financial or administrative reasons. Non-citizens (such as refugees, asylum-seekers and stateless people) should have equal access to health care, including PEP, in the country in which they are currently residing or staying.

2.2.2 Confidentiality

Personal information relating to PEP, such as the reasons for seeking it, having it provided and for HIV testing, needs to be confidential. Privacy and confidentiality considerations are the same as those for HIV testing (see the section on HIV testing and counselling guidelines in "further reading" section).

In the case of children, the rights of the child should be protected. The confidentiality of HIV test results should be consistent with the obligation to protect the right of children to privacy[5].

2.2.3 Informed consent

Informed consent for HIV PEP needs to be obtained in the same way as for any other health care procedure. Consent to any HIV testing in the context of PEP must also be obtained, in accordance with standard guidelines for HIV testing and counselling (see section 3.2 and the section on HIV testing and counselling guidelines in "further reading" section). HIV testing and counselling is often referred to as voluntary counselling and testing, when initiated by the beneficiary, or provider-initiated testing and counselling, when proposed by the services provider.

In special situations in which the individual has limited or no capacity to consent (such as children and unconscious or mentally ill adults), a parent or responsible person can provide consent. Depending on national or regional legislation, unreasonable refusal to consent may be overridden in cases where it is considered to be in the person's best interest.

2.3 Availability of and eligibility for post-exposure prophylaxis

Governments usually make decisions on allocating resources for preventing HIV transmission, taking into account the resources available in the country and the prevailing health status and priorities. The national decision-making process should be transparent and involve all stakeholders.

Several key factors should be considered when formulating a policy on PEP, in particular when determining when it will be made available. These include the prevalence of HIV infection, the availability of national antiretroviral therapy programmes and the risk of HIV transmission following potential exposure to HIV.

2.3.1 Prevalence of HIV infection

Most WHO Member States that have a high prevalence of HIV infection have national strategic plan for tackling HIV and AIDS. Ideally, national-level policy decisions about whether and how to provide PEP within a national strategy for preventing HIV transmission would be made in relation to the risk of HIV transmission. In theory, then, such decisions would consider the national and local prevalence of HIV infection. In practice, however, determining an HIV prevalence level

below which providing PEP should not be a public health priority is often problematic for one or more reasons:

- lack of reliable prevalence data; pockets of high prevalence within low-prevalence settings;
- differences in prevalence between exposed individuals and source subgroups;
- change of prevalence among various demographic groups over time; and
- the possibility that PEP might be denied to someone exposed to a known source of HIV infection.

Based on these considerations, it is recommended that decisions to implement PEP be mainly based on assessment of the risk of HIV transmission. If priorities need to be set because of pressure on resources, for example, policies on post-exposure prophylaxis should identify specific target groups.

In the context of national programmes, it is generally recommended that PEP, as much as possible, be available for people who are occupationally exposed and people who are sexually assaulted. The criteria for eligibility for PEP should be based solely on the risk of HIV transmission without any discrimination. There is a need for clear and accessible information about which categories of exposure are not eligible for it and why.

In settings with very low HIV prevalence, where health care workers and occasionally workers in other occupations (including, but not limited to, law enforcement personnel, emergency and rescue workers, fire fighters, prison guards, social service staff who work with injecting drug users, waste-disposal personnel and sex workers), may be more likely to be exposed to HIV-infected blood and body fluids, the priorities set for providing PEP based on exposure circumstances should be rationalized (see sections 4.3.3 and 5.3.2).

In settings where systems for delivering PEP for occupational exposure have already been initiated or are being developed, these could be used for developing similar systems for people who have been sexually assaulted. In areas with high HIV prevalence, occupational and non-occupational PEP should be developed simultaneously.

2.3.2 Availability of national antiretroviral therapy programmes

Post-exposure prophylaxis is easier to provide in a setting that already has a national antiretroviral therapy programme with its own system for drug procurement and supply management. However, the existence of a national antiretroviral therapy programme should not be a prerequisite for initiating a national PEP programme.

Where antiretroviral therapy is not yet available, the availability of PEP may help to prevent new infections and will encourage health care workers and other workers to care for people living with HIV. Providing it may also be an opportunity to strengthen health systems in preparation for subsequent antiretroviral therapy and/or programmes for preventing mother-to-child transmission, for example, by developing systems to provide information on HIV prevention and testing (voluntary counselling and testing as well as provider-initiated testing and counselling) to procure medicine and to train health care workers.

2.3.3 Eligibility criteria

Type and risk of exposure

Post-exposure prophylaxis should only be offered for exposure that has the potential for HIV transmission. PEP should be provided following exposure of non-intact skin (through percutaneous sharps injury or skin abrasion) or mucous membranes (through sexual exposure or splashes to the eyes, nose or oral cavity) to a potentially infected body fluid from a source that is HIV-positive or has unknown HIV status. Body fluids that may transmit HIV include blood, genital secretions and cerebrospinal, amniotic, peritoneal or pleural fluids.

In sexual exposure, the potential for HIV transmission arises if a condom was not used, broke or came off. The risk of transmission following receptive oral sex with ejaculation with a known HIV-positive source should be considered as very low due to the anti-HIV properties of saliva, although case reports suggest that infection can occur by this route [6–8]. The risk may increase if the exposed individual has significant oral disease, and PEP may be offered in such cases.

Chronic exposure

Post-exposure prophylaxis is not appropriate in the context of chronic exposure to HIV. However, high-risk single or episodic exposure (such as rape by a stranger or needlestick injury) may occur against a background of potential chronic exposure, such as regular and ongoing unprotected sex with an intimate partner. In these cases, the high-risk episodic exposure should be treated as such and PEP offered if the person is HIV-negative. However, the importance of reducing the ongoing risk within the intimate relationship should be emphasized as part of the counselling process.

Distinguishing between chronic and episodic exposure can be difficult. Having more than one potential episode of exposure is not inherently linked with evidence that chronic exposure. For example, medical-waste workers experiencing repeated sharps injuries have episodic rather than chronic exposure. Sex workers who would normally use a condom but have been sexually assaulted would also be eligible for PEP. Sexual abuse of children is often repeated but is usually episodic (occurring occasionally) rather than chronic (occurring regularly), suggesting eligibility for PEP. Any distinction made regarding eligibility in terms of exposure patterns should always be based on the relevance of PEP to prevent HIV infection from a single exposure and should never be a judgement of behaviour.

An assessment of an individual's exposure pattern should be based on client self-reporting.

The identification of repeated or chronic exposure to HIV should lead to greater emphasis on prevention. For example, recognition of repeated occupational exposure might provide the impetus for evaluating working conditions and, in turn, improve safety procedures in the workplace. The discovery of sexual abuse of children may provide an opportunity to expose the perpetrator and thus curtail further exposure. In the case of sexual assault by an intimate partner with whom a person is also having ongoing unprotected consensual sex, the likelihood that the ongoing exposure pattern will change needs to be assessed. However, this assessment is likely to be complicated when considering individuals who are unable to prevent chronic exposure,

such as women in violent intimate relationships. For others in similar chronic risk situations, a baseline risk assessment and counselling to reduce risk are critical components of a wider strategy for preventing HIV transmission and are probably more important than PEP alone.

In cases where PEP is not indicated because of the exposure is chronic, other critical prevention and care services should be provided. Effective interventions in these circumstances include referral to domestic violence organizations, providing testing and condoms and access to needle-exchange programmes.

Timing of post-exposure prophylaxis

When there is a risk of HIV transmission, post-exposure prophylaxis **should be initiated as soon as possible,** within hours and **no later than 72 hours** following the potential exposure. According to the results of animal studies, initiating PEP within 12, 24 or 36 hours of exposure is more effective than initiating it 48 or 72 hours following exposure[9]. Such studies have also established that PEP is not effective when given more than 72 hours following exposure and are the basis of the recommendations that individuals presenting more than 72 hours after potential exposure would not be eligible for it (Box 1).

Box 1. Negative indications for post-exposure prophylaxis

Post-exposure prophylaxis is **not** indicated:

- if the exposed person is HIV-positive from a previous exposure;
- in chronic exposure;
- if the exposure does not pose a risk of transmission, that is, after:
  - exposure of intact skin to potentially infectious body fluids
  - sexual intercourse using a condom that remains intact
  - any exposure to non-infectious body fluids (such as faeces, saliva, urine and sweat)
  - exposure to body fluids from a person known to be HIV-negative, unless this person is identified as being at high risk for recent infection and thus likely to be within the window period[a]; and
- if the exposure occurred more than 72 hours previously.

a The HIV test detects the antibodies produced by a person who has been infected with the HIV virus. However, the test will not give a positive result until sufficient levels of antibodies are present in the blood of an infected individual. The period between the time of infection and the point at which there are sufficient antibodies is known as the window period. Almost everyone living with HIV (99%) will have detectable levels of antibodies three months following transmission.

These eligibility criteria form the basis of the clinical management guidance given in the subsequent chapters of this publication.

2.4 Integrating post-exposure prophylaxis into HIV policies and services

2.4.1 Integrating post-exposure prophylaxis into HIV policies

National governments are strongly urged to consider providing post-exposure prophylaxis in the wider context of comprehensive national policies for preventing HIV transmission, occupational health and care for people who have been sexually assaulted.

A balanced prevention portfolio positions PEP as part of a national HIV strategy that emphasizes primary prevention. PEP should always be regarded as a secondary prevention measure, provided as a last effort to prevent HIV infection after primary prevention strategies have failed. These services should also be used as an opportunity to reinforce primary prevention behaviour. Providing PEP should not result in reduction to funding primary prevention efforts.

2.4.2 Integrating post-exposure prophylaxis into HIV services

Post-exposure prophylaxis services should be integrated into broader, and, wherever possible, existing HIV health service frameworks and services for people who have been sexually assaulted. They should not be developed in isolation from other HIV prevention, treatment, care and support programmes or from other health programmes and services.

2.4.3 Programme coordination

A representative of the health ministry or national health department should be responsible for developing, implementing and monitoring the national policy and plan for PEP. Ideally, a single designated representative of the national health department would be responsible for both occupational and non-occupational PEP programmes. Alternatively, separate individuals could take on these roles.

National policies must include clear guidelines for implementing PEP and delivering services. Policy documents should describe the operational network within the health system, clearly designate the people who should provide it, the core competencies and training needed, the delivery sites and referral centres. A code of practice, standard operating procedures and written algorithms for assessing risk should also be specified.

Ensuring that some of the key service components are in place prior to policy implementation may be necessary (see section 2.5.2).

2.4.4 National training plans

The introduction of Post-exposure prophylaxis needs to be supported by the development of human resources capacity through appropriate training. The main training targets include health care administrators, health care delivery staff (such as pharmacists, doctors, nurses, laboratory staff, social workers and psychologists) and the associated services such as the police, government employees and staff of nongovernmental organizations (see also section 2.5).

Ideally, PEP training should be introduced into curricula for all health care workers in both professional education and in-service training (see Annex 1).

The human resource and capacity issues associated with developing comprehensive systems of care for people who have been sexually assaulted should be considered. Budgets need to cover the costs of training, providing PEP through programmes for people who have been sexually assaulted within antiretroviral therapy service systems, or separately, and developing links between various support services, such as forensics, when appropriate.

Training of service providers (including home-based caregivers and providers of antiretroviral therapy) is critical to raise awareness and create management capacity. It is especially important that service providers keep understanding attitudes and maintain a non-judgemental demeanour when caring for people who have been sexually assaulted. Service providers may have to be trained to manage male-to-male sexual assault.

2.4.5 Funding

Post-exposure prophylaxis services, including drug supply, should be offered free of user charges. Adequate resources to fund the entire package of PEP services (section 2.5.2) should be identified at the outset; budgets must be sufficient to cover the cost of medicine and staff salaries as well as the costs associated with testing, counselling, developing and supplying educational materials, staff training and case reporting. There are also costs associated with disseminating information to generate awareness among frontline service providers, health care workers and the community. Quality assurance and controls should also be fully funded.

Budgeting decisions are usually made in relation to the availability of antiretroviral therapy for people living with HIV (see section 2.3.2). Some of the training costs could be shared by, or absorbed into, existing budgets for antiretroviral therapy and HIV prevention, which would help to mobilize resources for PEP as an integral part of these other services.

2.5 Implementing policy on post-exposure prophylaxis

An individual or a small team needs to take responsibility for implementing services. At the local level, certain categories of health care workers, such as infection control professionals, would be appropriate candidates for assuming responsibility for implementing PEP policy.

2.5.1 Operational guidelines

A code of practice, protocols and standard operating procedures for PEP services need to be formulated as part of the process of developing policy.

2.5.2 Post-exposure prophylaxis services

The comprehensive package of post-exposure prophylaxis services offered depends on the setting and context in which the exposure occurs. This needs to be resourced and should include mechanisms for linking all potential service providers.

HIV PEP services would include, as a core package:

- reporting assistance and possible referral capacity;
- risk assessment;

- counselling services for:
  - providing consent to PEP
  - pre- and post-HIV test counselling (for both the exposed person and the source person)
  - drug adherence and managing side effects
  - preventing the risk of transmission;
- HIV testing, to include:
  - initial testing of exposed individuals
  - testing of the source person, when possible;
- providing PEP medication, which includes:
  - the initial dose (as soon as possible following exposure and preferably within 72 hours)
  - the full course (28 days of treatment);
- support and follow-up; and
- appropriate record-keeping and documentation.

Support services that are highly desirable but not necessarily essential to providing PEP include:

- follow-up HIV testing at three and six months;
- medication to manage side effects (such as medication for nausea, diarrhoea or headache);
- monitoring of adherence;
- additional in-person clinical follow-up or 24-hour on-call advice from a provider with expertise in HIV PEP;
- hepatitis B and C testing;
- hepatitis B PEP and vaccination;
- pregnancy testing at baseline and follow-up (for all women of childbearing age);
- in case of exposure through sexual assault:
  - forensic examination;
  - trauma counselling and management including psychosocial support;
  - prophylaxis and management of sexually transmitted infections;
  - emergency contraception;
- needle and syringe exchange schemes (for injecting drug users).

Service components may be delivered at different points or levels of the health care system (primary, secondary or tertiary settings). Any written information for health care providers and/or patients should be readily accessible and written in simple and clear language. Annexes 2 and 3 provide sample scripts for service providers and information sheets for patients, respectively. The special needs of certain population subgroups, especially children and pregnant or breastfeeding women, should be taken into account and catered for (see section 3.3.6).

Service prerequisites – that is, functions and resources that ideally would already be in place before services are provided are as follows:

- standard operating procedures and protocols for delivering PEP (a multidisciplinary committee would usually develop local protocols);
- a written algorithm for risk assessment;
- prompt access to and clear protocols for delivering the first dose of PEP;
- adequate availability of PEP medication;
- HIV testing and counselling services;
- a supply of condoms;
- protocols governing counselling services (which would cover risk reduction, side effects of PEP medication and the importance of adherence and HIV testing); and
- links to local clinical and referral services (including for people who are not eligible for or decline PEP).

2.5.3 HIV testing and counselling

HIV testing should always be offered as part of the post-exposure prophylaxis service package based on informed consent with standard pre-test and post-test counselling according to national or local protocols. HIV testing should not, however, be mandatory nor a prerequisite for providing PEP drugs, and the testing results should be treated in the strictest confidence. These conditions apply to both the people potentially exposed and the people who are sources. Health personnel should never assume that an individual would not want an HIV test, even following a traumatic experience.

Delaying the HIV test, even for a few days, may be necessary when a person experienced in HIV testing and counselling cannot be accessed at the time of exposure. PEP services should employ staff with the appropriate expertise to provide pre- and post-test counselling or be able to refer clients to such services locally.

Whenever possible, PEP services should be closely linked to those for HIV testing and counselling. The development of PEP should not only enhance existing HIV testing and counselling services but also facilitate wider access to HIV testing, which is critical for strengthening prevention and for increasing access to treatment and care services for people living with HIV.

People should be clearly told that they have the right to defer or to refuse HIV testing. They should also be clearly informed about the risk of developing resistance to antiretroviral therapy, which might limit the possibility of treatment if they are HIV positive.

Exposed people who receive only part of the PEP medication at the first visit will have to return and may be more motivated or better understand the need to be tested at the following visit or to get the test results.

If the exposed person is likely to be HIV positive – because of past high-risk behaviour or high local prevalence – determining his or her HIV status as soon as possible is important so that PEP can be halted if necessary. If HIV testing is to be performed at the initial visit, rapid test should be performed, with release of results within one or two hours.

For children, while the evolving capacity of the child and the legislative framework will determine whether the child directly needs to give consent or the parent or guardian instead, service providers should always make sure the risk and benefits of testing are sufficiently explained to the child and/or the parent or guardian so that an informed decision can be made.

In emergency situations and refugee settings where HIV testing and counselling is not readily available but the potential risk of HIV transmission is high, providing PEP should never be conditional on HIV testing and counselling capacity. Developing HIV testing and counselling capacity should nevertheless be a high priority in such circumstances, and ideally, all providers of PEP should have appropriate counselling skills. In settings where people have difficulty in returning for additional consultations, the rapid HIV test should be performed at this time and the full course of PEP medicine provided.

HIV testing may be carried out during the initial visit or, if a starter pack has been given, at the first return visit to receive the remainder of the course of medication (or the first visit to a designated clinic to which the patient has been referred); counselling services must be included.

2.5.4 Service delivery sites

Optimal service delivery sites must be identified in each setting, according to national policy.

Providing initial and follow-up PEP services at locations close enough to the people who need them is likely to be one of the biggest challenges facing post-exposure prophylaxis delivery systems. The closer services are, the more likely clients are to present for care and follow-up. However, in most settings, providing the entire service package for PEP at every level of the health care system is not practicable.

Centralized service programmes may be appropriate in urban areas, but in more rural, less densely populated settings, service may need to be further decentralized. Even in locations where comprehensive programmes are available centrally, a timely initial dose of PEP may need to be provided at an accessible location, with referral to a local centre or clinic for follow-up. Providing follow-up services at home is another option requiring time and resources.

Problems related to service access are likely to be greater in rural areas. PEP is more likely to be initiated (that is, the first dose administered) at the district level, with patients being referred to a tertiary-level institution for the remainder of the initial management and thereafter back to the community for follow-up care. Nevertheless, other models of service provision may be appropriate: some countries have achieved excellent comprehensive provision through integrated centres in rural areas. The availability of a functioning transport system is likely to be a critical factor governing the feasibility of a referral-based system of care in both rural and urban settings.

