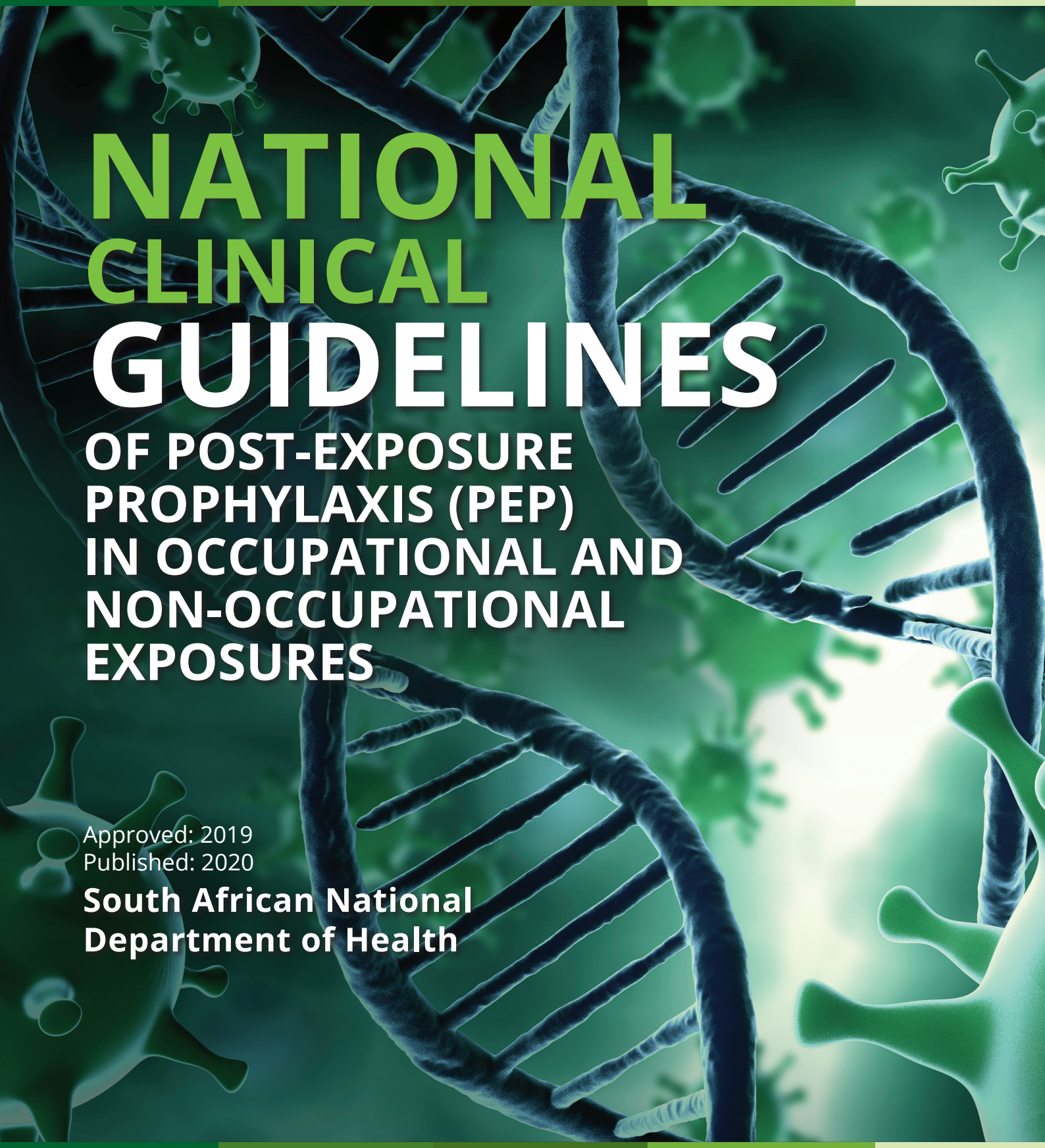

NATIONAL CLINICAL GUIDELINES

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

Approved: 2019
Published: 2020

South African National Department of Health

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Health
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Guidelines on the Management of Post-Exposure Prophylaxis (PEP) in Occupational and Non-Occupational Exposures

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Civitas Building, 222 Thabo Sehume St.
CBD Pretoria, 0001
012 395 8000
http://www.health.gov.za

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FOREWORD

The risk of contracting HIV and hepatitis B through occupational and non-occupational exposure, as well as the high incidence of unplanned pregnancies and sexual assault, mandated the development of an accessible and evidence-based post-exposure prophylaxis (PEP) guideline for South Africa.

The National Department of Health to this end has revised the 2007 PEP guidelines to ensure that a patient-centred, high-quality PEP service is available at all public health facilities and that this service responds to the Criminal Law (Sexual Offenses and Related Matters) Amendment Act 32 of 2007.

The 2019 PEP guideline has considered relevant national and international evidence-based recommendations and further aligned with the current Essential Medicines List recommendations and the most readily available, accessible, and tolerated prophylactic regimens.

It provides guidance for clinicians, managers, and trainers on the use of PEP for the prevention of HIV, hepatitis, unplanned pregnancies, STIs, and tetanus, within the context of a comprehensive care package that supports both the clinical and psychosocial aspects of post-exposure prophylaxis management.

The National Department of Health would like to express its commitment to providing the resources and support required for the implementation of these guidelines and to ensure that no client requiring PEP leaves a facility without being offered a comprehensive package of PEP related care.

Implementation of these guidelines will increase access to PEP services, align towards National Health Insurance and promote the departmental vision of A LONG AND HEALTHY LIFE FOR ALL.