A minimum level of clinical expertise needs to be defined at each level of provision, including for follow-up care providers. Providers need to be aware of the scope of their responsibility and how and when to refer people to other services. Consideration needs to be given to how advice can be accessed at the local health centre level: where such services are accessible, people should be able to consult their health care providers via the Internet or telephone.

Where health service expertise is limited or unavailable, the possibility of nongovernmental organizations assuming a role in dispensing PEP medication, at least the initial dose, can be

explored. Likewise, there may well be a role for home-based health care providers in delivering follow-up services. For instance, a clinic nurse could work with a home-based care provider, who, given adequate training, could monitor adherence and side effects. HIV testing and counselling and pregnancy testing can also be conducted in the home setting. Blood for serology can be collected at home and sent to a hospital or laboratory for analysis. Use of home-based care provider systems raises specific confidentiality and disclosure issues, which national guidelines would need to be address.

2.5.5 Procurement

An efficient system for procuring and managing supplies needs to be developed to maximize the availability of post-exposure prophylaxis. Such systems need to consider several related aspects of service delivery, including financial management, information management, monitoring, evaluation and overall programme management and coordination. Operational guidance about procurement of antiretroviral medicines is available in *A public health approach for scaling up antiretroviral (ARV) treatment: a toolkit for programme managers*[10].

2.5.6 Training

Ensuring that all potentially exposed individuals have prompt and confidential access to PEP requires providing appropriate training for staff at all referral points: that is, frontline service providers as well as teachers, counsellors and police officers. Training programmes for these groups need to raise awareness of the availability of and rationale for HIV PEP, such that exposed individuals get to a clinic (or other place where it is available) without delay and within 72 hours. This is likely to be especially relevant for workers with occupational exposure not related to health care and people who have been sexually assaulted.

Whereas basic awareness training is required for all frontline health care workers (such as emergency department staff, hospital clerks and admissions staff), direct service providers need more intensive training. The objective of the training is to provide health care workers and other staff involved in providing PEP with appropriate information to ensure their own protection from HIV infection, to strengthen primary prevention and to furnish service providers with the necessary expertise to handle the initial steps of post-exposure management for both themselves and others. Surveys have revealed that health care workers' understanding of the risk of HIV transmission and treatment options is often poor and should not be overestimated. Training programmes should thus be tailored to suit local needs, while ensuring that adequately trained staff members are available to assess exposure risk and to prescribe and manage PEP.

Training in post-exposure prophylaxis can be incorporated into training for HIV testing and counselling, antiretroviral therapy, occupational health and/or clinical management of people who have been sexually assaulted and professional clinical training programmes for health care workers. Basic awareness training can be provided in the workplace or as part of professional training schemes. Providing education that conveys a unified message about both occupational and non-occupational PEP is desirable.

Experience from several countries has shown that occupational programmes that include, on completion of didactic training, a direct mentoring component (with observed practice) can be

highly effective. A mentorship approach can be built around centres of excellence, with practical training occurring at the new site and/or at the centre of excellence. A system of ongoing mentorship (whereby experienced doctors or nurses mentor "new" nurses) can also be very beneficial. Follow-up can include regular periodic modular training (such as for 30 minutes once a week), such as for nurses serving in accident and emergency departments.

Annex 1 provides more specific guidance relating to the content of training programmes for specific groups of service providers. The ILO code of practice on HIV/AIDS and the world of work[4] provides more information about all aspects of training .

2.6 Monitoring and evaluation

Monitoring and evaluation of HIV post-exposure prophylaxis programmes is essential:

- to justify the investment of resources in policy planning, development and implementation;
- to identify progress and gaps in service provision;
- to assess safety;
- to assess quality control measures;
- to set priorities for and allocate resources effectively; and
- to identify lessons for the future planning and development of services.

Mechanisms for monitoring and evaluation must be considered during the initial stages of the process of designing policy and programmes and should be put in place before implementing programmes. Adequate resources should be allocated to monitoring and evaluation activities.

2.6.1 Data collection

Keeping monitoring and evaluation activities as simple as possible provides many benefits. The support of stakeholders is vital, and whenever possible, existing data sources (that is, data already collected for other purposes) should be used.

Data collection and analysis should be organized both locally and as part of a national registry. A national registry of exposure, post-exposure prophylaxis prescriptions and HIV infection will allow researchers and health care professionals to obtain an accurate picture of the current situation and to evaluate the effect of new and revised policies. The collective results of surveillance should be available to employers, workers and their representatives as well as to people who have been sexually assaulted and their advocates.

2.6.2 Indicators

Indicators can be extremely helpful tools for measuring and communicating the extent to which policies have achieved their objectives by demonstrating change over time. Indicators should be simple to construct and understand, be related to the programme and, above all, be measurable. Annex 4 provides possible indicators for evaluating PEP programmes.

2.6.3 Data confidentiality

The information held in data management systems that support programme evaluation must be kept confidential. Exposed individuals who are concerned that their medical information will not be coded and kept confidential may be less likely to report exposure and to adhere to recommended protocols. Access to the HIV-related information of exposed individuals should be strictly limited to health care personnel involved in prescribing and following up PEP, and such information may only be disclosed if legally required or with the consent of the person concerned.

2.7 Summary: key considerations for developing policy on post-exposure prophylaxis

- A national multisectoral commitment to provide post-exposure prophylaxis services is required.
- There are ethical reasons for integrating PEP into comprehensive national HIV prevention programmes.
- Determining the availability of and eligibility for PEP requires considering:
  - HIV prevalence;
  - the availability of antiretroviral therapy;
  - the risk of HIV transmission (based on the type of exposure); and
  - chronic exposure to HIV.
- PEP provision should be part of comprehensive policies for preventing HIV transmission, occupational health and care for people who have been sexually assaulted and integrated into broader, existing service frameworks.
- A representative of the national health department should be responsible for developing and implementing the national plan for PEP.
- Policies must include clear guidelines for implementing PEP: in particular, a code of practice, standard operating procedures and a written algorithm for assessing risk.
- PEP provision should be developed in the context of existing HIV testing counselling and antiretroviral therapy services.
- Service delivery protocols must ensure prompt access to the first dose of PEP.
- PEP services should be provided free of user charges and on a non-discriminatory basis.
- The capacity of human resources needs to be developed through training.
- Policies should consider legal and human rights, such as the principle of non-discrimination and the need for confidentiality and informed consent.
- Appropriate record-keeping and documentation are required.
- The confidentiality of data collection systems must be ensured.
- PEP provision should be monitored and evaluated; such activities must be considered as part of designing policy and programmes.

3. CLINICAL MANAGEMENT OF HIV POST-EXPOSURE PROPHYLAXIS

The clinical practice guidance in this chapter is intentionally general in nature; Chapters 4 and 5 provide more specific guidance for occupational exposure and exposure from sexual assault, respectively. The basic steps are broadly similar (Annex 5):

1: establishing eligibility for PEP;
2: counselling and obtaining informed consent;
3: prescribing and dispensing PEP medication;
4: conducting laboratory evaluation;
5: ensuring record-keeping; and
6: providing follow-up and support.

3.1 Establishing eligibility for post-exposure prophylaxis

Evaluating client eligibility for HIV post-exposure prophylaxis involves assessing the following:

- the timing of the potential exposure;
- the person's HIV status;
- the nature and risk of the exposure; and
- the HIV status of the source of the potential exposure.

3.1.1 Timing of post-exposure prophylaxis initiation

PEP should be initiated as soon as possible after exposure, within the first hours and no later than 72 hours after exposure. PEP should not be offered beyond 72 hours after exposure.

Animal studies indicate that PEP is not effective when given more than 72 hours after exposure. They are the basis of the recommendation that PEP should not be given to people who present more than 72 hours after exposure (see also section 2.3.3). Thus, to maximize its benefits, PEP to prevent HIV infection should always be started as soon as possible following exposure and within 72 hours of the potential exposure.

A first dose or, even better, a starter pack of PEP drugs should be made readily available to potentially exposed individuals and given according to national policy and local protocols. An HIV test should normally not be a condition of initiating PEP, nor should PEP be delayed until the results of an HIV test become available (unless rapid testing is used).

3.1.2 Pre-existing HIV infection

Post-exposure prophylaxis is intended for HIV-negative individuals only.

The possibility that the exposed individual has pre-existing HIV infection should always be explored as part of the process of assessing eligibility. PEP providers should be aware that both occupationally exposed workers and people who have been sexually assaulted may have other ongoing risks for HIV infection.

Potentially exposed people who are known or found to be HIV infected should not receive PEP.

They should, however, be offered counselling and given appropriate information about how to prevent further transmission. They should also be referred for clinical and laboratory assessment to determine their eligibility for antiretroviral therapy.

3.1.3 Assessment of the exposure to HIV

Post-exposure prophylaxis should be provided following significant exposure of mucous membranes (through sexual exposure or splashes to the eyes, nose or oral cavity) or non-intact skin (through percutaneous sharps or skin abrasion) to a potentially infectious body fluid from a source that is HIV infected or has unknown status.

The nature of the exposure should be assessed in detail to determine the risk of transmission and thus eligibility for PEP. Clinicians can apply a risk assessment algorithm to assist in the process of determining eligibility (Box 2).

Annex 6 provides the currently accepted recommendations governing PEP use according to the nature of the exposure. Chapters 4 and 5, respectively, discuss in more detail the risks associated with occupational exposure and exposure from sexual assault.

3.1.4 Assessment of the source's HIV status

Knowing the HIV status of the source of the exposure is extremely helpful. In case of sexual assault, identifying the perpetrator and obtaining informed consent to be tested is difficult. If the source tests negative, PEP need not be started (or can be discontinued) unless a clinician with expertise in diagnosing acute HIV infection suspects that the source may be acutely infected and in the window period. However, because PEP needs to be started as soon as possible after exposure, initiation it where indicated should not be delayed until the results of HIV testing of the source person are known.

Standard HIV testing and counselling protocols should be followed in testing the source of the exposure (see the section on HIV testing and counselling guidelines in the further reading). This includes obtaining informed consent prior to performing the test for HIV infection and keeping the results confidential (see section 3.2).

No simple mechanism or formula can be applied to determine the likelihood that an unknown or untested source is infected with HIV. Assessment of the HIV status of the source, and thus decisions about the eligibility for PEP, must therefore be based on available epidemiological data.

The definition of what constitutes a high-risk source varies both within and between counties. In settings with a high prevalence of HIV infection, assuming that all sources of unknown HIV status are infected is reasonable. Elsewhere, local and community epidemiology and knowledge of the demographic characteristics of the source can be used to predict the likelihood that the source is infected.

Box 2. Determination of eligibility for post-exposure prophylaxis

Individuals are eligible for HIV PEP if:

- exposure occurred within the past 72 hours;

and

- the potentially exposed individual is not infected or not known to be infected with HIV;

and

- mucous membrane or non-intact skin was significantly exposed to a potentially infectious body fluid;

and

- the source is HIV-infected or the HIV status is unknown.

3.2 Counselling for post-exposure prophylaxis

People who have been exposed should receive counselling about specific aspects of post-exposure prophylaxis, ideally at the time when they present following exposure. The counselling should include information about the importance of adherence and the possibility of side effects as well as advice about the risk of transmission as part of their counselling.

The PEP service provider should provide counselling on adherence and side effects. The sample scripts attached in Annex 2 provide guidance on both of these aspects of counselling. The people receiving PEP must comprehend the dosing instructions, and the counselling should include assessing their understanding. Counselling must be backed up with appropriate follow-up support services to maximize adherence to the PEP regimen and to manage any side effects (see section 3.7).

Counselling to reduce risk is also necessary to prevent the transmission of HIV to sexual partners, to children of breastfeeding mothers and to recipients of blood donations, if the exposed person has become infected. Risk reduction counselling should be given during the initial visit and reinforced in later visits. Condom use and/or other protective preventive measures should be encouraged until a HIV test after six months is negative.

Discussing the risk of HIV transmission associated with consensual sex after a person has been occupationally exposed or sexually assaulted may be difficult given the sensitive nature of the issue, but this dialogue is essential. Service providers need to be aware that some of the exposed people may not welcome the prospect of having to talk to sexual partners about the need to use a condom, and this can create barriers to follow-up and PEP adherence. Offering exposed individuals assistance in talking to their sexual partners about using condoms may be appropriate.

Counselling women of childbearing age about getting pregnant during post-exposure prophylaxis is critical. Whereas most drugs prescribed for PEP are regarded as safe during pregnancy (see section 3.3.6), women should be told of the possible risk of transmitting HIV during pregnancy, especially at the initial stage of infection.

People who have been exposed to HIV may need emotional support in the period following the exposure. The mental health and social service needs of these people should thus be met whenever possible. In particular, psychosocial and trauma counselling is recommended for people who have been sexually assaulted. Similarly, appropriate mental health counselling is advisable for occupationally exposed people.

Once people have received the appropriate information about PEP – what it entails and the risks and benefits – they will be able to provide informed consent. Box 3 lists the key points that should be explained as part of the process of obtaining informed consent. Annexes 2 and 3 provide a selection of sample scripts and patient information sheets that users of these guidelines might find helpful in obtaining informed consent.

Box 3. Facilitating informed consent for HIV post-exposure prophylaxis

In the process of seeking informed consent for HIV post-exposure prophylaxis, people who have been exposed to HIV must be made fully aware of the following:

- the risk of acquiring HIV infection from the specific exposure;
- what is known and not known about the efficacy of PEP;
- the importance of taking a HIV test and of receiving appropriate post-test counselling (although testing may be delayed if necessary);
- the possibility that they might already be infected with HIV will need to be assessed if they have not already had an HIV test;
- people already living with HIV should be referred to a local clinic for treatment of their infection, and if they had started PEP the medicine should be stopped when the diagnosis is confirmed;
- people with discordant rapid HIV test results should be offered PEP while waiting for pending laboratory-based confirmatory testing;
- that PEP medication will be discontinued if their initial HIV test is positive: this medication does not work for people living with HIV and could increase the risk of drug resistance among people already infected;
- the importance of adhering to medicine;
- the duration of the course of medicine (four weeks);
- the common side effects that may be experienced while taking PEP medicine;
- that they can stop taking PEP medicine at any time, but if they do so, they will probably not get the full benefit of PEP if the source to which they were exposed was HIV positive;
- PEP medicine can be taken during pregnancy and may protect the mother from getting HIV infection after exposure;
- that continuing to breastfeed while taking PEP is safe, although if women get infected by HIV while breastfeeding, the risk of transmitting HIV through breastfeeding is higher at the early stage of infection; appropriate counselling should discuss safe alternatives to breastfeeding if they are acceptable, feasible, affordable and sustainable; and
- exclusive breastfeeding is strongly recommended whenever alternatives are not possible.

Information provided as part of the informed consent process should be appropriate to the person's age, literacy skills and level of education and should take into account the context of the exposure. The consenting person must be able to understand the risks and benefits of the proposed intervention. The fact that taking PEP is not mandatory should also be made clear.

Informed consent for PEP services need not be written, and in special circumstances, for instance, in the case of children and when, for whatever reason, the exposed person lacks the capacity to consent, someone else can provide consent (such as a family member or guardian, the head of the hospital or a health care provider). Although every effort should be made to trace someone to obtain consent, in practice, time constraints will dictate how much effort can realistically be expended on this task. Above all, the issue of consent should never act as a barrier to providing services, as long as the person's best interests are served.

Obtaining informed consent for HIV testing is addressed separately (see section 3.5.1).

3.3 Prescribing and dispensing post-exposure prophylaxis medicine

The guidance given here is pertinent to HIV PEP, focusing on the question of which, and how many, antiretroviral drugs to use. Users are referred to WHO guidelines on the use of antiretroviral therapy for HIV infection in adults and adolescents and children in resource-limited settings[11] for more general information on antiretroviral medicines.

In most instances, WHO recommends a combination of antiretroviral drugs for PEP. Two-drug regimens based on two nucleoside reverse-transcriptase inhibitors should be used when drug resistance is not suspected. A two drugs regimen is preferred given the relative toxicity of antiretroviral medicines, the side effects and their negative impact on adherence to PEP prophylactic treatment. If drug resistance is suspected, a three-drug regimen based on two nucleoside reverse-transcriptase inhibitors plus a boosted protease inhibitor is recommended.

3.3.1 Post-exposure prophylaxis medicine regimens

The selection of antiretroviral medicines

The standard PEP regimen should comprise two nucleoside-analogue reverse-transcriptase inhibitors (Box 4). Three-drug regimens, comprising two nucleoside-analogue reverse-transcriptase inhibitors plus a boosted protease inhibitor, can be considered in situations where antiretroviral therapy resistance is known or suspected.

Unfortunately, there are no prospective data on the relative efficacy of two- and three-drug HIV PEP regimens. The advantages of using two drugs as opposed to three include the relative ease of administration (resulting potentially in better adherence, fewer side effects and lower costs) and the ease of procurement, storage and dispensing. In most cases, that is, when the source is unlikely to have HIV infection resistant to antiretroviral therapy, two-drug therapies are likely to be sufficiently potent to prevent HIV transmission. In such circumstances, the addition of a third drug is considered to supply only a small increase in potency but to add significantly to the risk of side effects and reduced adherence.

Box 4. Criteria for recommending treatment with two nucleoside-analogue reverse-transcriptase inhibitors

A regimen comprising two nucleoside-analogue reverse-transcriptase inhibitors is recommended if:

- the HIV status of the source person is unknown;

and

- the background prevalence of resistance to antiretroviral therapy in the community is less than 15%;

and

- the source person has never used antiretroviral therapy;

or

- the source person is unlikely to have HIV infection resistant to antiretroviral therapy, based on antiretroviral therapy and adherence history.

Table 1 lists the recommended two-drug combination nucleoside-analogue reverse-transcriptase inhibitor therapies for PEP. Generally speaking, countries are advised to use the same medicines as those that form the nucleoside-analogue reverse-transcriptase inhibitor backbone of its WHO-approved[i] first-line antiretroviral therapy (and as specified in national guidelines) for PEP.

Table 1. Recommended two-drug combination therapies for HIV post-exposure prophylaxis

Preferred regimens	Alternative regimens[a]
zidovudine + lamivudine	tenofovir + lamivudine stavudine + lamivudine

a In most countries, tenofovir is only available for antiretroviral therapy as an alternative drug. Emtricitabine is an acceptable alternative to lamivudine where it is available. Abacavir and didanosine are discouraged due to their relatively higher risk of potentially serious side effects.

i Post-exposure prophylaxis providers are advised to consult the regularly updated WHO document *Access to HIV/AIDS drugs and diagnostics of acceptable quality* for detailed guidance available at: http://mednet3.who.int/prequal. A list of WHO prequalified manufacturers is also continually updated and is available at: www.who.int/prequal/info_general/documents/Prequal_AnnualReport2005EN.pdf.

Box 5. Criteria for recommending treatment with two nucleoside-analogue reverse-transcriptase inhibitors plus a boosted protease inhibitor

A regimen comprising two nucleoside-analogue reverse-transcriptase inhibitors plus a boosted protease inhibitor can be considered if:

- the source person is HIV positive, taking antiretroviral therapy and is known to have signs of, personal history of or proven antiretroviral therapy resistance;

or

- the source person's HIV status is unknown;

and

- the background prevalence of resistance to antiretroviral therapy in the community exceeds 15% (where this is known).

If drug resistance is suspected and a third drug is considered necessary, it should be a boosted-protease inhibitor, not a non-nucleoside reverse-transcriptase inhibitor. In addition, nevirapine is not recommended for PEP due to the risk of toxicity and efavirenz should not be given to women who are pregnant or are of childbearing age because it is teratogenic. If the resistance profile of the source person is known, the selection of PEP medicines should take account of that profile. Table 2 lists the recommended three-drug combination therapies for PEP.

Table 2. Recommended three-drug combination therapies including a boosted protease inhibitor for HIV post-exposure prophylaxis

Preferred regimens	Alternative regimens[a]
zidovudine + lamivudine plus lopinavir with a ritonavir boost	zidovudine + lamivudine plus atazanavir with a ritonavir boost or saquinavir with a ritonavir boost or fos-amprenavir with a ritonavir boost tenofovir + lamivudine plus atazanavir with a ritonavir boost or saquinavir with a ritonavir boost or fos-amprenavir with a ritonavir boost (stavudine) + lamivudine plus atazanavir with a ritonavir boost or saquinavir with a ritonavir boost or fos-amprenavir with a ritonavir boost

a In most countries, tenofovir is only available for antiretroviral therapy as an alternative drug. Emtricitabine is an acceptable alternative to lamivudine where it is available. Abacavir and didanosine are discouraged due to their relatively higher risk of potentially serious side effects.

Appropriate information must be given to everyone exposed to HIV and therefore considering PEP about the risks and benefits of taking it in the context of pre-existing HIV infection. Of particular concern is the risk of developing antiretroviral therapy resistance to lamivudine.

Adherence

Studies in high-income countries have demonstrated that in people living with HIV, higher levels of drug adherence are associated with improved viral, immune and clinical outcomes[12]. Adherence rates of 95% or greater are required to maximize the benefits of antiretroviral therapy. Although parallel data are not available for PEP, the magnitude of the positive effects of high levels of adherence is generally assumed to be similar. Although PEP is taken for a relatively short time period (four weeks), providing adherence information and support is still important to maximize the efficacy of medicines.

Side effects

The most commonly reported side effects are nausea and fatigue[12]. Side effects can be reduced by prescribing a dual nucleoside-analogue reverse-transcriptase inhibitor rather than three-drug regimen, by prescribing medicine to reduce side effects (such as antiemetic for nausea) and by advising people on how to reduce side effects (for instance, by taking medicines with food). People should understand that side effects may be expected so that any symptoms experienced are not confused with symptoms of HIV seroconversion.

3.3.2 Duration of post-exposure prophylaxis

A complete course of PEP comprises 28 days of medicine (Box 6).

Given the paucity of PEP efficacy data in humans (for example, there are no studies on humans in which it has been taken for less than 28 days), the recommended duration of PEP for HIV infection, 28 days, is largely based on the findings of animal studies. Such studies have clearly demonstrated that courses of 28 days are more effective than those lasting for shorter periods (3 or 10 days).

Box 6. Prescribing post-exposure prophylaxis medicines: good practice

The recommended duration of PEP for HIV infection is 28 days. The first dose of it should always be offered as soon as possible after exposure. Once commenced, the full PEP should be taken unless there are specific reasons to stop. Starter packs with incremental full 28 days of dosing can be used.

To reduce waste, some countries have adopted a strategy whereby supplies are swapped between low-use areas and high-use areas to ensure that medicines are used before they expire.

3.3.3 Dispensing strategies

Initial dose

The first dose of PEP should always be offered as soon as possible after exposure, and if necessary, without waiting for HIV testing and counselling or the HIV test results of the source person (unless rapid testing, which provides results within one hour, is available) or, in the case of sexual assault, for the full forensic examination (see also section 3.1.1).

The initial provision of PEP (starter packs) may be limited to the first dose or may consist of the necessary drugs for 5–7 or more days. This strategy is often used when non-experts provide the initial care, with referral to PEP experts or a post-exposure prophylaxis clinic within the next few days.

When PEP has been initiated, facilitating access to a full 28-day supply of medicines is the next step. Several dispensing strategies can be used to achieve this. Strategies for dispensing drugs should aim to maximize access and adherence yet minimize drug waste. A key factor governing the choice of strategy is the ability of the person potentially exposed to HIV to return to collect further doses of medicine. This is something that should be evaluated as part of the process of assessing the risk of the potential exposure to HIV (see section 3.1).

The options for dispensing PEP at the initial consultation are as follows:

- starter packs: an initial supply of medicine to last 1–7 days;
- incremental dosing: providing medicine every week or two weeks to encourage follow-up and to minimize possible waste of medicine; and
- full 28-day dosing: supplying the full 28-day course of medicine at the initial visit, which may maximize the likelihood of completing the course if follow-up is a concern.

Starter packs

Starter packs are suited for use in emergency department settings. They usually contain sufficient medicine to cover the first few days of the PEP course (1–7 days) and are prescribed under the condition that the person receiving the medicine return to a designated clinic within 1–3 days to undergo complete risk assessment and HIV testing and counselling and to collect the rest of the course of medicine. Using starter packs is often favoured as it generally means that less medicine is wasted. For example, if the person decides for whatever reason not to continue with PEP, the rest of the course that might otherwise have been prescribed is not wasted. In addition, using starter packs means that non-specialist facilities need only stock small amounts of medicine, and thus less stock is wasted if it is not used by the expiry date.

A second advantage of this dispensing strategy, which requires timely follow-up to obtain the remainder of the medicine, is that it affords an experienced clinician the opportunity to discuss adherence, thus maximizing the likelihood that the course of medicine will be completed as prescribed. It also allows the decision to take PEP to be re-evaluated in light of results of testing the source person (if available) and risk assessment by an experienced clinician who may be less likely to prescribe it inappropriately (such as for low-risk exposure).

The primary concern associated with initiating PEP before the result of an HIV test is known is the risk of developing resistance to antiretroviral therapy among people who are not aware that they are infected with HIV and who are given a two-drug regimen. Resistance is unlikely to develop with starter packs given the short duration of treatment. PEP is discontinued if the exposed person is later found to be HIV-positive.

Incremental dosing

Many PEP programmes opt to dispense two weeks' worth of medicine at any one visit. In much the same way as starter packs do, incremental dispensing strategies, which mean that people have to return during the course, facilitate monitoring of adherence and side effects and provide opportunities for additional counselling and support.

Full 28-day dosing

In some instances, providing the full 28-day dosing of PEP medicine maximizes the likelihood of completing the course. In emergency settings, for refugees or internally displaced people and individuals who do not have ready access to health care facilities (such as those living in rural areas) and/or have dependants (such as children), there are valid reasons for dispensing a full 28-day course of PEP at the initial visit, whether the individual consents to HIV testing or not. The main disadvantage of supplying a full course of this medicine at the initial visit is that it reduces motivation to attend follow-up. For this reason, this strategy is often the least preferred of the three options listed above. Differentiating between those who have and those who have not had a baseline HIV test may be weighted when deciding how much medicine to prescribe at the initial visit versus the need for follow-up and support and the risk of developing drug resistance when a two-drug regimen containing lamivudine is prescribed to a person who is already infected with HIV.

3.3.4 Expertise needed to dispense post-exposure prophylaxis medicine

All PEP medicine, including starter packs, should only be prescribed and dispensed by designated people according to a predetermined protocol.

Designated service providers with the appropriate skills, training and expertise should take overall responsibility for managing PEP medicine package, including procurement and supply. Providers should be aware of the likely effects on availability and cost of using pre-packaged medicine, these being highly dependent on distribution and logistics systems.

PEP medicine needs to be dispensed with accurate information about what it is for, the possible side effects and how to alleviate them (Box 7). The importance of adherence – taking medicine at the correct time and completing the course – must also be conveyed. This information should be provided both verbally and in a basic written form, ideally at an appropriate literacy level (Annex 2 includes sample scripts covering the issue of adherence).

3.3.5 Other medicine

The PEP package should include medicine, if it is available, that can potentially alleviate the most common side effects of post-exposure prophylaxis, and thus increase adherence. This may include medicine to reduce nausea and, if zidovudine is being used, medicine to treat headache.

Box 7. Initiating post-exposure prophylaxis: good practice

Health services may find it helpful to develop a PEP kit containing some or all of the following items:

- a copy of the prescribed management protocol;
- a risk assessment checklist;
- suggested text to be used when discussing consent (see Annex 2);
- forms for documenting the case (see Annex 7);
- HIV testing and counselling forms, and laboratory tubes;
- referral letters; and
- various patient information sheets and leaflets, such as on the PEP process itself, medicine, the importance of adherence, possible side effects, HIV testing and counselling and safe sex and safe needle use (see Annex 3).

Post-exposure prophylaxis kits could also contain condoms and, depending on local protocols, either the initial dose of PEP medicine or sufficient PEP medicine to last 1–7 days.

3.3.6 Considerations for specific population groups

Children

PEP should be broadly available for children, and the challenges of ensuring children's access to it and of following up should be addressed. Poor follow-up rates and testing uptake are reported[13], and strategies to address children's needs for post-exposure prophylaxis require more attention.

Formulations and dose information appropriate for children (based on weight) should be made available, whenever possible. For children weighing more than 10–12 kg, medicine in tablet form is generally preferable to liquid formulations (syrups).

It is not recommended that children be referred to programmes for preventing mother-to-child transmission, as the drug regimens prescribed in such circumstances are not appropriate for PEP.

Pregnant women

Some antiretroviral therapy drugs are contraindicated in pregnancy, such as efavirenz and the combination didanosine + stavudine. The drug regimens recommended (see section 3.3.1) are regarded as safe during pregnancy, except for tenofovir + emtricitabine, for which insufficient data on use during pregnancy are available.

3.4 Laboratory evaluation

3.4.1 HIV testing

HIV antibody testing for the person exposed to HIV should be strongly encouraged when PEP is initiated. The advantages of being tested as soon as possible after an exposure are two-fold for the exposed person. First, it minimizes the use of PEP for people who are already living with HIV, thereby reducing drug waste and possible side effects linked with the uptake of this medicine. Second, people living with HIV who are treated with two nucleoside-analogue reverse-transcriptase inhibitors for 28 days may be at risk of developing antiretroviral therapy resistance, which limits treatment options when antiretroviral therapy is needed.

The availability of rapid HIV testing – which may give results within one or a few hours – is the preferred option for testing both the exposed person and the person who is the source of the exposure.

Using rapid testing not only helps to reduce the risk of prescribing PEP to people already infected, but when the source person tests negative for HIV infection and is unlikely to be in the window period, this prevents the exposed person from having to take PEP unnecessarily.

If delays in receiving test results are common, PEP should be prescribed based on the risk evaluation and the likelihood that the source person is HIV positive; further evaluation should be made after the test results are known.

A positive rapid test should be confirmed with a second different rapid test. If rapid testing is not available, offer pre-test counselling. People who have a positive rapid test result should be managed in accordance with WHO protocols[14]. The person may initially decline HIV testing and still receive PEP medicine. However, after HIV exposure, getting voluntary testing should be recommended during the counselling sessions.

HIV RNA testing by polymerase chain reaction generally has a very poor positive predictive value, especially in asymptomatic people with recent HIV exposure. Its use is therefore discouraged in the context of PEP.

3.4.2 Other laboratory testing

Additional laboratory testing should be offered according to national protocols and capacity.

Haemoglobin testing may be needed, especially when zidovudine is used for post-exposure prophylaxis in areas where anaemia is common. Alternative PEP regimens would then be advisable (Table 1).

Testing for other bloodborne diseases – such as hepatitis B and C – is also important; depending on the nature of the risk and the local prevalence, however, laboratory capacity may be limited.

3.5 Record-keeping

The tools and systems necessary for collecting data should be in place before post-exposure prophylaxis services are initiated.

Post-exposure prophylaxis services need to be documented at several levels. A national or regional registry should be maintained to document the extent and outcomes of PEP use. Data are also needed to evaluate PEP services: in particular, to identify trends, to make comparisons across services and over time, to guide future service planning and resource allocation, to support operational studies and to demonstrate accountability to donors. This can often be facilitated by using a set of programme indicators (see section 2.6.2). At the local level, incident reports are critical for reviewing when and how exposure occurs and for identifying safety concerns and possible preventive measures.

The quality of data will be compromised if reporting requirements are excessively time-consuming or complicated or too difficult. Thus, record-keeping systems should be kept as simple as possible. Data should be collected and analysed based on existing collection mechanisms whenever possible. The data collected as part of the record-keeping system also need to be reviewed and reported. The results of any data analysis should be shared with service providers and stakeholders.

Maintaining the confidentiality of client data is of paramount importance. Written records of risk assessments, HIV tests and PEP prescriptions should be subject to the same rigorous confidentiality controls as any other medical records. Secure systems for storing data and controls on access to medical records should be developed.

Annex 7 provides an example of a self-help client card that could be used for recording the outcome of an initial patient assessment and any follow-up consultations (see template 2: patient data in Annex 7). This type of record, which could be kept by the client, would be useful for people who are referred to other health service centres for follow-up visits. It may not be appropriate for all clients because of confidentiality considerations, nor is it intended to collect data.

3.6 Follow-up and support

3.6.1 Clinical follow-up

People who are prescribed should be offered follow-up and clinical monitoring; the main purpose is to monitor adherence and to identify and manage side effects. Although the availability of resources largely determines the frequency of follow-up clinical monitoring, it should ensure optimal adherence and adequately address side effects. All available methods of communication should be considered; for example, if in-person contact is not possible, a system of 24-hour telephone contact with service providers might offer a suitable alternative.

The ability to assess symptomatic clients for potential HIV seroconversion is desirable but requires specialized medical and laboratory services. People presenting with signs and symptoms

that are compatible with acute HIV infection should be referred to an HIV service provider, with their relevant history (information about the risk of HIV exposure, PEP regimen and follow-up data) for further evaluation.

3.6.2 Follow-up HIV testing

People potentially exposed to HIV should be encouraged to have HIV tests after completing post-exposure prophylaxis. If the available HIV antibody test is very sensitive, testing immediately after PEP is completed may initially indicate seroconversion outcome. However, testing at four or even six weeks after exposure does not always allow enough time to diagnose seroconversion. For this reason, it is recommended that HIV testing be performed 3–6 months after exposure. Seroconversion following PEP does not necessarily mean that it has failed, as seroconversion may result from ongoing exposure.

3.6.3 Follow-up counselling

In addition to the counselling outlined above, appropriate psychosocial support and/or further treatment assistance should be offered to all people who have received PEP, as and when required. Exposed individuals should be made aware of the support services available and how to access them until the entire process – including all testing – is completed. This could be achieved by using a wider range of communication methods or by partnering with other local services to provide support during extended hours.

Table 3. Clinical management of HIV post-exposure prophylaxis: a summary

Item	Recommended action and notes
Eligibility	Exposure within 72 hours Exposed individual not known to be infected with HIV Significant exposure Person who was the source of exposure is HIV infected or has unknown HIV status
Informed consent for post-exposure prophylaxis	Information about risks and benefits Consent may be given verbally
Medicine	Two nucleoside-analogue reverse-transcriptase inhibitors (usually part of first-line antiretroviral therapy medicines) Dispensed by appropriately qualified person Add a boosted protease inhibitor to the regimen if drug resistance is likely
Time to initiation	The initial dose of antiretroviral medicines should be given as soon as possible but no later than 72 hours after exposure
Duration of therapy	28 days
HIV testing with informed consent and pre- and post-test counselling according to protocols	Baseline HIV test in exposed person Follow-up HIV testing 3–6 months after exposure Rapid HIV test of the source person if feasible and based on informed consent and standard operating procedures
Additional laboratory evaluations	Pregnancy testing Haemoglobin (for zidovudine-containing PEP regimens) Hepatitis B and C screening if available and based on the prevalence of the diseases
Counselling	For adherence; side effects; risk reduction; trauma or mental health problems; and social support and safety
Referral	Referrals as appropriate
Record-keeping	Maintain accurate, confidential records
Follow-up – clinical	Assess and manage side effects Assess and support adherence

4. OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS: POLICY ISSUES AND CLINICAL MANAGEMENT

4.1 Background

The vast majority of incidents of occupational exposure to bloodborne infections occur in health care settings. HIV, hepatitis B and hepatitis C are among the potentially most serious bloodborne pathogens, and the possibility of exposure to these agents is a major cause of anxiety for health care workers worldwide. Exposure can result in a variety of health effects for the individual, ranging from mild to extreme anxiety to chronic illness and premature death as well as significant effects on an individual's family and community, both short term and long term.

As suggested in the introduction, in some parts of the world, the risk of occupational exposure to HIV among health care workers is likely to be increasing. This is partly because more people living with HIV are coming into contact with health systems for treating HIV infection and partly because the proportion of people living with HIV who have invasive procedures is increasing.

The use of HIV post-exposure prophylaxis for occupational exposure is based on limited direct evidence, as there is no randomized controlled clinical study. Such a study is neither ethically nor practically feasible due to the sample size it would require[13]. The only case-control study of health care workers in the United States, France and the United Kingdom demonstrated an 81% reduction in the likelihood of HIV infection associated with zidovudine use.