Dr A Pillay

Acting Director-General: Health

November 2019

ACRONYMS

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine aminotransferase
HCVAb	Hepatitis C antibody
ART	Antiretroviral therapy
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
CHWs	Community health workers
d4T	Stavudine
DRV/r	Darunavir/ritonavir
EC	Emergency contraception
EFV	Efavirenz
ELISA	Enzyme-linked immunosorbent assay
FBC	Full blood count
FTC	Emtricitabine
HBIG	Hepatitis Immunoglobulin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCW	Healthcare worker
HIV	Human Immunodeficiency Virus
HTS	HIV testing services
LPV/r	Lopinavir/ritonavir
M&E	Monitoring and evaluation
NDOH	National Department of Health
NIDS	National Indicator Datasets
NNRTI	Non-Nucleoside Analogue Reverse Transcriptase Inhibitor
NVP	Nevirapine
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PHC	Primary health care
PLHIV	People living with HIV
RAL	Raltegravir
RPR/TP Ab	Rapid plasma reagin Treponema pallidum antibody
RPV	Rilpivirine
PrEP	Pre-exposure Prophylaxis
SAHIVCS	Southern African HIV Clinician Society
STI	Sexually transmitted infection
TDF	Tenofovir
WHO	World Health Organization

DEFINITIONS OF TERMS

Term	Definition
Acute infection	The period in which an individual becomes HIV-infected and before HIV antibodies can be detected by a serological assay
Adolescent	Young person aged 10 to 19 years, inclusive
Adult	A person older than 19 years
Antiretroviral (ARV)	Antiretroviral drugs refer to the medicines active against HIV
Antiretroviral therapy (ART)	ART refers to the use of a combination of three or more antiretroviral (ARV) drugs to achieve viral suppression and is given for life
Child	The age by which a child is defined differs according to the the context for which the child is seeking services. For example, definitions may vary for a case of sexual assault, or a girl seeking access to TOP, HIV testing, contraception or other services. The appropriate definition should be determined on a case-by-case basis depending the individual's care needs
Healthcare provider	Anyone who renders healthcare; including doctors, nurses, pharmacists, trained counsellors, and community health workers (CHWs)
HIV status	It refers to reports of HIV-positive, HIV-negative, or HIV-inconclusive based on test results
HIV Testing Services (HTS)	HTS describes a process initiated by an individual who wants to learn his or her HIV status. All forms of HIV testing and counselling should be voluntary and adhere to the five C's: consent, confidentiality, counselling, correct test results, and connections to care, treatment, and prevention services. Quality assurance of both testing and counselling is essential in all approaches to HIV testing and counselling.
Infant	A child younger than one year of age, including unborn children in the context of prevention-of-mother-to-child transmission
Post-exposure prophylaxis (PEP)	Preventive medical treatment started immediately after exposure to an infectious agent to prevent infection.
Pre-exposure prophylaxis (PrEP)	The use of antiretroviral drugs by HIV-negative people before potential exposure to prevent the acquisition of HIV. Currently, PrEP refers to daily oral PrEP (tenofovir/emtricitabine or tenofovir alone) but may incorporate other formulations over time.
Use of ARV drugs for HIV prevention	Refers to the HIV prevention benefits of using ARV drugs, including: • preventing vertical transmission of HIV by treating the mother during pregnancy and breastfeeding, • using ARV drugs to reduce the transmission of HIV among serodiscordant couples, • using ARV drugs to prevent people from acquiring HIV when they are exposed to HIV (PEP and PrEP), and • ART for HIV-positive individuals to reduce viral load.

INTRODUCTION

Background and context

HIV represents the primary burden of disease in South Africa, with an estimated national prevalence of 12,6% in 2017.[1] The HIV annual incidence among individuals aged 15 to 49 years is estimated at 1,27% and 1,20% among youth aged 15 to 24 years.[2] South Africa had 3,7 million people living with HIV (PLHIV) on antiretroviral treatment (ART) in the public and private sectors at the end of June 2016, making it the largest treatment programme in the world. This is 50% of the 7 million people currently estimated to be living with HIV in South Africa.[2]

Hepatitis B virus (HBV) is also an important public health issue in South Africa. The introduction of the HBV vaccine into the country in 1995 has had demonstrated benefit, but the exposure to, and prevalence of chronic Hepatitis B surface antigen (HBsAg) positivity remain unacceptably high. There is currently no nationally representative HBV prevalence survey, but a systematic review based on observational studies performed in the general population amongst blood donors, healthcare providers, and pregnant women between 1965 and 2013, reported that South Africa had an estimated 6,56% HBsAg seroprevalence.[3] The high prevalence of these diseases in South Africa is cause for concern as many populations are at a high risk of acquiring HIV and HBV following exposure to blood or other bodily fluids.

The risk of transmission following occupational exposure by means of a sharps injury is highest for HBV (30%), followed by HCV (1 - 2%) and HIV (0,3%). It has been estimated that globally 66 000 HCWs have been infected with HBV through occupational exposure.[4]

According to the South African Demographic and Health Survey, 2016, around 20% of pregnancies in women aged 15 - 49 years are unwanted.

This guideline aligns with the South African Primary Healthcare Level Essential Medicines List (2019), the WHO PEP guidelines (2014) and the Southern African HIV Clinicians Society guidelines (2015), promoting simplification and adherence support to individuals receiving PEP.