Health care workers are, however, not the only category of workers at risk of contracting HIV and other bloodborne pathogens. Workers in many other occupations, such as law enforcement personnel (such as the police), rescue workers, prison administration employees (such as guards) and social services staff (in particular those who have frequently contact with sex workers or with their environment and injecting drug users) also risk exposure to HIV while performing their duties. Refuse collectors, including those who operate in public spaces (such as beaches and parks), are also at risk.

Gauging the true extent of occupational exposure is difficult both for health care workers and non–health care workers. Partly due to stigma and the lack of awareness and availability of PEP services, the frequency of occupational exposure is likely to be grossly underreported, and available data thus almost certainly underestimate the problem.

Although strictly applying standard (universal) precautions remains the primary intervention to prevent the transmission of HIV, providing post-exposure prophylaxis offers the possibility of preventing the development of HIV in workers who may have been exposed to sources of infection in the workplace. Access to PEP in these circumstances is undeniably a matter of human rights to health (and is also in accordance with providing a healthy work environment). Nevertheless, providing occupational PEP services may confer additional benefits, including contributing to better staff health and, in many settings, improving or alleviating problems relating to staff morale and retention.

4.2 Policy issues

4.2.1 Workplace policies on HIV and AIDS and HIV post-exposure prophylaxis

Policy principles

All workplaces should have a policy on HIV and AIDS. Workplace HIV and AIDS policies should address issues of HIV-related stigma and discrimination in accordance with the ILO code of practice on HIV/AIDS and the world of work [4]. Both national and local policies should reflect the principles of non-judgemental worker support, enhanced communications, equality and personal choice.

Occupational policies should be founded on the principles that a healthy work environment remains a high priority and that primary prevention of HIV transmission should be reinforced.

The most important response to the risk of occupational exposure is to prevent it from occurring. Primary prevention should include standard (universal) precautions and safe injection practices for preventing injuries. This is achievable by educating and informing workers about safe practices, identifying unsafe practices, improving the safety of equipment and ensuring adequate supply of protective equipment and implementing quality control and monitoring systems. Efforts to manage the effects of exposure (including making PEP available) must not detract from risk reduction and management strategies to prevent exposure.

In health care settings, standard (universal) precautions are considered the minimum standard of care for preventing the transmission of bloodborne pathogens. The same principles, whereby blood or other body fluids and tissues from all people are considered to be potentially infectious, should be applied in developing safe work protocols in all workplaces.

Workplace policies on HIV and AIDS should include guidelines for the management of potential exposure. These guidelines should include the appropriate use of PEP as part of management strategy.

Policies relating to HIV and AIDS and the management of occupational exposure in the workplace need to be underpinned by legislation that addresses issues such as occupational health and safety standards, voluntary counselling and testing, confidentiality (of health records and HIV status), privacy and anti-discrimination. Confidentiality must be maintained with respect to both the exposed worker and the source person. HIV testing or PEP should never be mandatory at workplaces. Workers must give consent before HIV testing and before receiving PEP.

The employer is responsible for providing workers with information about post-exposure prophylaxis, including how to obtain prompt advice about the potential transmission risks and how to report exposure at work. If there is any risk of occupational HIV exposure, all workers should have access to HIV testing and counselling. Such services should be provided without user charges.

PEP should be available in accordance with the provision of a healthy work environment. The risk of acquiring other bloodborne infections such as hepatitis B and C is much higher than the risk of acquiring HIV. Thus, the management of occupational exposure to infectious agents should not be limited to HIV PEP alone. For instance, measures such as vaccination and PEP for hepatitis B may also be included.

Exposures should also be managed in the context of supporting the rights of people living with HIV in the workplace. In workplaces where people living with HIV are supported and can work without discrimination, workers may be more likely to comply with protocols and to report exposure.

Coverage

Policies on occupational PEP should apply to all workplaces and to all people in a given workplace, including employees, visitors, volunteers, students, private contractors, consultants as well as patients.

Since people can potentially be exposed to blood or body fluids and tissues in many workplaces, national policies on occupational PEP must be adaptable to a wide range of settings. Policies should cover workers in both public and private workplaces as well as those working in the informal sector, such as sex workers.

Policies on occupational PEP should cover all types of exposure.

In any workplace setting, workers could potentially be exposed to blood, body fluids and tissues through practices inherent to their work or via contact with a discarded needle. They could also be exposed through sexual exposure as a result of assault. Policies on occupational PEP should extend to all types of exposure, including sexual exposure.

The risk of HIV transmission should be carefully assessed in both health care and non–health care settings. Prompt assessment and intervention, supported by communication of risk, can significantly reduce the anxiety workers experience after exposure. Further, adopting transparent standard protocols, risk assessment procedures, counselling and follow-up (when appropriate) will not only support the worker and encourage staff retention but will also lead to improving understanding of how HIV transmission can be prevented in the workplace.

Importance of social dialogue

The management of occupational exposures to HIV, including the provision of post-exposure prophylaxis, should be perceived as a matter requiring multisectoral input and responsibility rather than simply as a public health issue. Successfully developing and implementing national policy on HIV and AIDS in this setting requires a process of extensive collaboration between government departments, private and public sector employers, workers and their representatives, professional and industry associations, people living with HIV and other stakeholders in the world of work (see Article 4.5 of the ILO code of practice on HIV/AIDS and the world of work[4].

A policy will not be used if there is little support, encouragement or incentives for its implementation. Moreover, policies that are difficult to understand, expensive to implement and/or are issued without proper consultation and training are unlikely to have the desired impact on workers' actual practices. Experience has repeatedly shown that policies are more effectively implemented if employers and workers feel that they have some ownership of the policies. Strategies for implementing and disseminating national policy must therefore be formulated when policies are developed. The respective roles of various stakeholders in developing, implementing, resourcing and monitoring the policy should be made explicit at the outset. The

support of government and local employers or institutions in this respect is essential. Disciplinary measures for non-compliance with the policy should be specified.

Compensation

Social security systems and occupational health schemes should provide benefits for workers who have contracted HIV infection at work similar to those received by workers for other industrial injuries, diseases or serious illnesses. The same principles should apply to managing compensation for occupational exposure to blood and body fluids or tissues as to any industrial accident.

In the absence of national compensation guidelines, individual employers may be able to develop their own compensation package using ILO's Convention 121[14] as a basis. However, employers should bear in mind that any mechanism for providing worker compensation needs to be consistent with national occupational health and safety regulations. Governments, employers and workers' organizations are responsible for ensuring that all the necessary steps are taken to make compensation available for workers who contract HIV infection in the workplace.

Resources and budgeting

Resources to enhance the adoption of standard precautions, and to provide health promotion and HIV testing and counselling programmes, should be identified and developed when PEP is introduced. Workplace health promotion programmes, especially in areas with higher prevalence of HIV infection, will help to prevent HIV transmission by promoting changes to both lifestyle and workplace risk factors.

Policies and measures that help prevent HIV transmission in workers can often be justified based on cost-effectiveness: they have the potential to increase staff retention rates, reduce sickness-related costs and reduce human resources costs for the recruitment and training of new staff.

Monitoring and evaluation

Programmes to manage PEP and strategies to prevent exposure are difficult to monitor and evaluate or even accurately cost without accurate baseline data on the numbers of incidents of occupational exposure that occur. For instance, many retrospective surveys of health care workers show high rates of needle-stick injuries but low rates of reporting, even in areas with high prevalence of HIV infection and where HIV PEP is available. These findings underscore the urgent need for improved reporting and data collection in relation to occupational exposure and rates of seroconversion. A lack of data, however, should not be used as an excuse for delaying the introduction of PEP services.

Future improvements in data collection and staff awareness of policies are likely to lead to an apparent increase in exposure at least initially. An increase in reporting of exposure should not necessarily be interpreted as an increase in the actual numbers of exposure incidents occurring in workplaces.

4.2.2 Policy implementation and local management of occupational exposure to HIV

Local protocols or plans should outline how national policies will be put into practice. Protocols thus need to specify who is responsible for implementing the recommended actions and practices and detailing where they will take place, who will carry them out and who will be accountable.

Local protocols for the management of occupational exposure to HIV need to reflect many service elements besides the prescription of PEP medicine (Box 8). These are intended not only help to prevent the transmission of HIV but also to provide epidemiological data, identify unsafe practices, reduce anxiety and increase staff retention and productivity. Infection control professionals, occupational health and safety officers or senior health care staff could implement protocols for occupational PEP.

Box 8. Occupational exposure: recommended minimum service levels

Following potential exposure to HIV, workers should have immediate access to post-exposure prophylaxis 24 hours a day, 7 days a week, regardless of the location or type of work undertaken. The minimum is risk assessment and the first dose of PEP medicine.

Clear communication and information processes should be used to inform workers about the availability of post-exposure prophylaxis and the conditions under which it is provided, the person in charge of providing PEP, the reporting mechanisms and the necessity to report immediately after exposure (Box 9).

The tone of written protocols should be supportive and not punitive and should aim to reflect the needs of the workers rather than to protect employers from litigation. Protocols should foster a climate that encourages the reporting of exposure.

Good local adherence to workplace policies on HIV and AIDS can be encouraged by including these policies as criteria for industry and health care accreditation programmes or other schemes for recognizing performance.

Box 9. Delivering HIV post-exposure prophylaxis in the workplace

Protocols for HIV post-exposure prophylaxis services in the occupational setting should ensure or provide for the following:

- consistent implementation of policies across all departments;
- the availability of resources and skills necessary to implement the policies;
- the identification of delivery sites for PEP and a referral and reporting system;
- making all managers and workers aware of the policies;
- identifying and training service providers;
- education and training for workers;
- including PEP into accreditation, performance review or other quality assurance programmes;
- developing documentation and reporting mechanisms;
- developing monitoring and evaluation mechanisms for evaluating the impact of the strategy;
- developing outcome indicators; and
- a review process that regularly evaluates the effectiveness of the policy.

4.3 Clinical management of occupational HIV exposure[i]

Table 3 lists the resources required to support the provision of HIV post-exposure prophylaxis in the occupational setting.

Table 3. Resources needed for the clinical management of occupational exposures to HIV: a summary

Setting	Resources required
All workplaces	Current protocol Designated person or position to: • implement the protocol; • document exposure; • report on exposure; • provide or ensure ongoing support for the exposed person and their significant others; and • provide or ensure follow up and support for the exposed worker. Worker awareness of: • first aid after exposure; • what exposures to report; and • to whom they should report. Supervisor and manager awareness of: • importance of relieving workers from duty for risk assessment; • how to access risk assessment for exposed workers; and • the documentation required. Allocation of resources needed to provide the above Committee or designated person to provide occupational health and safety review of all exposure Reporting forms and protocols Monitoring and evaluation system Regular updating of the protocol (every two years is recommended)
Non–health care workplaces (additional to above)	Arrangement with clinical service(s) that will provide workplace with: [a] • risk assessment (24 hours – or all hours worked); • post-exposure prophylaxis prescription and management if required; • HIV testing and counsellingb; and • staff training.
Hospital or health centre (additional to above)	Trained staff able to perform risk assessment 24 hours a day (or arrangements to provide this – such as having staff on call or using a telephone service)[b] Stocks of PEP starter packs[b] Provision for 24-hour prescription of PEP[b] Provision of HIV testing and counselling[b] Laboratory testing for HIV[b] Referral to HIV specialist for continuation of PEP and follow-up

a In larger workplaces, the employer may provide some of these services.

b If providing these resources on site is not feasible, arrangements can be made for referrals to another local facility. Referrals should not be made on an ad hoc basis once exposure has occurred but as part of formal arrangements between facilities.

i This section addresses issues that are specific to occupational exposure and needs to be read in conjunction with Chapter 3: Clinical management of HIV post-exposure prophylaxis.

4.3.1 First aid

First aid is a term describing the set of actions that should be taken immediately after potential exposure occurs. The aim of first aid is to reduce contact time with the source person's blood, body fluids or tissues and to clean and decontaminate the site of the exposure.

If the skin is broken following an injury with a used needle or sharp instrument, the following is recommended.

- Do not squeeze or rub the injury site.
- Wash the site immediately using soap or a mild disinfectant solution that will not irritate the skin. WHO recommends the use of a chlorhexidine gluconate solution.
- If running water is not available, clean the site with a gel or other hand-cleaning solution, whatever is customarily available.
- Do not use strong solutions, such as bleach or iodine, to clean the site as these may irritate the wound and make the injury worse.

After a splash of blood or body fluids, the following is recommended.

- After a splash contacts unbroken skin, do the following.

  Wash the area immediately.

  If running water is not available, clean the area with a gel or other hand- rub solution, whatever is customarily available.

  Do not use strong disinfectants.

- After a splash contacts the eye, do the following.

  Irrigate the exposed eye immediately with water or normal saline.

  Sit in a chair, tilt the head back and have a colleague gently pour water or normal saline over the eye, pulling the eyelids up and down to make sure the eye is cleaned thoroughly.

  If contact lenses are worn, leave these in place while irrigating the eye, as they form a barrier over the eye and will help protect it. Once the eye has been cleaned, remove the contact lenses and clean them in the normal manner. This will make them safe to wear again.

  Do not use soap or disinfectant on the eye.

- After a splash contacts the mouth, do the following.

  Spit the fluid out immediately.

  Rinse the mouth thoroughly, using water or saline, and spit again. Repeat this process several times.

  Do not use soap or disinfectant in the mouth.

4.3.2 Reporting exposure

Once first aid has been performed, the exposed worker should report the incident to the designated person, usually a supervisor or manager. Having reported the incident, the worker should then be released from duty so that an immediate risk assessment can be performed (see below).

A designated person should oversee the investigation of both reporting and exposure incidents, as specified in local protocols. This process should be subject to privacy and confidentiality controls. All workers should therefore be aware of the reporting protocols operating in their place of work and know to whom to report in the event of potential exposure.

Incident reporting systems that are applicable to all workers should be kept as simple as possible. When reporting precedes the risk assessment, it can be used to inform this assessment.

Retrospective surveys of health care workers' experiences of needle-stick injuries[15] demonstrate that exposure is underreported to varying degrees in all settings. Factors that discourage reporting of occupational exposure include ignoring that PEP is available and efficient, fear of reprimand, uncertainty regarding the confidentiality of the results, lack of awareness that a protocol exists for managing occupational exposure and a lack of support and encouragement to report. Fear of HIV testing and results because of the likelihood of previous exposure(s) in an individual's private life may also play an important role in the underreporting of occupational exposure. In settings with a high prevalence of HIV infection, workers may not report exposure because they do not want to know their HIV status and are thus reluctant to take an HIV test.

Reporting exposure not only ensures optimum treatment for the potential exposure for the worker, but also generates much-needed data about occupational exposure to support safety planning and evaluation of PEP programmes. Creating a climate in which workers feel able to discuss HIV-related issues in their professional and private lives is therefore advantageous. Regular communication can help to alleviate stigma and also encourage testing as a means of preventing further infection and to access treatment if needed. Box 10 summarizes the factors that have been found to encourage reporting.

Box 10. Encouraging reporting of potential exposure to HIV in the occupational setting

Factors that have been found to encourage reporting include:

- clear guidelines and lines of communication;
- prompt action based on a management plan that is easy to follow without excessive paperwork;
- a supportive work environment and appropriate transparent information on employment safety and protective measures;
- being relieved from duty immediately without question or blame;
- availability of PEP services to exposed workers as soon as possible after exposure;
- assurances that the reporting and documentation systems maintain confidentiality;
- access to trained assessment staff;
- awareness of the supportive nature of the policy;
- availability of options for risk assessment, testing and PEP; and
- ongoing evaluation of best practices and safety in the workplace.

4.3.3 Establishing eligibility for post-exposure prophylaxis

Assessment of exposure risk after occupational exposure

A trained person should assess risk as soon as possible after every incident of occupational exposure, no matter what time of day the exposure occurs. The purpose of such assessment is to determine the severity of the exposure and whether any immediate health care action (such as the provision of PEP) is required. The risk assessment should be performed as close to the workplace as possible, depending on the competence of workplace support.

Local protocols should designate the person to be contacted for the purposes of assessing risk in the event of potential exposure. If no one on site has the necessary skills, risk assessment could be performed by some other means, for instance, by telephone, radio or some other method of communication over distance by an approved person or service as identified in the protocol.

The risk should always be assessed as soon as possible, and if the risk is considered to be significant, PEP can be initiated within 72 hours of the exposure (Box 11). In cases the risk assessment cannot be conducted within the 72-hour time limit, regardless of the reason, the first dose of PEP medicine can be given as a precautionary measure. If, however, subsequent assessment determines that the exposure was not significant, it should be discontinued.

Even if the exposure is not assessed to be significant for HIV transmission, prompt intervention – including assessment and communication of risk – can significantly alleviate worker distress and anxiety following exposure. Table 4 lists some of the factors to consider as part of the risk assessment process. All types of occupational exposure do not carry an equal risk of transmitting HIV infection (Box 12). Some types of exposure are unquestionably high risk, such as a spontaneously bleeding injury caused by a large bore hollow needle immediately after it has been used to withdraw blood from a vein or an artery of a person known to be living with HIV. Others, however, pose very little risk. Examples in this category would include exposure to body fluids other than blood, splash exposures to non-mucous membranes or superficial injuries that do not cause bleeding. Some contacts with blood or body fluids are not usually considered to constitute exposure: for instance, when the contact is only to intact skin (see also section 3.1.3).

Box 11. Risk of HIV transmission: occupational exposure

The probability of acquiring HIV infection following percutaneous (through the skin) exposure to blood known to be infected with HIV is generally accepted to be about 0.3%. This figure is derived from studies carried out in well-resourced countries with a low background prevalence of HIV and may not necessarily apply to countries with higher prevalence or in more resource-constrained settings where the reuse of medical supplies and equipment is higher and the overall safety standards are lower.

Between these extremes, some types of exposure pose a small risk of HIV transmission epidemiologically. Unfortunately, a standard classification cannot be derived based on the probability of infection that can be applied in all settings to determine the level of risk at which

PEP should be given. A type of exposure not considered to pose a "significant" risk in an area of low prevalence may be assessed to be "significant" in a region or population subgroup with either a high prevalence and/or a large number of late presentations of HIV infection, meaning that the source person is more likely to have an undiagnosed late-stage infection and thus be more likely to transmit HIV infection.

Box 12. Recommended eligibility criteria for post-exposure prophylaxis in occupational settings

(1) less than 72 hours has elapsed since exposure;

and

(2) the exposed individual is not known to be HIV infected;

and

(3) the person who is the source of exposure is living with HIV or has unknown HIV status;

and

(4) exposure was to blood, body tissues, visibly blood-stained fluid, concentrated virus, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid or amniotic fluid;

and

(5) exposure penetrated the skin with spontaneous bleeding or deep puncture **or** splash of significant amount of fluid to mucous membrane **or** prolonged contact of an at-risk substance with non-intact skin;

and

(6) if the skin was penetrated, exposure was from a recently used hollow bore needle or other sharp object visibly contaminated with blood.

Table 4. Factors to be considered in risk assessment at the workplace

Type of exposure or source	Factor
Sharps injury	The type (solid or hollow bore) and size of the needle or sharp object What the needle or sharp object had been used for The severity of the injury Whether the penetration site bled The type of blood or body substance to which the person was exposed The amount of blood or body substance to which the person was exposed Whether the injury was through gloves or clothing When the exposure occurred How recently the sharp had been used
Splash	The type of body fluids to which the person was exposed Whether the fluid to which the person was exposed contained blood The amount of blood or body substance to which the person was exposed Whether non-intact skin or mucous membrane was exposed When the exposure occurred
Source of the blood, body fluids or tissue	Identity of the source person (known or unknown) HIV status (if known) Stage of HIV infection (if known) HIV RNA viral load (if known) Antiretroviral therapy history of the source person (if known) Estimated population prevalence of HIV, including geographical region and country prevalence and prevalence within the cultural, ethnic or behavioural group

Assessment of the source person

A person who is the source of an exposure only needs to be identified and HIV tested if the results would lead to a change in the exposed *worker's treatment* is clinically managed. If the exposure is assessed as posing no or a very low risk of HIV transmission, the source person does not need to be tested given that PEP would not be prescribed even if the source person were found to be infected with HIV. If, however, the exposure is significant, testing of the source person should be encouraged and carried out according to locally prescribed HIV testing and

counselling protocols. Testing source people in all workplace settings requires consent. The exposed worker must not be involved in obtaining consent from the source person for HIV testing.

If the source person can be tested and consents to testing, the test results should be taken into account when deciding whether to continue PEP in cases where it has started. Even if the source person is found to be HIV antibody negative at the time of the incident, the probability that the source person is in the window period must be assessed before any decision is made to discontinue PEP.

If the source person's HIV infection status is unknown at the time of exposure, use of PEP should be decided on a case-by-case basis after considering the type of exposure and the clinical and/or epidemiological likelihood that the source person is HIV infected. Under such circumstances, however, standard precautions require that all source people be regarded as potentially HIV infected and PEP be initiated, if indicated by the severity of exposure. Similarly, in settings where rapid testing techniques are not available, waiting for the results of source testing should not be allowed to jeopardize the timeliness of commencing post-exposure prophylaxis if the source person may be HIV positive, and under such circumstances PEP should therefore be given after significant exposure.

4.3.4 Prescribing and dispensing post-exposure prophylaxis medicine[i]

Local protocols need to outline the arrangements for prescribing and dispensing post-exposure prophylaxis medicine. Ideally, starter packs – or the initial dose of PEP – should be available 24 hours a day and dispensed within 4 hours of the exposure. Large workplaces could have these starter packs or kits on site.

All workers should be aware of which post-exposure prophylaxis services are available to them. In the interest of maintaining privacy and confidentiality, workers should be given the option to access services away from the workplace.

4.3.5 HIV testing and counselling

The rationale for testing for HIV soon after occupational exposure is to establish a baseline against which future test results can be compared. If a worker tests negative for HIV at the baseline test, subsequent infection identified by follow-up testing can theoretically be proved and confirmed to be related to the occupational exposure (depending on the time of the infection and the consideration of other risks or exposure incidents). However, caution should be exercised when establishing any links, as only genotypic testing of both the source person and the exposed person can prove and confirm the origin of the infection.

In occupational settings, performing an HIV test immediately after exposure might not be feasible for any number of reasons. For instance, the exposure may have occurred outside normal business hours or in a setting in which HIV testing and pretest counselling are not readily available. Alternatively, a worker may feel unable to give informed consent to testing immediately after the exposure incident due to anxiety. Given its importance for the exposed person, HIV testing should thus be offered as

i Section 3.3.1 outlines the two- and three-drug regimens recommended for post-exposure prophylaxis.

soon as the appropriate conditions arise, always respecting patient confidentiality, with informed consent and with the support of pre- and post-test counselling. If necessary, the baseline HIV test can be performed up to several days after exposure. For example, if a starter pack was given immediately after an exposure, the HIV test may be offered to the individual when he or she returns for the remainder of their PEP medicine or, if a full course of medicine was prescribed, during follow-up visits.

Post-exposure prophylaxis should never be delayed if HIV testing and counselling is not immediately available.

Although baseline HIV testing may be a prerequisite for workers wishing to claim compensation, HIV testing should not be a requirement for receiving PEP. Although exposed workers should be encouraged to discover their HIV status and have an HIV test, this process should be viewed as separate from the emergency response of starting PEP. The benefit to the exposed worker of taking an HIV test is that it avoids the possibility of exposing an HIV-positive person to a full 28-day course of dual nucleoside reverse-transcriptase inhibitor therapy that could limit the efficacy of these drugs for antiretroviral therapy if needed, and moreover, it gives that person a chance to receive appropriate care and antiretroviral therapy, if needed.

Providing HIV testing and counselling in the workplace comprises a valuable opportunity to advise exposed workers about their non-occupational risk of becoming HIV infected. Thus, failure to provide services of this nature constitutes a missed opportunity to provide counselling to a potentially HIV-negative person. Likewise, failure to diagnose a pre-existing HIV infection is a missed opportunity to link workers with appropriate health care and to provide information on ways to reduce subsequent transmission.

In the occupational setting, pretest counselling should discuss (in addition to what is covered in standard pretest counselling; see section 3.5.1) the legal implications of HIV diagnosis and disclosure (including professional practice issues), any past occupational and non-occupational risks of acquiring HIV infection, any workplace-specific issues and safe practice. If the exposure is assessed as significant, irrespective of whether the offer of post-exposure prophylaxis is accepted or not, workers must be given advice and guidance on safe practices to follow until they are known to be HIV negative – including ones related to safe sex. This could include providing condoms and contraceptives, as appropriate. Exposed workers should be advised not to share injecting equipment, not to donate blood or tissues and not to breastfeed if there are safe alternatives to exclusive breastfeeding.

Confidentiality must be maintained, unless the worker elects to disclose the exposure. Under such circumstances, and in view of the fact that workers' families, partners and colleagues may well feel anxious about the risk of HIV transmission, these groups of individuals should be offered information and support as well. Due to the sensitive nature of the information discussed during the course of risk assessment following an exposure incident, workers should be given the option to receive counselling and blood testing outside the workplace.

4.3.6 Follow-up

Any worker who may have been exposed to HIV must be offered fully confidential follow-up services, preferably coordinated by a designated health care professional, such as a staff health

doctor or nurse or an infection control coordinator. This person would be responsible for coordinating blood results, arranging post-test counselling and reminding the worker when their follow-up blood tests are due. This person should also make sure that all the necessary forms and reports, including an incident report, have been completed, and ensure confidential storage of all documentation relating to the incident.

An incident report should always be completed. Its purpose is to support health and safety reviews, as well as compensation claims, should they arise. It is equally important that the occupational health and safety aspects of the incident be reviewed, as this will determine whether any unsafe practices or equipment in the workplace need to be addressed.

If seroconversion occurs, the exposed worker should seek health care advice promptly to determine whether and how their professional work needs to be modified and whether the employer needs to be informed about his or her condition (Table 5).

Table 5. Management of occupational post-exposure prophylaxis

Most occupational exposure with the potential to transmit HIV occurs in health care settings, but workers in other occupations may also be at risk and should also be protected. The average risk for a health care worker to get infected after exposure to a needle-prick injury with potential infected blood is about 0.3%.

Policy principles

- All workplaces should have a policy on HIV and AIDS; this policy should include the provision of PEP.
- Policies relating to the management of HIV risks in occupational settings need to be underpinned by legislation.
- The successful implementation of policies requires collaboration between employers, workers and their representatives and government.
- Policies and protocols should reflect the principles of non-judgemental worker support, equality and personal choice and should be supportive and not punitive.
- Appropriate post-exposure management should be available regardless of the time of day that the exposure occurred, the location or the type of work being undertaken.
- Policies on occupational PEP should apply to all workplaces and cover all the people who may be in a given workplace and all types of exposure.
- Primary prevention remains the preferred strategy for reducing the risk of HIV transmission in occupational settings; PEP must not detract from strategies that prevent exposure.
- Confidentiality must be maintained for both the exposed person and the source person.
- Neither HIV testing nor PEP should ever be mandatory.
- Workers need access to confidential HIV testing and counselling if there is a risk of occupational HIV exposure.
- Compensation should be provided for workers who have contracted HIV at work.

Implementation guidance

- All workers must be informed about the availability of PEP, how it can be accessed and to whom to report in the event of an incident.
- Workers should be able to access at least the first dose of PEP within 4 hours of the exposure (and no later than 72 hours), 24 hours a day, 7 days a week.
- First aid should be initiated immediately after potential exposure.
- The exposed worker must report the exposure to their supervisor.
- A skilled person should assess the risk as soon as possible after every occupational exposure.
- In the interests of maintaining privacy and confidentiality, workers should be given the option of receiving services away from their workplace.
- HIV testing of the exposed person and the source person (according to standard protocols for HIV testing and counselling) is strongly encouraged but is not a prerequisite for PEP.
- Workers who receive post-exposure prophylaxis should be given guidance on risk reduction measures to follow until they are known to be HIV negative and/or referred for clinical assessment if subsequently found to be HIV positive.
- The worker's family, partner or significant others may also need to be offered information and support if the worker chooses to disclose the incident to them.
- A designated person should provide follow-up services.
- The occupational health and safety aspects of the incident should be reviewed.
- Baseline data are needed to monitor and evaluate programmes and protocols.

5. POST-EXPOSURE PROPHYLAXIS FOR PEOPLE WHO HAVE BEEN SEXUALLY ASSAULTED: POLICY ISSUES AND CLINICAL MANAGEMENT

5.1 Background

Specific challenges to the wider use of post-exposure prophylaxis among people who have been sexually assaulted include:

- integrating HIV risk assessment (and counselling specific to HIV and PEP) into a trauma context;
- providing comprehensive services for treatment and care of people who have been sexually assaulted;
- lack of specific services for people who have been sexually assaulted;
- insufficiently trained or overburdened staff;
- lack of available HIV testing and counselling services;
- lack of knowledge about PEP among police, health care providers and other frontline service providers (such as teachers or counsellors who handle cases of sexual or domestic violence or sexual abuse of children); and
- lack of patient and community information, and difficulties with follow-up, typically because of transport problems.

5.2 Policy issues

5.2.1 Policies for care for people who have been sexually assaulted should include HIV post-exposure prophylaxis

PEP for people who have been sexually assaulted should not be developed in isolation but, as far as possible, be considered in the context of existing HIV prevention and treatment programmes and services for people who have been sexually assaulted. Post-exposure prophylaxis services should ideally be developed as a component of programmes that provide a comprehensive package of services for people who have been sexually assaulted, including social, health care and legal services. This is consistent with *Guidelines for medico-legal care for victims of sexual violence*[16] and *Clinical management of rape survivors: developing protocols for use with refugees and internally displaced persons*[17].

Institutions caring for people who have been sexually assaulted should thus consider developing policies that include providing PEP, particularly in areas with a high prevalence of HIV infection. In settings where dedicated services are not available for people after they have been sexually assaulted, it is recommended that consideration be given to developing capacity to manage care of people who have been sexually assaulted alongside obstetric and paediatric services.

Accessibility and organization of post-exposure prophylaxis

Governments should ensure that appropriate information about post-exposure prophylaxis services is widely available, and if necessary, initiate programmes to increase public awareness about the availability of services and of PEP for people who have been sexually assaulted.

Appropriate clinical sites must be identified for initial and follow-up care. Options are:

- hospital or clinic rape centres (for initial and follow-up visits);
- local primary care clinics (for follow-up visits); and
- home-based care(for follow-up visits).

Local protocols could allow for post-exposure prophylaxis initiation at the district level (that is, supply of a starter pack), followed, if needed, by referral to a tertiary level institution for complete risk assessment and clinical management. Follow-up care and support could be provided in appropriate clinical settings, preferably as close as possible to the local community, so long as the person does not need to be evacuated or protected for security reasons.

Centralized and decentralized systems for care and support services for people who have been sexually assaulted each have their own advantages and disadvantages. Many experts recommend that follow-up care be available at or close to home. Home visits may positively influence adherence rates and can be very costly.

Reporting of a sexual assault should never be a condition of receiving post-exposure prophylaxis or any other services after sexual assault (government-sponsored or other).

People who have experienced sexual assault may choose to go to the police to report the assault and to bring charges against the alleged perpetrator. Although victims of sexual violence should be encouraged to report the assault, and supported in doing so, they should not be coerced to do so, and this should never be a precondition for receiving post-exposure prophylaxis. People should be able to report the sexual assault and receive treatment and care without bringing charges.

People who have been sexually assaulted often have to see and disclose to many different service providers: this should be minimized to the greatest possible extent. Assuring confidentiality needs to be a priority in all reporting.

Specific needs of certain population subgroups

Protocols governing the reporting of cases of sexual abuse of children should be in accordance with national laws. In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child should always be the primary consideration[18].

Informed consent should be obtained from the caregiver when feasible and appropriate support strategies put in place to help the child and the caregivers to adhere to the post-exposure prophylaxis. The WHO guidelines *Antiretroviral therapy of HIV infection in infants and children in resource-limited settings: towards universal access*[19] can be used to guide the appropriate dosing of PEP medicine for children.

Refugees and internally displaced people may have special needs due to specific circumstances. Key concerns are: that the prevalence of sexual violence can be relatively high, especially when sexual violence is employed as a weapon of war, and the lack of laboratory facilities (which limits

the possibility of HIV testing). When refugees and internally displaced people are not in camps, consideration should be given to the difficulty in tracking people and providing follow-up care and support and the need for providing protection from further harm. The WHO and UNHCR (Office of the United Nations High Commissioner for Refugees) document *Clinical management of rape survivors: developing protocols for use with refugees and internally displaced persons*[20] offers comprehensive guidance on the appropriate care for people who have been sexually assaulted, including post-exposure prophylaxis.

5.2.2 Policy implementation and local management of people who have been sexually assaulted

Post-exposure prophylaxis services must be offered as part of a comprehensive care package for people who have been sexually assaulted and not as a stand-alone intervention.

The elements of basic PEP services are listed in Chapter 2 of these guidelines (see section 2.4.2). In cases of sexual assault, however, PEP should be part of a comprehensive package of services needed by people who have been sexually assaulted. These include pregnancy advice (and emergency contraception and access to legal abortion where the law permits it); pregnancy testing at baseline and follow-up; prophylaxis and management of sexually transmitted infections; and crisis, post-trauma and risk reduction counselling.

5.3 Clinical management of people who have been sexually assaulted[i]

In sexual assault cases, provision of PEP is often considered as the last step in the lengthy process of reporting to the police, providing health history, undergoing a health care examination and forensic evidence collection and attending laboratory and HIV testing and counselling sessions. The full range of services is rarely in place. Where services for people who have been sexually assaulted already exist (or are being developed), treatment protocols may need to be reoriented to ensure that the first dose of PEP is provided as early as possible (see section 5.3.1).

5.3.1 The initial post-assault visit

The recommended steps in the management of people who have been sexually assaulted at the initial post-assault visit are as follows.

1. Provide initial crisis intervention (such as emotional support) and first aid.
2. Explain to the person who has been sexually assaulted what will happen while she or he is at the clinic. The person should be informed about the general process involved for both the general health examination and, if also conducted at this location, the forensic examination.
3. Conduct a general health examination, including overall status and recording injuries.
4. Assess the risk of HIV transmission.

i This section addresses issues that are specific to exposure to sexual assault and should be read in conjunction with Chapter 3: Clinical management of HIV post-exposure prophylaxis.

5. If appropriate, offer the initial dose of PEP medicine, either prior to HIV testing or, if rapid testing results are available, within an hour or two immediately after obtaining the test results. If forensic evidence is to be collected, it should first be confirmed whether oral sex was performed, as in this case an oral swab should be obtained before taking any medicine.
6. If rapid testing is available, offer HIV pre-and post-test counselling.
7. Provide clinical management and collect forensic evidence, including pregnancy assessment and presumptive treatment of sexually transmitted infections.

Ideally, and in the interests of ensuring confidentiality, people who have been sexually assaulted should be seen and treated in a private room. Patient records and other forms of case documentation should include demographic information, details of the sexual assault and potential HIV exposure, health status, including the results of any pregnancy test and mental health status, description of injuries, other possible HIV risks, any symptoms, follow-up and tracking information and notes about any referrals to other services (see *Clinical management of rape survivors: developing protocols for use with refugees and internally displaced persons* for more details). Medicine dispensing records should note the date and time when the first dose of PEP was taken. All records should be stored in a safe locked place.

5.3.2 Establishing eligibility for post-exposure prophylaxis

Exposure risk assessment

The risk of becoming infected with HIV from sexual assault may be higher than that from consensual sex (Box 13), as the presence of trauma tends to increase transmission risk. Transmission risk is also elevated by the presence of sexually transmitted infections and if the exposed person is an adolescent girl (the immaturity of the vaginal and cervix cells increasing susceptibility to HIV infection).

Box 13. HIV transmission risks: sexual exposure

The estimated risk of acquiring HIV infection from a single episode of consensual receptive vaginal intercourse is between 0.1% (1 in 1000) and less than 1% (1 in 100) and, from a single episode of consensual receptive anal sex, is between 1% and 5% (1 to 5 in 100).

As indicated elsewhere in these guidelines, post-exposure prophylaxis is most effective if given within hours and no later than 72 hours after exposure. People who have been sexually assaulted presenting later than 72 hours post-assault would normally not be considered to be eligible for post-exposure prophylaxis. However, in the case of ongoing sexual assault that occurs over a number of hours or days, the 72-hour time limit should be applied to the most recent potential exposure (Box 14).