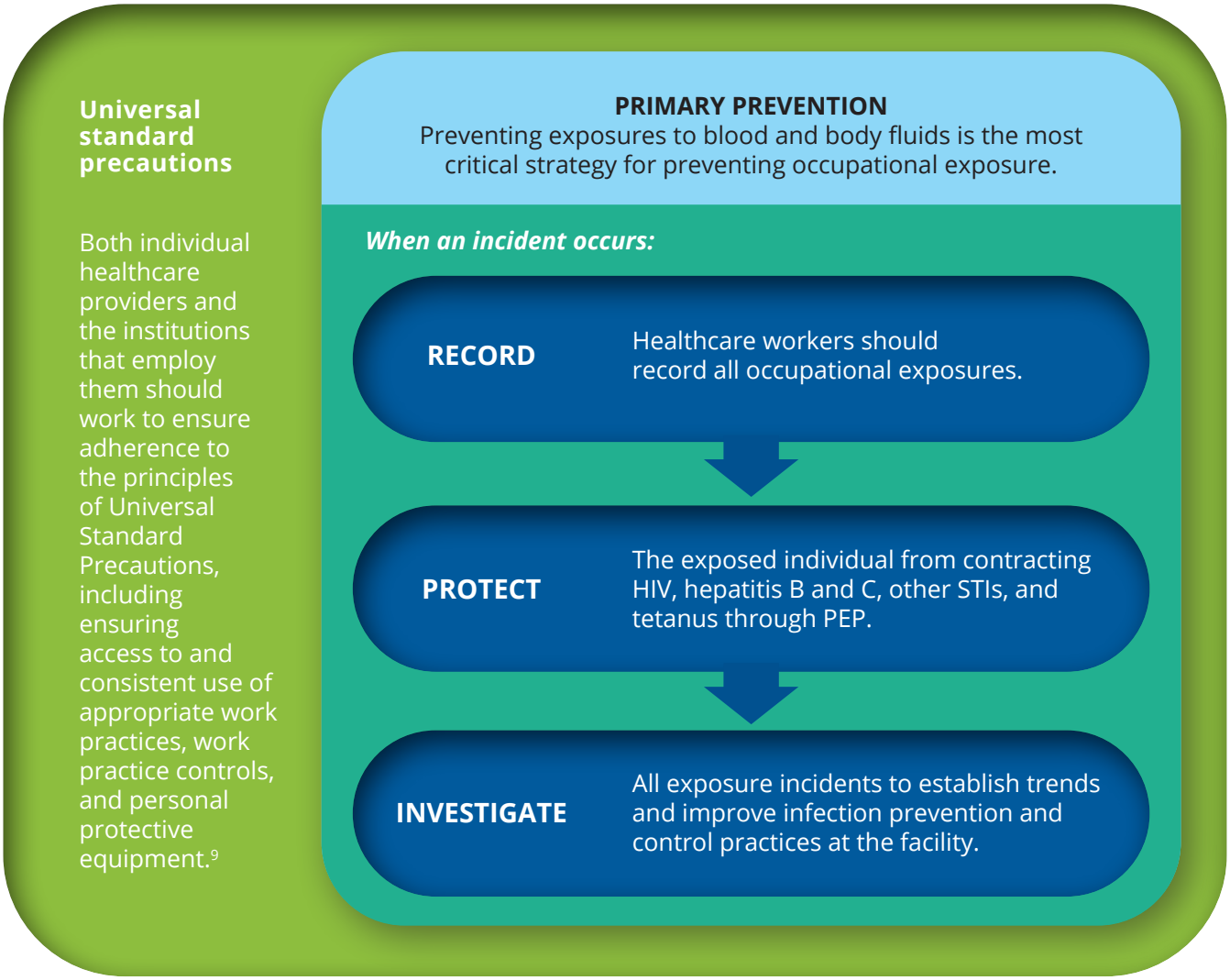
This Guideline is designed to be used in conjunction with:

- *The Patients' Rights Charter*
- *National Management Guidelines for Sexual Assault Care* (2003)
- *National Health Act* (No. 61 of 2003)
- *Termination of Pregnancy Amendment Act* (No. 38 of 2004)
- *Children's Act* 2005 (No. 38 of 2005)
- *Department of Health's National Sexual Assault Policy* (2005)
- *National Comprehensive STI Clinical Management Guidelines* (2017)
- *National Contraception Clinical Guidelines: A companion to the National Contraception and Fertility Planning* (2012)
- *National Department of Health Directives and Instructions on conducting a Forensic Examination on Survivors of Sexual Offence Cases* (2012)
- *National Guidelines for the management of Viral Hepatitis 2019*
- *National HIV Testing Services Policy* (2016)
- *Guidelines for Expanding Combination Prevention and Treatment Options: Oral Pre-Exposure Prophylaxis (PrEP) and Test and Treat* (T&T) (2016)
- *The South African National Sex Worker HIV Plan* 2016 – 2019
- And all other relevant legislation

These updated recommendations are based on systematic reviews of the effectiveness of PEP suggesting that the use of antiretroviral (ARV) drugs following occupational and non-occupational exposure reduces the risk of acquiring HIV infection when administered as PEP and is likely to be cost-effective in high-risk groups.[5, 6] The efficacy of ARV drugs in preventing HIV infection following exposure is further supported by the effectiveness of ARV drugs in preventing mother-to-child transmission of HIV and, more recently, pre-exposure prophylaxis (PrEP).[7]

Yet, WHO cautions *"As with any prevention intervention, effectiveness depends critically on high levels of adherence and completion of the prescribed course. Other factors that may influence PEP effectiveness include the timing of initiation, level of exposure risk, and possible drug resistance. Given these considerations, PEP may never be considered 100% effective, and PEP should form part of a* ***wider strategy for avoiding acquiring HIV infection and other blood-borne viruses****, including hepatitis B virus and hepatitis C virus."*

A wider strategy is illustrated in the figure below and should include universal standard precautions and primary prevention of occupational exposures. If these mechanisms fail, the exposed individual must be protected through PEP, and the incident should be documented and investigated to determine how similar incidents can be prevented in the future.



South African context

South Africa introduced PEP in the public sector in 2002. Previous guidelines differentiated between occupational and non-occupational exposures. Given the very high background prevalence of HIV infection in Southern Africa, HIV exposure risk outside the occupational setting is high, and the distinction between occupational and non-occupational exposure is less helpful for decision-makers. The generalised nature of the epidemic creates differences in risk group demographics that must be accommodated by local PEP guidelines.

For these reasons, these recommendations do not distinguish between types of exposure, population, or occupational and non-occupational settings. To improve access and completion rates for PEP, ***the same drug regimen is recommended, irrespective of exposure source.*** Although there is no difference in approach to offering PEP for occupational and non-occupational exposures, the health needs of the exposed individuals should never be compromised. PEP provision should be carried out in the context of the standard of care appropriate for the presentation of the exposed individual.

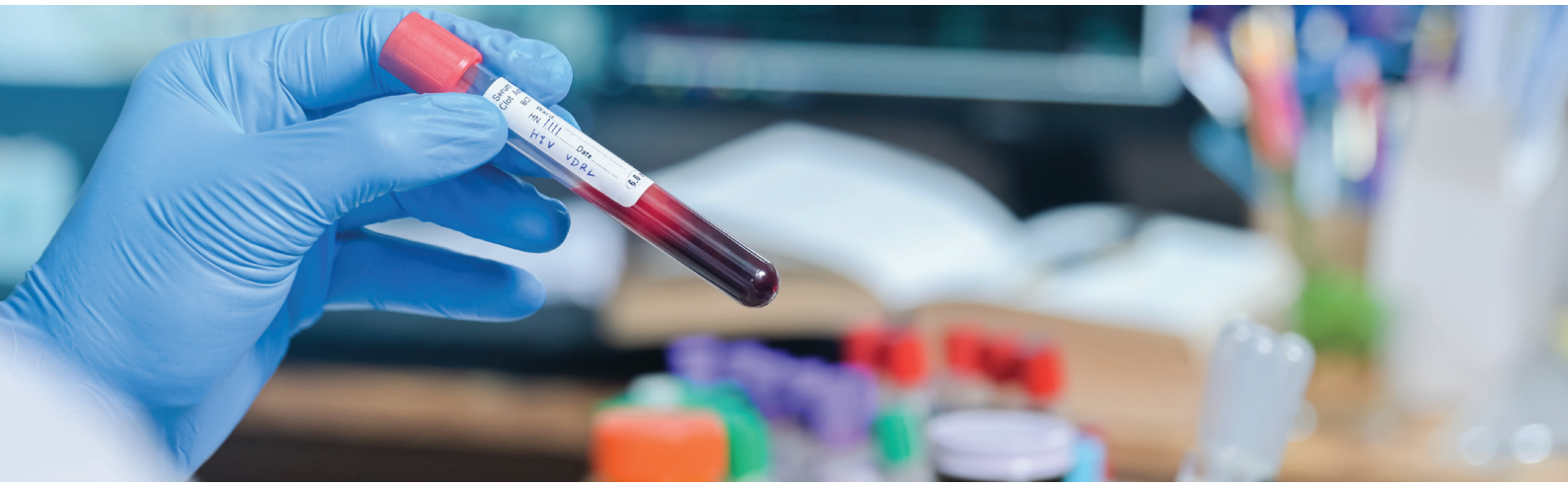
Sexual assault is rampant in South Africa. Although crime statistics can reveal how many sexual assaults are reported to the police, they do not tell us how many are actually committed, and consequently, few receive PEP. The threat of HIV transmission is considerable in non-consensual intercourse, or sexual assault, due to injuries sustained by the victim. This is especially true for child victims who may suffer repeated abuse and more severe genital and rectal injuries. Abrasions and lacerations (broken skin) have been found in 22% to 90% of patients reporting sexual assault.[10]

The health needs of the client are paramount in post-rape care. This includes the need for HIV and hepatitis prevention and treatment, as well as immediate and long term psychological support, pregnancy prevention, and treatment for STIs.

There are almost no data on other forms of exposure; however, the continued high incidence and prevalence of HIV in South Africa amongst the general population suggests that exposure is ongoing and high risk.

Purpose of the guidelines

The purpose of this guideline is to ensure that healthcare providers at all levels of care in South Africa are following the most up-to-date recommendations for post-exposure prophylaxis for HIV and HBV, following either occupational or non-occupational exposure to blood or bodily fluids. Application of these guidelines by health care workers will improve access and adherence to PEP. Additionally, recommendations for PEP for sexually transmitted infections (STIs), tetanus, and the prevention of unwanted pregnancies are also provided.