Box 14. Recommended post-exposure prophylaxis eligibility criteria among people who have been sexually assaulted

(1) less than 72 hours has elapsed since exposure;

and

(2) the exposed individual is not known to be HIV infected;

and

(3) the person who is the source of exposure is HIV infected or has unknown HIV status;

and

(4) a defined risk of exposure, such as:

receptive vaginal or anal intercourse without a condom or with a condom that broke or slipped;

or

contact between the perpetrator's blood or ejaculate and mucous membrane or non-intact skin during the assault;

or

receptive oral sex with ejaculation;

or

the person who was sexually assaulted was drugged or otherwise unconscious at time of the alleged assault and is uncertain about the nature of the potential exposure;

or

the person was gang raped.

Assessing the risk of HIV transmission from the source person

In practice, most people who have been sexually assaulted will be managed based on the assumption that the source person is unknown or, if identified, has unknown HIV status (Annex 6).

If the source person is of unknown HIV status, providing post-exposure prophylaxis after a sexual assault is generally recommended if exposure was significant. Evaluation of whether exposure was significant should take into account the overall prevalence rate of HIV infection in the general population or in specific vulnerable groups.

Whenever feasible, based on standard protocols and informed consent, HIV testing of source people is strongly recommended.

5.3.3 Informed consent for post-exposure prophylaxis after sexual assault

Post-exposure prophylaxis should not be given without informed consent. Annex 3 includes a sample patient information sheet listing the points that need to be covered when obtaining informed consent to HIV PEP from people who have been sexually assaulted. Consent may be given verbally.

People who have been sexually assaulted should provide separate consent for the collection of forensic specimens. If HIV testing and/or blood monitoring are required, this should also be made clear during the process of seeking informed consent for PEP.

The issue of consent can be especially challenging when people have experienced trauma, such as sexual assault, or are unconscious. It is also problematic with children, adolescents or those with either physical or mental disabilities that impair their understanding or ability to communicate. It is therefore recommended that local protocols allow a parent or guardian to give consent for post-exposure prophylaxis when consent from people who have been sexually assaulted cannot be obtained. Protocols should always be formulated to ensure that the best interests of the person are served at all times.

Similar to protocols for other emergency procedures or urgent situations, some jurisdictions permit a designated official, such as hospital superintendent, to provide consent to initiate PEP where consent cannot immediately be obtained.

5.3.4 Pregnancy testing and emergency contraception

Pregnancy testing should be available to all women of childbearing age, but lack of availability should not prevent post-exposure prophylaxis from being provided. Ideally, all women of childbearing age who are raped should be offered a pregnancy test as part of sexual assault care services. If the initial pregnancy test is negative, clients should also be offered a second pregnancy test, a month later, to determine whether they have become pregnant from the recent exposure. If pregnancy testing is not available, a flow chart for assessing pregnancy risk should be used to assess the likelihood of a woman's risk of becoming pregnant as a result of the assault *(see Clinical management of rape survivors: developing protocols for use with refugees and internally displaced persons)*.

Women who are pregnant at the time of presentation can still be offered post-exposure prophylaxis (see also section 3.3.1). Women who are not pregnant at the time of presentation should be offered emergency contraception. Emergency contraceptives can be given up to 120 hours (five days) after a sexual assault.

Mothers who are breastfeeding should be advised that, if they became HIV infected as a result of the exposure, the risk of transmitting the virus to the child through breastfeeding is high (considering the high viral load associated with the initial stage of HIV infection). Appropriate counselling should be offered based on exclusive breastfeeding, and safe alternatives to breastfeeding should be discussed when they are acceptable, feasible, affordable and sustainable.

5.3.5 Care of children after sexual assault: special considerations

In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child should always be the primary consideration. Protocols governing the reporting of cases of sexual assault of children should be in accordance with national laws.

Informed consent should be obtained from the caregiver when feasible. For appropriate medicine dosing, *Antiretroviral therapy of HIV infection in infants and children in resource-limited settings: towards universal access* can be used to guide the appropriate dosing of PEP medicine for children.

5.3.6 Follow-up

Side effects from the post-exposure prophylaxis medicine and adherence as well as mental health needs and referral to other services should be addressed in a series of follow-up visits. Clinical signs and symptoms of sexually transmitted infections should be investigated and treated. Sexually transmitted infection prophylaxis and PEP for hepatitis B infection should be discussed (Box 15).

Box 15. Management of post-exposure prophylaxis among people who have been sexually assaulted

- The estimated risk of acquiring HIV infection from a single episode of consensual receptive vaginal intercourse is between 0.1% (1 in 1000) and less than 1% (1 in 100) and, from a single episode of consensual receptive anal sex, is between 1% and 5% (1 to 5 in 100). Risks may be higher in the context of sexual assault, particularly when there is trauma and multiple rape.

Policy principles

- All countries should have a policy on the services provided for people who have been sexually assaulted. These policies should include post-exposure prophylaxis whenever sufficient resources are available.
- People who have been sexually assaulted, were exposed to unprotected receptive vaginal or anal intercourse or contact with blood or ejaculate to mucous membrane or non-intact skin and report within 72 hours would be eligible for PEP.
- Post-exposure prophylaxis should be offered as part of an integrated package of post–sexual assault care and HIV prevention services.
- Reporting of the sexual assault must not be a condition of receiving PEP or other post–sexual assault services.
- HIV testing is recommended but should never be mandatory nor a precondition for receiving PEP.
- Assuring confidentiality is essential.
- Appropriate clinical sites for providing initial and follow-up care must be identified.
- Specialist counselling skills and expertise are required for providing PEP services to people who have been sexually assaulted, especially children.
- Specific considerations for sexually abused children include issues of informed consent and appropriate medicine dosing.
- Always act in the best interests of the child.

Policy implementation

- Current protocols for managing people who have been sexually assaulted may need to be reoriented to ensure that the first dose of PEP is provided as early as possible during the initial evaluation and management.
- Separate consent should be obtained for the collection of forensic specimens for HIV testing and blood examinations.
- People who have been sexually assaulted who request that HIV testing be delayed should be given a PEP starter pack and asked to return within 3–4 days for follow-up.
- Pregnancy testing, emergency contraception and presumptive sexually transmitted infections treatment should be available to all women who have been raped.

Side effects, adherence, mental health problems and referral needs should be monitored and addressed in a series of follow-up visits. Repeat HIV testing and counselling should be encouraged at 2–4 months after exposure and again at 4–6 months

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ANNEX 1
TRAINING REQUIREMENTS

A basic level of information about HIV and HIV post-exposure prophylaxis should be included in workplace training for all workers and in public education campaigns, wherever possible. As a minimum, the basic level of training should achieve:

- an understanding of how HIV is transmitted;
- an understanding of how the risks of HIV transmission can be minimized; and
- awareness of availability of and access to PEP.

Those engaged in specific occupations need to receive the basic awareness training elements suggested in the table below.

Group	Training requirements (minimum)
Workplace administrators, managers and supervisors	How to implement workplace policies on HIV and post-exposure prophylaxis How to implement policies on providing care for people who have been sexually assaulted Strategies to prevent or manage stigma and discrimination in the workplace and for providing non-judgemental PEP services to workers and people who have been sexually assaulted Strategies to maintain the confidentiality of workers How to maintain a safe workplace Budgeting and procuring resources Record-keeping, monitoring and evaluation of PEP services
Government employees, staff of nongovernmental organizations, the police and other key public workers	Information about eligibility for and availability of PEP and how to access and refer exposed individuals to post-exposure prophylaxis services Strategies to prevent or manage stigma and discrimination in the workplace and for providing non-judgemental post-exposure prophylaxis services to workers and people who have been sexually assaulted Strategies to maintain the confidentiality of exposed individuals
Workers' representatives	Content of and how to use workplace policies on HIV and PEP Information about eligibility for and availability of post-exposure prophylaxis and how to access and refer exposed individuals to post-exposure prophylaxis services Strategies to maintain the confidentiality of workers How to maintain a safe workplace

Group	Training requirements (minimum)
Workers who may be exposed to blood or other body fluids	Content of and how to use workplace policies on HIV and PEP How to perform first aid following occupational exposure Information about eligibility for and availability of PEP and how to access and refer exposed individuals to post-exposure prophylaxis services Infection control protocols relevant to the workplace, such as standard (universal) precautions and use of personal protective equipment Risk assessment for HIV transmission and post-exposure prophylaxis Strategies to maintain the confidentiality of co-workers and patients Incident reporting and confidential record-keeping
Workplace health and safety officers	Content of and how to use workplace policies on HIV and post-exposure prophylaxis How to perform first aid following occupational exposure Information about eligibility for availability of PEP and how to access and refer exposed individuals to post-exposure prophylaxis services How to perform risk assessment for HIV transmission and eligibility for PEP Strategies to maintain the confidentiality of workers Infection control protocols relevant to the workplace, such as standard (universal) precautions and use of personal protective equipment How to assess the environment and maintain safe working practices and conditions Incident reporting and confidential record-keeping

B. Training of service providers

Ensuring the integration of the management of HIV post-exposure prophylaxis in the curricula of education and training for health care workers is critical. On-the-job training of health workers should also be organized regularly and be linked with the monitoring and evaluation of the programme. It includes the following.

Group	Training requirements (minimum)
Health workers providing post-exposure prophylaxis services	How to implement policies on HIV and post-exposure prophylaxis How to provide appropriate care for people who have been sexually assaulted Information about eligibility for and availability of post-exposure prophylaxis and local access and referral mechanisms How to explain HIV transmission to workers and patients How to perform risk assessment for HIV transmission and eligibility for post-exposure prophylaxis How to help workers and patients develop strategies for preventing HIV transmission for the future Strategies to maintain the confidentiality of workers and patients Basic counselling skills Communication and counselling skills for working with vulnerable populations Understanding the use of post-exposure prophylaxis medicine: indications, actions, dosing, side effects and adherence How to obtain true informed consent Legal issues pertaining to providing post-exposure prophylaxis, HIV testing and maintaining confidentiality Incident reporting, confidential record-keeping, monitoring and evaluation Other services locally available and how to make referrals

Group	Training requirements (minimum)
Health workers providing HIV testing and counselling services	Information about eligibility for and availability of PEP and local access and referral mechanisms How to explain HIV transmission to workers and patients How to perform risk assessment for HIV transmission and eligibility for PEP How to help workers and patients develop strategies for preventing HIV transmission for the future Strategies to maintain the confidentiality of patients Basic counselling skills Communication and counselling skills for working with vulnerable populations Local guidelines for the provision of HIV testing and counselling How to obtain true informed consent Legal issues pertaining to providing PEP, HIV testing and maintaining confidentiality Confidential record-keeping Other services locally available and how to make referrals

ANNEX 2
SAMPLE SCRIPTS FOR HEALTH CARE PROVIDERS

Communicating some of the concepts of these guidelines to individuals who have been potentially exposed to human immunodeficiency virus (HIV) and thus may be eligible for post-exposure prophylaxis can be difficult. The sample "scripts" given below are intended to assist health care providers in this task. Users of these guidelines are reminded that these sample scripts are designed to be adapted to suit individual and local circumstances, such as literacy and language facility, cultural factors and service availability. Users should stress the fact the information gathered in interviews and in the patient information sheets (Annex 3) will be treated with utmost confidentiality.

Script 1: Explaining HIV exposure and transmission risk, and how post-exposure prophylaxis may help prevent infection following occupational exposure

I would like to talk with you for a few minutes about HIV and the medicine that may help to prevent HIV infection we call "post-exposure prophylaxis".

Risk of infection

Can you tell me what you know about getting HIV infection?

Interviewer can then correct any misconceptions the person may have.

Most people who are exposed to HIV just once don't get the infection. It's like when a child is sick and you hold him or her. You are exposed to the virus that is making the child sick, but your body fights it and you don't get sick. Or when you walk into a room full of people who may have all sorts of infections, you are exposed but don't necessarily get ill.

With HIV, after you have had a needle-stick or a splash to the eye or mouth, the virus may enter your body, but it does not always get all the way into your bloodstream. Most of the time your body fights and kills the virus before this happens. So although you have been exposed to the virus, you are not infected with it. But if your body fails to kill the virus and it gets into your blood system, then you will have HIV infection. It's only then that the HIV test would turn positive, and this could take up to six months.

The body is very good at fighting the HIV virus. Even if the person with whom you have had contact was definitely infected with HIV, the chance – or risk – of you getting the HIV infection after a needle-stick or a splash to the eye or mouth is very small. The risk of getting HIV infection from a person known to be HIV positive has been estimated to be about 3 in 1000 (0.3%) for injury with a sharp object and even less, 1 in 1000 (0.1%), for a mucous membrane splash. This means that for every 1000 people who come into contact with the blood of a person who has the HIV infection, only two or three will become infected themselves.

The risk is slightly greater for certain types of exposure, such as a needle-stick from a hollow-bore needle that has visible blood on it or from needles that have been in an artery or a vein and if the source person has a high viral load (that is to say, the person is very sick).

The good news is that in all these cases your risk of getting HIV is relatively low. Hopefully post-exposure prophylaxis, if you decide you want to take it, can lower your chance of getting HIV infection even further.

Post-exposure prophylaxis medicine

Have you ever heard of a type of medicine called post-exposure prophylaxis, which is used to prevent HIV infection after a needle-stick or splash to the eye or mouth? If so, please tell me what you know about it.

[The interviewer can then correct any misconceptions the person may have.]

This medicine has been used in many situations where a person has been exposed to HIV. For example, it has been given to health workers who have had a needle-stick injury while working with a person who has HIV infection. Similar medicine is used to help prevent pregnant women from passing on HIV to their babies. The medicine works by helping the body to fight the virus, which stops it from getting into a person's blood system so they don't get infected. This is why we are offering you this medicine if you would like to take it. Not everyone who has taken this medicine has been protected, but research has shown that taking this medicine does reduce the chance of getting HIV infection after exposure.

I would like to tell you a few things about post-exposure prophylaxis to help you decide if you might want to take the medicine.

The medicine is a pill that you take morning and evening every day for 28 days. For the medicine to work, it is important that you take a pill twice each day, once in the morning and once in the evening. *[Adapt to specific dosing instructions.]*

About half the people who take this medicine experience some side effects. Side effects are unwanted symptoms that you might get from taking a medicine that is meant to help you; for example, a tablet you use to take away a headache might give you heartburn. For post-exposure prophylaxis, the side effects can include nausea, fatigue and headache *[modify depending on the medicine used for post-exposure prophylaxis]*. Side effects often improve or disappear after a few days, but for some people they don't get better. We will help you if you have severe side effects from this medicine. You need to weigh up the possible benefits – that is, that the medicine might help your body fight the HIV and prevent you from getting the infection – against the possible risks – that is, that you might have side effects. We don't know for sure that taking PEP means that you won't get HIV infection, but we think it will help.

To get the full benefit from post-exposure prophylaxis, you must take the pills, at the right times, for the full 28 days. If you change your mind, or if you get side effects that are too unpleasant, you can stop taking them at any time. However, it is best if you contact me, or *[name an appropriate person]*, before you stop taking them, in case there are ways in which we can help you or things that I have not explained clearly that have made you uncertain about whether you want to finish the medicine. If you do decide to take the medicine, you should start straight away.

[If the person is pregnant or there is a possibility of pregnancy:] Some types of post-exposure prophylaxis medicine can be used safely in pregnancy. You would not want to expose your baby to unnecessary medicine, but if you get HIV infection during pregnancy, your baby would have some risk of becoming infected with HIV.

Can you tell me how you feel about all of this? Or perhaps you would like to ask some questions about post-exposure prophylaxis?

Script 2. Explaining about HIV exposure and the risk of transmission and how post-exposure prophylaxis may help prevent HIV infection following sexual assault

I would like to talk with you for a few minutes about HIV and the medicine that may help to prevent HIV infection we call "post-exposure prophylaxis".

Risk of infection

Can you tell me what you know about getting HIV infection?

Interviewer can then correct any misconceptions the person may have.

Most people who are exposed to HIV just once don't get the infection. It's like when a child is sick and you hold him or her. You are exposed to the virus that is making the child sick, but your body fights it and you don't get sick. Or when you walk into a room full of people who may have all sorts of infections, you are exposed but don't necessarily get ill.

After you have had sex with someone who is infected with HIV, the virus does not always get all the way into your bloodstream. Most of the time your body fights and kills the virus before this happens. So although you have been exposed to the virus, you are not infected with it. But if your body fails to kill the virus and it gets into your blood system, then you will have HIV infection. It's only then that the HIV test would turn positive.

The body is very good at fighting the HIV virus. Very few people actually get HIV infection after being raped. Many people are exposed to HIV by having unprotected sex or by being raped, but even if the sexual partner or rapist was definitely HIV positive, the chance – or risk –of getting the HIV infection is very small. In your case, the risk of getting HIV infection is:

- between 1 in 1000 (0.1%) and 1 in 100 (1%) or even less for receptive vaginal intercourse; and
- between 1 and 3 in 100 (1–3%) for receptive anal intercourse.

For receptive oral intercourse with ejaculation, transmission is very rare, but it can happen.

The risk is increased with visible trauma, if either yourself or the perpetrator has any sexually transmitted infection or if there were multiple perpetrators. Adolescent girls with cervical ectopy are also at slightly higher risk.

[Adapt to specific circumstances – the above data refer to unprotected intercourse with a person known to be HIV-positive.]

The good news is that your risk is relatively low. Hopefully post-exposure prophylaxis, if you decide you want to take it, can lower your chance of getting HIV infection even further.

Post-exposure prophylaxis medicine

Have you ever heard of a medicine called post-exposure prophylaxis, which is used to prevent HIV infection after rape or other sexual exposure? If so, please tell me what you know about it.

[The interviewer can then correct any misconceptions the person may have.]

This medicine has been used in many situations where a person has been exposed to HIV. It has been given to health workers who have had a needle-stick injury while working with a person who has HIV infection. Similar medicine is used to help prevent pregnant women from passing on HIV to their babies. The medicine works by helping the body to fight the virus, which stops it from getting into a person's blood system so they don't get infected. We don't know for sure whether it works in the same way after sexual exposure but we hope that it does. This is why we are offering you this medicine if you would like to take it. Not everyone who has taken this medicine has been protected, but research has shown that taking this medicine does reduce the chance of getting HIV infection after exposure.

I would like to tell you a few things about post-exposure prophylaxis to help you decide if you might want to take the medicine.

The medicine is a pill that you take morning and evening every day for 28 days. For the medicine to work, it is important that you take a pill twice each day, once in the morning and once in the evening. *[Adapt to specific dosing instructions.]*

About half the people who take this medicine experience some side effects. Side effects are unwanted symptoms that you might get from taking a medicine that is meant to help you; for example, a tablet you use to take away a headache might give you heartburn. For post-exposure prophylaxis, the side effects can include nausea, fatigue and headache *[modify depending on the medicine used for PEP]*. Side effects often improve or disappear after a few days, but for some people they don't get better. We will help you if you have severe side effects from this medicine. You need to weigh up the possible benefits – that is, that the medicine might help your body fight the HIV and prevent you from getting the infection – against the possible risks – that is, that you might have side effects. We don't know for sure that taking post-exposure prophylaxis means that you won't get HIV infection, but we think it will help.

To get the full benefit from post-exposure prophylaxis, you must take the pills, at the right times, for the full 28 days. If you change your mind, or if you get side effects that are too unpleasant, you can stop taking them at any time. However, it is best if you contact me, or *[name an appropriate person]*, before you stop taking them, in case there are ways in which we can help you or things that I have not explained clearly that have made you uncertain about whether you want to finish the medicine. If you do decide to take the medicine, you should start straight away.

[If the person is pregnant or there is a possibility of pregnancy:] Some types of post-exposure prophylaxis medicine can be used safely in pregnancy. You would not want to expose your baby to unnecessary medicine, but if you get HIV infection during pregnancy, your baby would have some risk of becoming infected with HIV.

Can you tell me how you feel about all of this? Or perhaps you would like to ask some questions about post-exposure prophylaxis?

Script 3: Adherence counselling

I want to explain to you how to take the medicine you have been prescribed.

Post-exposure prophylaxis medicine works best when the level in your blood stays roughly the same throughout the day. To make this happen, it is important that you take your medicine at regular intervals. In other words, you need to take the dose that you have been prescribed at certain times. For instance, if the medicine needs to be taken twice a day, you should take one dose in the morning, at regular times when you have breakfast or get up, and one in the evening, for example, when you eat dinner or go to bed. For some medicine, there are other instructions: for example, they must be taken with or without food.

These instructions must also be followed.

It is also important that you remember to take each dose. We should think about what you do every day to see if there is anything that might make you miss taking the medicine or if there is anything that might remind you to take it at set times. The full course of medicine is four weeks, so we need to think about what you might be doing over the next four weeks.

I have some tips that might help you take your medicine correctly.

- Use daily life events as cues to take your medicine, such as brushing your teeth or eating meals.
- Establish a set place to take your medicine.
- Try taking medicine with food as this can help to reduce nausea, a common side effect of this medicine. Is food available when you need to take your medicine?
- Consider your work or school patterns and whether taking medicine will mean telling colleagues or family members about post-exposure prophylaxis.
- Think about the days when your routine is different. For example, on weekends, a change in your routine could make you more likely to forget a dose. If you are planning to be out in the evening, it's okay to take a dose a bit early or to take a dose with you.
- Some people find that, when they lie down, although they do not intend to fall asleep, occasionally they do. If you think there is a chance that you might fall asleep if you lie down, you should consider taking the medicine before lying down, even if you do not expect to sleep.
- Set a mobile phone, or some other form of alarm, as a reminder for taking your pills.
- If you feel you can, you could ask family or friends to help you remember to take your medicine.

If you do forget to take your medicine at the right time, you should still take it if it is less than halfway to the time for your next dose. For example, if you usually take your medicine at around 10 in the morning and again at 10 in the evening, but forget the dose at 10 in the morning, you can still take it if you remember to do so before, say 3 in the afternoon. However, if you don't remember until after 4 in the afternoon, then don't take it, but take the next dose at 10 in the evening as usual. Never take a double dose of your medicine.

Speak to your health care worker or doctor if you have any problems or questions.

Script 4: Side-effect counselling

[Adapt according to the specific medicine prescribed and to the availability of clinical follow-up services.]

I want to talk about the post-exposure prophylaxis medicine you will be taking. As for any medicine, you may experience some side effects (unwanted symptoms) caused by the medicine. Not everybody experiences side effects, but about half the people taking PEP do, and these can be worse for some people than for others. Most of these symptoms are mild and will disappear in few days, but you need to know what you should do if you get any of these.

It is important for you to let us, or *[referral centre]*, know if you get any symptoms, because we can usually help you to find a way to reduce these symptoms or we may possibly change your medicine.

[For individuals receiving zidovudine-containing regimens:]

About half the people who take zidovudine experience fatigue, nausea or headache. For most people, these symptoms are relatively mild and improve within a few days. A couple of more serious side effects are associated with taking zidovudine, but these are extremely rare among people taking the drug for only 28 days. One is inflammation of the liver, which is called drug-induced hepatitis, and the other is suppression of the bone marrow, which can cause you to have fewer red or white blood cells. A decrease in red blood cells is called anaemia and can cause fatigue and shortness of breath. A decrease in white blood cells is called neutropaenia, and this can make you more susceptible to certain kinds of infections. As I said before, both of these side effects would be extremely unusual with a 28-day course of medicine, but if they occur, we would expect that both your liver and bone marrow would return to normal after you had finished your course of medicine. However, it is important for you to understand that we cannot guarantee that you will not have serious side effects from taking this medicine. But as far as we know, no one who has taken zidovudine for 28 days has ever had any long-term side effects.

[For individuals receiving stavudine-containing regimens:]

The main side effect you need to be aware of is numbness, tingling or burning in the tips of the fingers and the tips of the toes. This is called peripheral neuropathy. If you experience this symptom for more than a day, please let us know. We can reduce the likelihood of this symptom continuing by either lowering the dose of your medicine or by changing it to something else. The longer this symptom is present, the more likely it is that it will not go away once you stop taking your medicine. So it is very important for you to let us know if you have any numbness or tingling in the tips of your toes or fingers.

[For individuals receiving tenofovir-containing regimens:]

Common side effects include nausea and abdominal discomfort. Tenofovir can cause problems with the kidneys, but this would be very unusual with a 28-day course.

[For individuals receiving a third antiretroviral agent:]

[The specific side effects of that medicine should be described.]

Script 5: Explaining HIV testing in the context of post-exposure prophylaxis

[This information is supplementary to that given to the person as part of standard counselling before HIV testing.]

I would like to explain to you why we would like you to have an HIV test.

Post-exposure prophylaxis will not help a person who already has HIV infection. Although the medicines you would take for it are similar to those used to treat HIV infection, you would be taking less antiretroviral medicine than someone who has HIV infection would need. If a person who has HIV infection takes post-exposure prophylaxis, the virus might develop resistance to the HIV medicines, which means that if a person is given medicine to treat the HIV infection later, the medicine will not work as well. It is important therefore to know whether you are already HIV positive, ideally as soon as possible after you start PEP.

We will give you an HIV test at the same time as we give you your post-exposure prophylaxis medicine or, if you only receive a starter pack, at your first follow-up visit. This first HIV test will not tell us anything about the effect of the exposure you just had. What it will tell us is whether or not you already have HIV infection from previous exposure. If you are already HIV positive, you need to stop taking PEP medicine.

The results of your first HIV test will be available within *[insert time taken for results to become available according to local arrangements for HIV testing]*. We will provide you with your HIV test result as well as counselling and information about the meaning of your results.

[In the case of a rapid HIV test:]

It is very important that you understand that a positive result in a rapid HIV test might not mean that you really are HIV positive. The rapid test is very accurate, but an initial positive test needs to be confirmed with a second rapid test or a standard test. It will take *[insert time taken for results to become available according to local arrangements for HIV testing]* for the result of the second test to come back. You may choose to take PEP while you wait for the confirmatory test result.

If your HIV test is positive, we will be able to refer you to HIV care services. If you need medicine to treat HIV infection, it will be available through *[insert relevant details according to local arrangements for HIV treatment and care]*.

Once you have completed your 28-day course of post-exposure prophylaxis medicine, you should take a second HIV test even if you decide not to use PEP or if you stop taking medicine before you complete a full 28-day course. This follow-up HIV test will tell you whether you got HIV infection from either this exposure or from another exposure incident in the previous few months. If you do take PEP, we strongly recommend that you take a follow-up HIV test in 2–4 months' time and another in 4–6 months' time.

[The interviewer should then complete, or refer the person for, pretest counselling according to the national and/or local standard protocols for HIV testing and counselling.]

ANNEX 3
SAMPLE PATIENT INFORMATION SHEETS

These are sample printed patient information sheets designed to be given to the patient to take away and read at their leisure. Patient information sheets should be regarded supplementing and not replacing verbal information given by the health care provider. The sample sheets presented here may need to be adapted to the literacy and language facility level of the patient group for whom they are intended.

Patient information sheet 1: Occupational exposure

HIV and occupational exposure to blood or body fluids: what you need to know

Several infectious diseases are spread by contact with an infected person's blood or their body fluids or tissues. Hepatitis B, hepatitis C and HIV infection are examples of diseases that are spread in this way. Someone may be infected with one of these viruses without even knowing it – and you may not realize that their body fluids or tissues are infectious.

If you have been exposed to someone's body fluids or tissues – through an accidental needle-stick injury, by performing first aid, as a result of an accident or violence in the workplace or by some other means – it is important that you know what to do to minimize your risk of becoming infected with HIV or any other bloodborne virus.

First aid

Immediately after the exposure, you should take the following steps to clean the site of the exposure to help reduce the risk of infection.

If the skin is broken following an injury with a used needle or sharp instrument:

- Wash the site immediately using soap or a mild disinfectant solution.
- If running water is not available, clean the site with a gel or hand-rub solution.
- Do not use any strong solutions, such as alcohol, bleach or iodine, as these may irritate the wound and make the injury worse.

After a splash of blood or body fluids:

- To unbroken skin:
  - Wash the area immediately.
  - If running water is not available, clean the area with a gel or hand-rub solution.
- To the eye:
  - Wash the exposed eye immediately with water.
  - If you are wearing contact lenses, leave them in place while washing the eye, as they form a barrier over the eye and will help protect it. Once the eye has been cleaned, remove the contact lenses and clean them in the usual way. This will make them safe to wear again.
  - Do not use soap or disinfectant on the eye.
- To the mouth:
  - Spit the fluid out immediately.

- Rinse the mouth thoroughly and spit out again. Repeat this process several times.
- Do not use soap or disinfectant in the mouth.

Risk assessment

After first aid, immediately report the exposure to your supervisor or manager. You should then be released from your duties so that risk can be assessed.

The purpose of the risk assessment is to determine whether you are at risk of getting infected with a virus as a result of your exposure. Most workplace exposure actually carries very little risk. However, if you are assessed to have had significant exposure, you may be able to take post-exposure prophylaxis. "Prophylaxis" is something that you can do or a medicine that you can take that may prevent you from getting an infection or disease. Some types of medicine may help to prevent HIV infection after exposure to HIV. To maximize the effect, however, this medicine should be taken as soon as possible after exposure.

The things you might be asked about during risk assessment include:

- the type and size of the needle or sharp instrument;
- for what purpose the needle or sharp instrument had been used;
- the amount of blood or body fluids or tissues to which you were exposed;
- whether you were injured with a sharp object and whether the wound bled;
- whether the injury was through gloves or clothing;
- when the exposure occurred; and
- your personal risk for acquiring HIV infection.

The possibility of post-exposure prophylaxis may be discussed with you if:

- the exposure was to blood, visibly blood-stained fluid, concentrated virus, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid or amniotic fluid;

and

- the exposure was from a recently used hollow bore needle or other sharp instrument visibly contaminated with blood;

and

- the exposure occurred less than 72 hours previously;

and

- the exposure consisted of:
  - skin penetration with spontaneous bleeding or deep puncture; or
  - a significant amount of splash of fluid to mucous membrane; or
  - prolonged contact of fluid with broken skin.

Post-exposure prophylaxis

If the exposure is assessed to carry sufficient risk, you may be offered post-exposure prophylaxis. It is your choice whether or not you take the medicine. You may be asked to sign a consent form.

If you decide to take post-exposure prophylaxis, you should start it as soon as possible. The medicine you will be given is intended to stop the virus from multiplying in the body, so the earlier they are taken, the more chance they have to be effective. You will need to take PEP for four weeks. You can stop taking it at any time, but if you do, you will not get the full benefit of the medicine.

Before deciding whether or not you want to use post-exposure prophylaxis, you should be given the opportunity to discuss its advantages and disadvantages with your supervisor or a designated health care provider *[adapt according to local protocols]*. Several things need to be discussed with you at that time.

- **How and when to take the medicine**. This may involve asking questions about your living and working conditions. Depending on what is available in your area, you will either be offered the full 28-day course of medicine straight away or you may be given a starter pack containing enough medicine for *[insert as appropriate]* days. Arrangements would then be made for you to see a specialist doctor before you finish this medicine, who would prescribe the remainder of the four-week course.
- **Whether you may be pregnant**. You can take post-exposure prophylaxis if you are pregnant. In fact, if you are pregnant, it is even more important that you take the medicine, as the chance of the HIV infection being passed to your unborn baby if you become infected with HIV as a result of the exposure is quite high.
- **Side effects**. Side effects are unwanted symptoms you may experience while taking the medicine. Some people, for example, feel sick or tired when taking PEP medicine.
- **No guarantee**. You should be made aware of the fact that, although strong evidence indicates that post-exposure prophylaxis may prevent infection with HIV, it is still not guaranteed.

HIV testing and pre-test counselling

A blood test may not reveal the presence of HIV and other bloodborne viruses until several months after exposure. However, it is recommended that you have a test for HIV infection within a few days of exposure. The reason for testing for HIV soon after occupational exposure is to establish a baseline against which to compare future test results. If you are HIV negative at the baseline test but later test positive, it may be possible to show that the occupational exposure caused the infection depending on the time of the infection and on the presence of other risks or exposure incidents.

If you are HIV positive at the baseline test, post-exposure prophylaxis is not appropriate and, if started, should be discontinued. This is to prevent you from developing resistance to medicine that may be needed later to treat HIV infection.

Before being tested, you will be asked to give informed consent. This means that you will be given information – about the advantages and disadvantages of the HIV test – to help you decide for yourself whether or not to take the test. You should receive counselling before blood is taken for testing, during which your risks for HIV infection, personal as well as occupational, need to

be assessed. Due to the sensitive nature of the information discussed, you may wish to have the counselling and blood testing done outside the workplace.

You should also be told how to get the results of the test. The results of HIV blood tests, whether negative or positive, are always given in person – never over the phone, in the mail or to another person. Where facilities for rapid testing are available, the result of an HIV test can be obtained within one hour. If rapid HIV testing is not available, it usually takes 2–3 days to get the result.

Follow-up blood tests for HIV need to be done to show whether you have become infected as a result of exposure. They need to be done three months after exposure and, if PEP was taken, again six months after exposure.

Prevention of transmission

If your exposure was assessed as being significant, you will be given advice about how to avoid transmitting the virus to anyone else until you know for sure that you are HIV negative. You will be advised on how to practice safer sex – and given information on what this means – so you can protect your sexual partners. You will also be told not to share injecting equipment, not to donate blood or tissues and not to breastfeed if there are safe alternatives to exclusive breastfeeding.

Occupational health and safety

Any exposure that occurs in the workplace should be reported and recorded in some way. There are two reasons for this. One is to make sure that you can prove how the exposure occurred if you need to make a claim for compensation, and second, so that steps can be taken to prevent this type of exposure from happening again to another worker.

After any workplace incident, a health and safety review should be conducted to determine whether any unsafe practices or equipment in the workplace need to be changed or improved.

Summary

The risk of acquiring infection following occupational exposure is small. Nevertheless, bloodborne viruses can cause serious health problems. For this reason, should an accident occur, it is important that you know exactly what to do:

- make sure you know how to perform the appropriate first aid;
- always report exposure incidents no matter how trivial you think they are; and
- never perform your own risk assessment; a properly trained person must do this for you.

If you have any questions

To schedule or reschedule an appointment, contact *[insert relevant information]*.

For questions or problems related to your exposure or your medicine contact *[insert relevant information]*.

Patient information sheet 2: Sexual assault exposure

Preventing HIV infection after sexual assault: what you need to know

What is PEP?

Post-exposure prophylaxis is a course of medicine taken to try to prevent HIV infection among people who may have been exposed to HIV as a result of sexual assault. PEP is only effective if taken within 72 hours of the assault. In addition to a 28-day course of medicine to prevent HIV infection, people are given first aid care, counselling and follow-up visits.

What is the risk involved with my exposure?

Determining the exact chance of becoming infected with HIV from a single exposure incident is difficult. Although the average risk of infection from one exposure incident is very small, the actual risk of a given individual from a single specific exposure incident cannot be calculated. Unfortunately, HIV infection can be acquired from a single episode of unprotected sexual intercourse.

The average risk for a single unprotected sexual exposure from a source person known to be HIV positive is as follows. For receptive anal intercourse, the risk is between 1% and 5% (1–5 in 100) and, for receptive vaginal intercourse, between 0.1% and 1% (between 1 in 1000 and 1 in 100). The risk from receptive oral sex with ejaculation is even lower, although transmission can happen this way.

To put these figures in perspective, health care workers who experience a needle-stick injury have a risk of getting infected of about 0.3% (3 in 1000). Post-exposure prophylaxis is generally recommended in such cases. The infection risk associated with blood splashes to the eye or mouth is lower, about 0.03% (3 in 10 000). Although PEP may be offered for exposure of this type, it is not generally recommended because the risk is so small.

What do we know about the effectiveness of post-exposure prophylaxis?

We do not know for sure whether post-exposure prophylaxis will prevent HIV infection following sexual exposure, as people who have taken PEP after sexual exposure to HIV have not been studied yet. However, it has been shown to be effective in some related situations. For example, one study showed that using zidovudine among health care workers with needle-stick injury after the incident reduced the risk of getting HIV infection by about 80%. Zidovudine has also been given to pregnant women living with HIV to prevent their unborn babies from getting HIV infection. Several studies have found that babies whose mothers take zidovudine are about two thirds less likely to get HIV than those whose mothers do not. Babies who are given zidovudine (or other similar medicines) directly at birth are also much less likely to become HIV infected. Results of tests in animals also suggest that post-exposure prophylaxis medicine can help to prevent HIV infection but that the medicine works best if started as soon as possible after exposure. There is probably no benefit to using PEP medicine if the exposure happened more than 72 hours before.