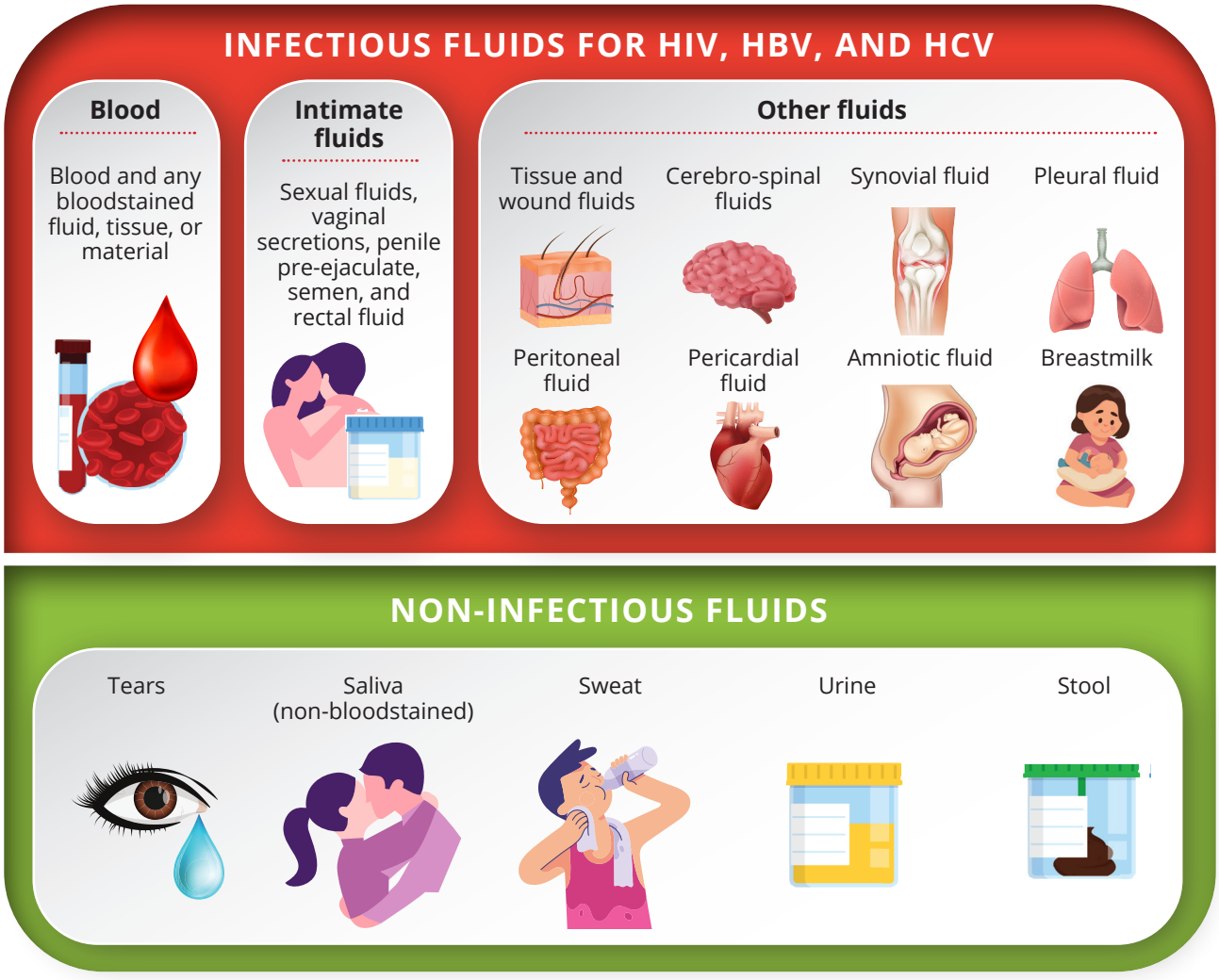
SECTION 1

EXPOSURES THAT POSE A RISK OF HIV, HBV OR HCV TRANSMISSION

To understand if an exposure poses a risk for HIV, HBV or HCV infection, it is important to differentiate between infectious and non-infectious body fluids, as well as the type of exposure. Box 1 below outlines which fluids are infectious and which are non-infectious. Box 2 outlines the types of exposures of an occupational, sexual, or inadvertent nature that may bring a person into contact with infectious fluids.

The risk of transmission from exposure to infectious fluids is associated with several factors, including the presence of blood in fluid; the amount of blood; type of injury; duration of exposure; the viral load and clinical state of the infected source person (increased risk with increased viral load); and the immune status of the "recipient". Other factors that influence the risk of transmission include the type of sexual penetration, with a higher risk being associated with receptive anal and vaginal intercourse.

Box 1.1 Infectious vs non-infectious fluids



Box 1.2 Types of exposure to infectious body fluids

Occupational exposure

- Needle-stick injuries
- Deep percutaneous sharps injuries
- Splashes of blood or body fluids onto mucous membranes of eye/nose/mouth
- Exposure of non-intact skin to blood or body fluids

Sexual exposure

- Sexual assault involving vaginal or rectal penetration
- Unprotected consensual intercourse
- Burst condoms

Inadvertent exposure

- Sharing needles during recreational intravenous drug use
- Accidental injuries with improperly disposed of medical waste/needles
- Contact with used condoms
- Human bites (risk for HBV only, not HIV)
- Contact sports with blood exposure
- Roadside assistance at motor vehicle accidents (contact with bodily fluid and non-intact skin)
- Expressed breast milk from another mother given to infant unintentionally, or breastfeeding of infant of another mother
- Pre-mastication of food if sores in mouth of person chewing food (this practice must be discouraged)
- Violent assaults, including knife attacks and bullets travelling through one person and lodging in another
- Animal attacks with repeated blood exposures on several people at once
- Tattooing

Adapted from the following Guidelines:

Guideline on the management of occupational and non-occupational exposure to the human immunodeficiency virus and recommendations for post-exposure prophylaxis: 2015 Update. Southern African Journal of HIV Medicine. Vol 16, No 1.a399

The Western Cape Guidelines for the Management & Post-Exposure Prophylaxis of Potential HIV and Hepatitis B Exposure in Children, Adolescents & Adults, October 2016

This list is not exhaustive, and all cases should be assessed by a healthcare worker to determine if the exposure constitutes a significant risk.

SECTION 2

PACKAGE OF CARE FOR THE MANAGEMENT OF THE EXPOSED INDIVIDUAL

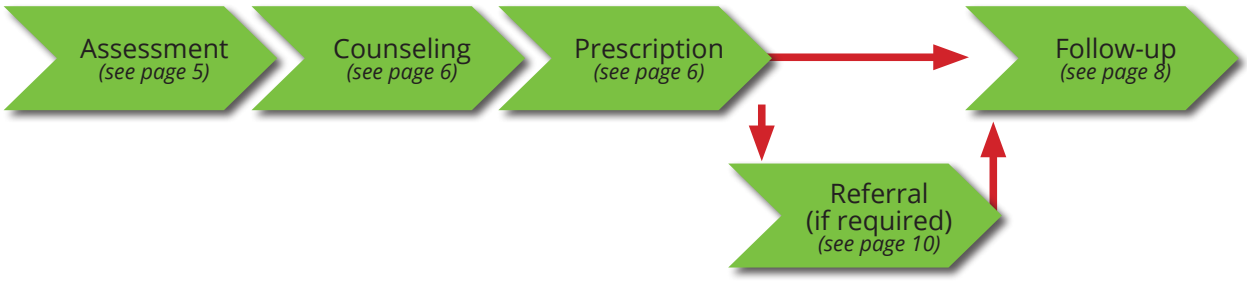
General principles of PEP

- All occupational exposures should be treated as a **medical emergency**
- If there is an acute (within 72 hours) history of sexual assault, treat as a **medical emergency**
- Offer PEP as early as the exposed individual presents at the facility. **No exposed individual should leave a facility without being offered PEP.**
- Wherever possible, investigations for concomitant infections should be requested on both the **source and exposed individual**. If the source individual is unknown or refuses to test, the exposed individual must be treated as if the source is HIV-positive.
- Occupational exposures must be regarded as preventable, and investigation must be conducted to strengthen prevention policies and practices at healthcare facilities.