How can I stay HIV negative?

Although the chance of getting HIV from a single sexual act is relatively low, the most helpful thing you can do is to avoid becoming infected with HIV is to not have unsafe sex. Safe sex (also

called safer sex or protected sex) is a set of practices that are designed to reduce the risk of infection during sexual activities to avoid developing sexually transmitted infections, including HIV. Conversely, unsafe sex refers to engaging in sexual activities without the use of any barrier contraception or other measures to prevent the transmission of sexually transmitted infections. You should also avoid sharing needles to inject drugs.

How does the post-exposure prophylaxis programme work?

[Adapt according to local programme arrangements.]

The first time we see you, we will ask you questions about the circumstances of the sexual assault to ensure that you would benefit from post-exposure prophylaxis. We will then talk to you about taking an HIV test. A health care worker will take your health history, examine you and evaluate whether you have been exposed to the risk of HIV infection.

If you are considered to be at risk of getting HIV infection as a result of the exposure, you will be offered a 28-day course of PEP medicine. At your first visit, you will given enough medicine to last you until your second appointment, which will be usually be within *[insert as appropriate]* days of the first appointment.

We will also help you to make arrangements to see an HIV counsellor and to get your HIV test results. At this time, your counsellor or health care provider will talk more about the steps you can take to help you avoid transmitting HIV in the unlikely event you do become infected as a result of your recent exposure and how you can avoid HIV infection in the future. The counsellor or health care provider will want to ensure that you are taking your medicine correctly and tolerating it well.

At your second appointment, assuming you were initially prescribed a starter pack, you will be given the rest of your course of medicine. The results of other tests you may have had will also be reviewed. You may be referred for more counselling or to other services that might help you. If you need or want to, you can see the HIV counsellor or health care provider again. Contact details are given at the bottom of this information sheet.

You will be asked to return for another HIV test in six weeks, in three months and again in six months *[modify as appropriate]*. This is to ensure that you have stayed HIV negative. If, however, you should become HIV positive, we will offer you both health care and further support.

What other resources are available?

[Modify according to local availability.]

We can refer you to a variety of counselling services and mental health programmes, legal services and other resources. We can assist you in accessing these services. Please let us know whether there is any other way we can help you.

If you have any further questions

For questions or problems related to this programme or your medicines, call *[insert relevant details]*.

Contact details

To schedule or reschedule an appointment, contact the clinic at *[insert relevant details]*.

Patient information sheet 3: post-exposure prophylaxis starter packs

Use of post-exposure prophylaxis starter packs: patient information

You have been started on post-exposure prophylaxis to prevent HIV infection and supplied with a starter pack containing enough pills for *[insert as appropriate]* days. You are advised to take these pills every day as prescribed, without missing a dose.

The full course of PEP is 28 days (four weeks). To continue your course of PEP, please contact:

_____
[insert name of doctor or clinic to which the patient will be referred]

before these pills run out. It is best to make your arrangements to obtain more pills on the first working day after you start post-exposure prophylaxis.

When you go to the doctor or the clinic to collect your prescription, you will be asked to attend for a routine follow-up appointment, which may include some blood tests and medical examinations.

You are also advised to have a test for HIV (if not available on site) as soon as possible and at the latest within the next few days.

HIV testing and counselling is available at:

_____
[insert name of service]

If you need more information, if you are unsure about taking PEP or if you experience any unexpected side effects, please contact:

_____
[insert name and contact details of relevant health care provider]

Patient information sheet 4: post-exposure prophylaxis medicine

The content of this patient information sheet applies to the two named medicines only (zidovudine and lamivudine). It is intended to serve as an example only and should be adapted to whatever post-exposure prophylaxis medicine regimen is available locally.

Zidovudine and lamivudine combination tablet: patient information

What is post-exposure prophylaxis?

Post-exposure prophylaxis is a course of medicine that can be taken after possible exposure to the HIV virus to help prevent infection. Prophylaxis, in this case, means medicine that you can take to protect you from getting the HIV infection.

Does post-exposure prophylaxis prevent people from getting HIV after being exposed to HIV?

Post-exposure prophylaxis may be helpful in preventing people from getting HIV infection after an exposure, but it is not guaranteed to work for everyone. It is effective only if you take the medicine soon after exposure and regularly for 28 days.

Which post-exposure prophylaxis medicine will I be taking?

The post-exposure prophylaxis medicine you will be taking is a combination pill containing two medicines, zidovudine and lamivudine.

How should I take my medicine?

The combination pill may be taken with or without food but will probably be less likely to cause an upset stomach if it is taken with food. Take one pill twice a day, one in the morning and one in the evening, for 28 days.

Why is it important to take my medicine correctly?

Anti-HIV medicine works best if it is kept at a constant level in the bloodstream. Post-exposure prophylaxis medicine will not work as effectively if it is used at lower than the recommended doses, if doses are skipped or if it is not taken at regular intervals. This is why taking this medicine as instructed above is especially important.

Do these medicines interact with other medicines?

The zidovudine + lamivudine combination pill does not interact with any commonly known medicines.

What are the possible side effects of these medicines?

The most common unwanted side effects of the zidovudine + lamivudine combination pill are fatigue or tiredness, nausea and headache. About half the people who take this medicine might have one or more of these symptoms for a few days. These symptoms usually go away by themselves. More rare side effects include anaemia (which can make you feel weak or out of breath) and changes in the liver. All of these are very rare among people only taking 28 days of medicine, and if they do occur, they will improve once the medicine is stopped.

If you need assistance please contact:

_____
[insert name and contact details]

ANNEX 4: INDICATORS FOR EVALUATING HIV POST-EXPOSURE PROPHYLAXIS PROGRAMMES

Important factors to consider in developing a system for monitoring and evaluating post-exposure prophylaxis provision are the objectives of the evaluation, the end-users of the results and the costs. The sets of indicators proposed below are designed to evaluate PEP programme performance and are grouped for convenience according to programme resources (inputs), outputs and outcomes.

In the table, the indicators that can be used at the national level are italicized.

Programme area	Indicator
Inputs	
Resources	• Percentage of estimated needs funded
Human resources	• National coordinator trained and in charge of the programme • Number of local coordinators trained and in charge
Outputs	
Policy development	• *Post-exposure prophylaxis included in the national or regional policy on HIV prevention* • Post-exposure prophylaxis included in local HIV protocol • *Post-exposure prophylaxis included in the national and local occupational health policy* • *Post-exposure prophylaxis included in the national policy on care for people who have been sexually assaulted* • Monitoring and evaluation plan included in PEP policy
Training	• Post-exposure prophylaxis included in academic and on-the-job training curricula of health care workers • Number of training programmes developed, implemented and evaluated • Number and percentage of care providers trained in providing PEP services (by category)
Post-exposure prophylaxis services	• Number and percentage of PEP sites delivering post-exposure prophylaxis according to protocol • Number of post-exposure prophylaxis sites linked to HIV testing and counselling sites or directly providing HIV testing and counselling

Programme area	Indicator
Coverage	• *Percentage of district facilities offering post-exposure prophylaxis services* • Percentage of primary, secondary and tertiary facilities with PEP medicine available on site • The number and percentage of districts with at least one health facility providing PEP and HIV testing and counselling • Number of post-exposure services provided/number of requests for services • Percentage of people prescribed PEP starter pack who return for the complete course of medicine • Percentage of people prescribed PEP who take the full course of medicine • Percentage of people who have baseline and follow-up HIV testing
Outcomes	
Knowledge	• Public and worker awareness of post-exposure prophylaxis availability • Health care provider awareness of eligibility for PEP and programmes • Proportion of health care workers with knowledge of the reporting and referral system in case of exposure
Behaviour	• Number of people reporting sexual assault or occupational exposure • Number of people seeking services for PEP • Percentage of people seeking PEP and eligible for post-exposure prophylaxis medicine • Percentage of people accepting PEP • Percentage of people eligible for post-exposure prophylaxis and receiving it • Satisfaction with post-exposure prophylaxis services • *Proportion of people taking the full course of PEP medicine* • Proportion of people accepting testing and counselling at first visit or returning for testing and counselling • Proportion of people who have been exposed and undergoing HIV testing after three months and six months • Proportion of people who have been exposed, received PEP and taken HIV testing after three months and six months

Programme area	Indicator
Attitudes	• Reported stigma and discrimination experienced in PEP services
Efficacy	• Proportion of individuals who became infected (seroconversion) tested 3–6 months after exposure despite taking PEP according to protocol and risk reduction counselling • Number of people reporting sexual assault or occupational exposure • Percentage of people seeking post-exposure prophylaxis and eligible for PEP medicine • Proportion of people accepting PEP • *Proportion of PEP services delivered for occupational versus non-occupational exposure* • Satisfaction with PEP services • *Proportion of people who adhere to and take the full course of PEP* • Proportion of people accepting testing and counselling at first visit or returning for testing and counselling • Proportion of people reporting on reducing high-risk behaviour after PEP counselling

ANNEX 5 SAMPLE CHECKLISTS FOR THE CLINICAL MANAGEMENT OF HIV POST-EXPOSURE PROPHYLAXIS

Services	Day 0[a]	Day 3[b]	Week 4	Month 3	Month 6
1. Immediate management steps					
• First aid	X				
• Reporting and relief from duty	X				
• Exposure risk assessment	X				
If the exposure is assessed as being significant, proceed with services 2–7. If the exposure is assessed as low risk or if PEP is declined, offer services 5 and 7 only.					
2. Post-exposure prophylaxis discussion and counselling					
• Discuss post-exposure prophylaxis	X				
• Obtain informed consent	X				
• Give first dose of PEP medicine	X				
3. Source testing and risk assessment					
• Obtain consent for HIV testing or information on HIV treatment history	X				
• Conduct rapid HIV testing (if available)	X				
• Conduct risk assessment (consider window period, population prevalence and high-risk behaviour)	X				
If the source person is subsequently revealed to be HIV negative, discontinue PEP.					

Services	Day 0[a]	Day 3[b]	Week 4	Month 3	Month 6
4. Post-exposure prophylaxis prescription					
• Confirm eligibility for PEP	X				
• Assess prior HIV risk	X				
• Dispense PEP medicine	X	X (if a starter pack is given)			
• Conduct adherence counselling	X	X	X		
• Conduct side-effect counselling	X	X			
• Consider likelihood of pregnancy	X				
5. HIV testing and counselling					
• Conduct HIV counselling and testing with informed consent (arrange a further visit to obtain results when they are available)d	X	X (if not done at day 0)		X	X (if PEP medicine is taken)
• Consider counselling and support for significant others	X	X		X	
• Give advice on how to prevent transmission	X	X			
Anyone found to be HIV positive should be referred for treatment and support, and PEP, if commenced, should be discontinued. PEP medicine should not be prescribed to HIV-positive individuals.					

Services	Day 0[a]	Day 3[b]	Week 4	Month 3	Month 6
6. Other laboratory testing					
Conduct other testing (as appropriate) for:					
• pregnancy	X		X		
• hepatitis B and/or C antibodies	X			X	X
• haemoglobin			X		
7. Follow-up					
• Provide ongoing support		X	X	X	X
• Provide referrals, as appropriate	X	X	X	X	X
• Review symptoms		X	X	X	
• Conduct occupational health and safety review		X			
8. Post-sexual assault examination					
• Perform physical examination	X				
• Collect forensic specimens	X				

a On presentation.
b Assumes that a three-day PEP starter pack is given *[modify to reflect local prescribing protocol].*
c If PEP is declined, offer services 5, 6 and 7 only. Add 8 if PEP services are provided after sexual assault.
d A further HIV test at six weeks is optional.

ANNEX 6 POST-EXPOSURE PROPHYLAXIS FOR HIV INFECTION: GENERAL RECOMMENDATIONS ON REGIMEN

The following table gives an overview of current recommendations governing the use of post-exposure prophylaxis to prevent HIV infection in individuals who may have been exposed to HIV, according to the type of exposure and the HIV status of the person who is the source of exposure.

Exposure type	HIV positive	Unknown HIV status
Percutaneous: more severe[a]	Offer a two-drug regimen[b]	Consider population or subgroup prevalence
Percutaneous: less severe[c]	Offer a two-drug regimen	Do not offer PEP
Sexual	Offer a two-drug regimen[b]	Consider population or subgroup prevalence
Splash[d]: more severe[e]	Offer a two-drug regimen[b]	Consider population or subgroup prevalence
Splash: less severe[f]	Post-exposure prophylaxis is not recommended, but a two-drug regimen may be offered on request	Do not offer PEP

Negative HIV status: do not offer post-exposure prophylaxis if there is no risk that the source person is in the window period. The window period is a period of several weeks in which newly infected people do not produce enough HIV antibodies to give a positive result in most standard tests for HIV infection. An HIV test conducted during this first stage of HIV infection is likely to give a negative result. However, at this time the virus is developing in the body and can be transmitted to others. For HIV, the window period is about 22 days.

[a] Examples include injury with a large hollow-bore needle, a deep puncture and contact with visible blood on a device or a needle used in artery or vein.

[b] If an HIV-positive source has known or suspected resistance to antiretroviral therapy or if the background prevalence of antiretroviral therapy resistance in the community is more than 15%, three drugs (two nucleoside reverse-transcriptase inhibitors plus a protease inhibitor) should be offered.

[c] Examples include injury with a small-bore or solid needle and a superficial injury.

[d] Includes exposure to non-genital mucous membranes or to non-intact skin.

[e] Examples include exposure to a large volume of blood or semen.

[f] Examples include exposure to a smaller volume of blood or semen or to less infectious fluid (such as cerebrospinal fluid).

Source: adapted from: Panlilio AL et al. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for post-exposure prophylaxis. *Morbidity and Mortality Weekly Report (MMWR)*, 2005, 54(No. RR-09):1–17.

ANNEX 7
SAMPLE DOCUMENTATION TEMPLATES

The templates below are designed to be adapted to suit local conditions. They contains the most important elements of the patient's health history, results of physical examination and risk assessment and the care plan that need to be documented to support responsible provision of post-exposure prophylaxis. Template 1 could be used as a consent form and checklist for PEP providers, template 2 for registering patient data at the facility level. These data could be compiled into a national registry. Additional information, such as details of vaccinations and follow-up of any abnormal test results, may be added as appropriate.

Template 1: Consent form and checklist for post-exposure prophylaxis

Name _____ **Record number** _____

I understand that I have had an exposure incident that may be a risk for HIV transmission.

I have been given the following information relating to the use of post-exposure prophylaxis:

- the risk of HIV transmission with and without it;
- the benefits and risks of taking post-exposure prophylaxis;
- the use of post-exposure prophylaxis during pregnancy;
- the risks of taking post-exposure prophylaxis if I already have HIV before this exposure;
- that post-exposure prophylaxis is not guaranteed to prevent HIV transmission;
- the possible side effects of the post-exposure prophylaxis medicine;
- the benefits of HIV testing: now and again at three and six months;
- other recommended blood tests;
- that the usual course of post-exposure prophylaxis is four weeks and that I can stop at any time, although this will reduce the effectiveness;
- the importance of taking the correct dose of the medicine at the right time;
- the importance of taking precautions to prevent HIV transmission (such as using condoms and not sharing needles) for the next six months;
- not to donate blood, semen or body tissues for the next six months; and
- *[for health care workers:]* any safe work practices necessary for the next six months.

I have understood this information and have been given the opportunity to ask questions and have received satisfactory answers.

☐ I voluntarily consent to post-exposure prophylaxis.

☐ I decline post-exposure prophylaxis.

Name _____ **Signature** _____
[The signature is optional, as WHO recommends not to request signed consent.]

Date _____

I confirm that I have provided information about post-exposure prophylaxis as listed above.

Name _____ **Signature** _____

Position _____ **Date** _____

Template 2: Patient registry card data

Patient details

ID/patient card no.: ☐☐ ☐☐☐☐

Date of first visit: ☐☐/☐☐/☐☐☐☐

Date of exposure: ☐☐/☐☐/☐☐☐☐

Time of exposure (range): ☐☐:☐☐ – ☐☐:☐☐

Hours between exposure and post-exposure prophylaxis:

_____

Exposure type:

☐ Occupational ☐ Non-occupational

☐ Receptive vaginal ☐ Receptive anal

☐ Receptive oral with ejaculation

☐ Sharps injury (instrument):

_____

☐ Other (such as mucous membrane splash)

_____

HIV status of source person:

☐ Known positive ☐ Unknown

Antiretroviral therapy history of source person:

☐ None or unknown ☐ Yes (describe)

_____

Date of last HIV test: ☐☐/☐☐/☐☐☐☐

Result of last HIV test:

☐ Positive* ☐ Negative

Other exposure incidents in past six months (number and type):

_____

Health history

Pertinent past health history:

_____

Alcohol use:_____

Drug allergies: ☐ None known ☐ Yes

If yes, specify: _____

Current medicine taken: _____

_____

Age (years): _____ Sex: ☐ F ☐ M

Symptoms (if status unknown)*

Signs of possible acute HIV infection (include duration):

_____

Evaluated or referred for evaluation:

☐ Yes ☐ No

Clinical assessment* Thrush: ☐ Yes ☐ No

Lymphadenopathy: ☐ Yes ☐ No

Kaposi sarcoma: ☐ Yes ☐ No

Other: _____

Risk assessment and care plan

HIV exposure confirmed and seeking post-exposure prophylaxis

Post-exposure prophylaxis medicine:

☐ Zidovudine + lamivudine one oral tablet twice daily or ☐ Other _____

☐ Reviewed with patient: drug information, adverse events, emergency phone numbers, medicine adherence and use of alcohol

☐ Follow-up appointment made

☐ Sexually transmitted infection treatment

☐ Emergency contraception

Laboratory tests ordered:

☐ HIV test

☐ HIV positive (refer for counselling and evaluation)

☐ HIV negative

Pregnancy test result:

☐ Positive ☐ Negative ☐ Not available

☐ Other (specify): _____

☐ Referrals: _____

Notes: _____

Signature: Date:

_____

* Please note that, if the test is positive or if there is any clinical symptom of HIV infection at the preliminary visit, post-exposure prophylaxis should not be proposed and the patient should be referred to a treatment centre.

Photograph: Gideon Mendel/The International HIV/AIDS Alliance/Corbis

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