Standard of care for the exposed individual at the primary care level

Figure 1 provides an overview of the steps in the care pathway. The standards of care for each step are outlined in the text below. In line with good clinical practice, the presentation of the patient should determine the care pathway and the interventions that will be required.

Figure 2.1 The care pathway for the exposed individual requiring PEP



Assessment

1. Clinical assessment and assessment of eligibility for PEP

Every person exposed to potentially infectious fluids should be assessed by a trained healthcare provider. Essential components of the assessment include the mechanism of exposure and examination of any wound. Initial first-aid treatment should be provided as indicated.

Eligibility for PEP will be determined by:

- The mechanism of exposure,
- Any existing medical conditions (e.g. HIV-positive status)
- The client's immunity status (e.g. against HBV and tetanus)
- Pregnancy status and childbearing potential (when considering eligibility for emergency contraception after sexual exposure)
- Time since exposure

Table 2.1 below summarises who is eligible for the different types of PEP based on the eligibility criteria listed above.

It is important to consider that a single exposed individual may have experienced multiple mechanisms of injury. For example, a victim of sexual assault may have been exposed to infectious body fluids, but may also have wounds or cuts that require prophylaxis for tetanus.

2. Baseline Investigations at the first assessment

The clinical and laboratory assessments of both the source and the exposed individual play an important role in the management of the exposed individual. Do not delay initiating PEP while awaiting confirmatory test results on the source patient and exposed individual.

Table 2.1 Baseline investigations for the exposed individual and source

Laboratory tests at baseline	Source	Exposed adult, adolescent or child	For further information on testing for this condition see page
HIV	Rapid test plus 4th generation ELISA (NHLS test)	Rapid test plus 4th generation ELISA (NHLS test) For HIV testing in children < 2 years see *page 28*	**HIV testing for exposed adults and adolescents** on *page 22* **HIV testing for exposed children** on *page 27*
Hepatitis B	Surface antigen	Surface antibody (HBsAb) ‡	*See page 31*
Hepatitis C	HCV antibody	HCV antibody †	*See page 34*
Pregnancy test*	-	Beta hCG	*See page 36*
Syphilis*	RPR/TP antibody	RPR/TP antibody §	*Please refer to the Sexually Transmitted Infections Management Guidelines, 2015*
Creatinine	-	If TDF will be part of PEP	
FBC	-	If AZT will be part of PEP	

HBV, Hepatitis B virus; HCV, Hepatitis C virus; FBC, full blood count; ELISA, enzyme-linked immunosorbent assay; HBsAg, Hepatitis B surface antigen; Ab, antibody; RPR, rapid plasma reagin; TP, Treponema pallidum; HBsAb, Hepatitis B surface antibody; TDF, tenofovir; PEP, post-exposure prophylaxis; AZT, zidovudine; PCR, polymerase chain reaction.

† Only if high risk for HCV, or if source is positive or unknown

‡ Can be omitted if exposed individual known to be protected (natural immunity or vaccination)

§ Only if the source patient was positive

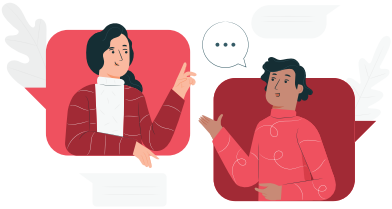
* Only if sexual exposure

Source: Adapted from the Guideline on the management of occupational and non-occupational exposure to the human immunodeficiency virus and recommendations for post-exposure prophylaxis: 2015 Update.[11]

Table 2.2 Deciding who needs which type of PEP based on the mechanism of exposure

Type of prophylaxis	Mechanism of exposure (see Box 2): Exposure to blood or other infectious bodily fluids (occupational or inadvertent exposures)	Mechanism of exposure (see Box 2): Sexual exposure	Mechanism of exposure (see Box 2): Wounds Cuts, abrasions, punctures, bites, and other open wounds	Timeframe within which PEP is most likely to be effective	Prophylaxis is not indicated if	For more details on this type of PEP, please refer to page
HIV prophylaxis	✓	✓		Within **72 hours**	The following exposures do not require HIV PEP: • If the exposed individual is already HIV-positive. • If the source is confirmed HIV-negative by laboratory ELISA test and the window period has been excluded. • Exposure to bodily fluids that do not pose a significant risk of HIV transmission: tears, non-bloodstained saliva, sweat and urine.	*page **20*** (adults and adolescents) *page **26*** (children)
HBV prophylaxis	✓	✓	**Human bites** require prophylaxis for HBV	Within **7 days** after perinatal and needle stick exposures Within **14 days** after sexual exposure	There is NO need for investigation and therapeutic intervention if the exposed person: • Has HBV infection at the time of exposure • Was vaccinated with known good response • If the source is HBsAg-negative, even if the exposed individual is not vaccinated or does not know their vaccination status. Refer these clients for testing and vaccination.	*page **30***
Emergency contraception		✓		As soon as possible, but within 5 days of unprotected intercourse	The following women do not require emergency contraception: • Women who are already pregnant • Women who are covered by other means of contraception, • Prepubescent girls who have not started menstruating and who have NO signs of breast development.	*page **33***
STI prophylaxis		✓		Within **72 hours**		*page **32***
Tetanus prophylaxis			✓	Within **48 hours**	History of > 3 doses of adsorbed tetanus toxoid-containing vaccine	*page **34***

Counselling and support



The exposed person should be counselled on the following aspects:

- The potential conditions that the client has been exposed to, based on their exposure type.
- Risks, benefits, and effectivity of PEP
  - The risks of transmission
  - The benefits and risks of PEP
  - The effectiveness of PEP
- Taking PEP
  - PEP should be started as soon as possible (preferably at the assessment visit) and within the timeframes outlined in Table 3
  - The need to take prophylaxis for the full period prescribed and to complete all doses
  - Possible side-effects of medication (antiretroviral therapy and contraception).
- Testing for HIV
  - Obtain **consent** for an HIV test if HIV-negative or unknown.
  - If the **source person** is present, provide counselling and obtain voluntary consent to have the necessary laboratory tests performed (*see page 22*). The source individual must receive counselling and treatment if found to be positive on any of the tests.
  - For HIV testing in adults, see **HIV testing for exposed adults and adolescents** on *page 22*
  - For HIV testing in children, see **HIV testing for exposed children** on *page 27*
- The importance of follow-up appointments and follow-up testing as outlined in Table 2.1 on *page 18*
- The importance of condom use for four months after exposure to prevent HIV and HBV transmission to sexual partners
- Emotional support
  - Emotional support and counselling must be given to address anxiety related to the risks of transmission
  - If unable to counsel due to **injuries or emotional status**, arrange follow-up for counselling within 48 hours or refer for appropriate support and counselling. **Do not delay PEP**.
  - Counselling must be available on an ongoing basis to deal with side-effects of the medication.

Prescription

Healthcare providers may be in doubt about the risk posed by the source of exposure. In such cases, the rule of thumb is *"if in doubt, immediately start HIV PEP and then get advice"*.

- All PEP must be initiated **as early as possible** following exposure (to HIV, hepatitis, pregnancy, or tetanus).
- **Do not delay initiating PEP while awaiting confirmatory test results** on the source patient and exposed individual.
- Any prescription of PEP should follow **counselling and consent** based on an understanding of the risks and benefits (as outlined in the counselling section above).
- Always assess for **underlying comorbidities and potential drug-drug interactions** before prescribing, e.g. enzyme inducers (including efavirenz, carbamazepine) cause a significant reduction in levonorgestrel concentrations within emergency contraception (*see page 36*). For a comprehensive list of potential drug interactions with ART please see annexure 3 on *page 38*
- A **full 28 day supply** of medication for HIV PEP must always be given if possible. Starter packs are not recommended due to the risk of defaulting treatment.
- **Side effects must be monitored and managed** appropriately to promote adherence (e.g. anti-emetics for nausea).

PEP regimens

PEP regimen for	Please see section	On page
HIV (adults, adolescents, and pregnant women)	PEP regimens for adults, adolescents, and pregnant women	*See page 24*
HIV (children)	PEP regimen recommendations for children	*See page 28*
Hepatitis B	Post-exposure prophylaxis for the prevention of Hepatitis B	*See page 31*
Emergency contraception	Pregnancy prevention	*See page 36*
STI prophylaxis	STI prevention	*See page 34*
Tetanus	Tetanus prevention	*See page 38*

Follow-up

At each follow-up visit, the following aspects should be addressed:

a. If still on the prophylactic regimen, check for side-effects, provide adherence counselling and support, and re-assess for any possible drug interactions. Re-emphasize the importance of returning for all follow-up appointments.

b. Manage anxiety and provide other psychosocial support as indicated.

c. Provide specific support in cases of sexual assault.

d. Counsel again on the importance of risk reduction interventions, until the final infection status is confirmed.

e. Depending on the type of exposure, provide the relevant follow-up laboratory tests, as indicated in Table 2.3 below.

f. If the client tests positive for any condition, link them to treatment and care.

Table 2.3 Laboratory monitoring at follow-up visits

Condition	Exposed adult, adolescent or child		
	2 weeks	6 weeks	4 months
HIV		Rapid test plus 4th generation ELISA For HIV testing in children < 2 years see table 4.1 on *page 14*	Rapid test plus 4th generation ELISA For HIV testing in children < 2 years see table 4.1 on *page 14*
			Surface antigen ‡
Hepatitis B			For occupational exposures: ensure the health care worker has a HBsAb > 10 units/mL 1 – 2 months after the last vaccine dose
Hepatitis C		HCV PCR†	
Syphilis*			RPR/TP antibody §
Creatinine and eGFR	If TDF will be part of PEP		
FBC	If AZT will be part of PEP		
Pregnancy test*		Repeat pregnancy test if normal menstrual period did not occur within 4 weeks of exposure	

HBV, Hepatitis B virus; HCV, Hepatitis C virus; FBC, full blood count; ELISA, enzyme-linked immunosorbent assay; HBsAg, Hepatitis B surface antigen; Ab, antibody; RPR, rapid plasma reagin; TP, Treponema pallidum; HBsAb, Hepatitis B surface antibody; TDF, tenofovir; PEP, post-exposure prophylaxis; AZT, zidovudine; PCR, polymerase chain reaction.

† Only if high risk for HCV, or if source is positive or unknown

‡ Can be omitted if exposed individual known to be protected (natural immunity or vaccination)

§ Only if the source patient was positive

* Only if sexual exposure

Source: Adapted from Guideline on the management of occupational and non-occupational exposure to the human immunodeficiency virus and recommendations for post-exposure prophylaxis: 2015 Update.[11]

Considerations for specific populations

Health Care Providers

Healthcare providers are at significant risk of blood-borne infections through exposure in occupational settings. Primary prevention should include universal precautions and safe injection practices to prevent injuries and secondary transmission, as outlined on *page 8*. All occupational exposures should be reported immediately and investigated. Follow-up for healthcare providers should respect confidentiality, and reporting and recordkeeping should be in accordance with national occupational health policies.

Survivors of sexual assault

All persons subjected to sexual assault, including members of the LGBTI community and persons with disabilities, should receive PEP as part of a broader package of care. This package should include first-line support, emergency contraception, obtaining forensic specimens, prophylaxis for STIs, and psychological interventions. Other people who have been sexually assaulted, including men, children, and adolescents, need to have psychosocial issues considered in combination with PEP, as part of the standard package of care. Care should be taken to ensure referral to appropriate services and multidisciplinary team involvement in combination with adherence support.

Pregnant and lactating women

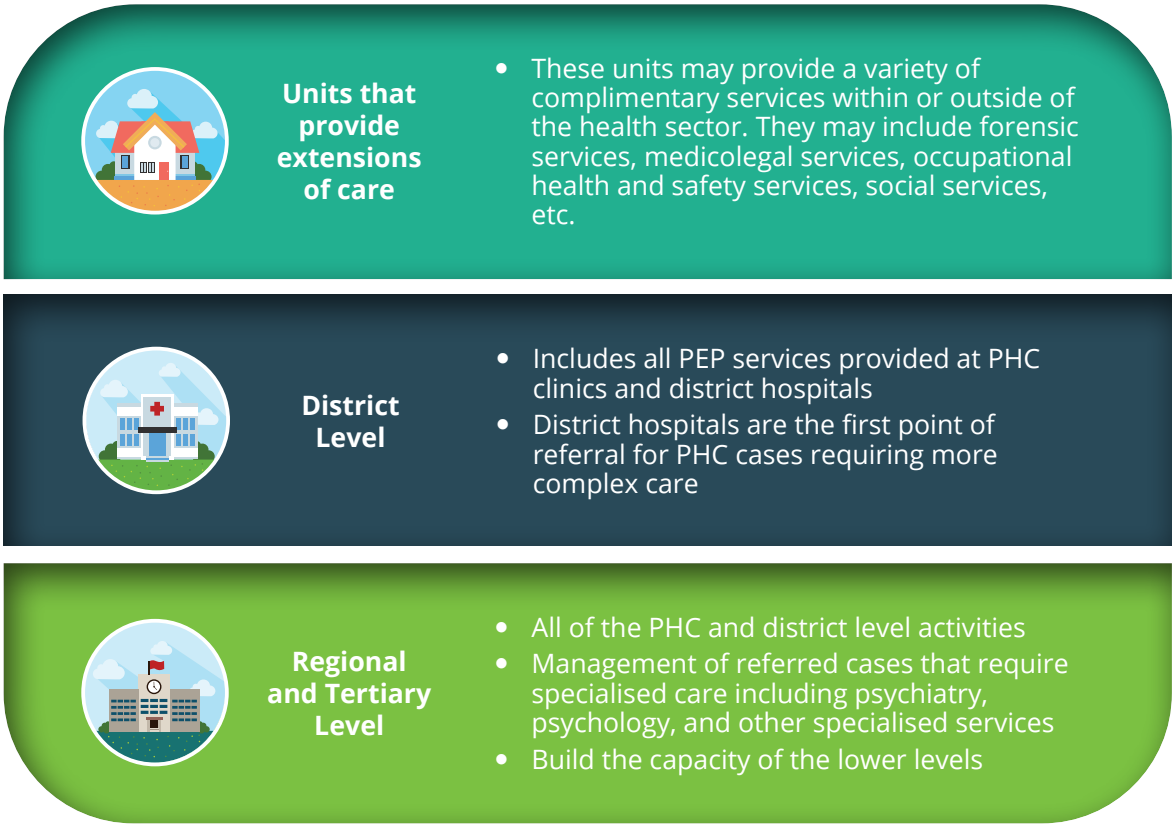
None of the current agents recommended for PEP of HIV, HBV, or tetanus are contraindicated for pregnant women.[4] DTG carries a low risk of neural tube defects if used in the first six weeks of pregnancy. The women should be counselled on the risks and benefits of DTG use and be enabled to make an informed choice. Breastfeeding should not contraindicate PEP for HIV, but the risks and benefits of continuing breastfeeding while HIV transmission risk is unknown should be discussed with the mother.[4]

Regimens for STI prophylaxis in pregnant women differ from non-pregnant persons, as outlined on *page 32*.

Interventions at higher levels

PEP interventions aim to provide PEP as early as possible. Therefore, the interventions described above under the PHC level represent **the minimum package of care** that should be provided to any exposed individual. **No client should leave a facility without PEP being offered.** The patient's clinical presentation and the healthcare worker's assessment will determine if an opinion should be sought from a specialist or referral centre, or if a referral to a higher level is required.

Figure 2.2 Interventions at higher levels



SECTION 3

POST-EXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV IN ADULTS AND ADOLESCENTS

Indications for HIV PEP

PEP must be offered to all individuals with exposures that pose a risk of HIV transmission. The risk of acquiring HIV following exposure is determined by the nature of the exposure and the infectiousness of the source patient. High-risk exposures involve exposure to a larger quantity of viruses from the source patient, either due to exposure to a larger quantity of blood or because the amount of virus in the blood is high.

Any one of the following is associated with an increased risk of occupational HIV transmission:

- deep percutaneous sharps injuries
- percutaneous exposure involving a hollow needle that was used in a vein or artery
- visible blood on the sharp instrument involved in a percutaneous injury
- the source patient has WHO Stage 4 disease or is known to have a high VL: the higher the VL, the higher the risk of transmission

The transmission risk for non-occupational exposures is more difficult to assess. However, any client reporting exposure (e.g. a burst condom) should be managed as exposed, even if that exposure cannot be proven

In instances when the risk of infection is extremely low or non-existent, post-exposure prophylaxis (PEP) is not indicated, as the risks of PEP will far outweigh the benefits. However, support and reassurance should be provided.

PEP is NOT indicated when:

- The material the person was exposed to is not infectious for HIV, e.g. vomitus, urine, faeces or saliva, unless these are visibly bloodstained.
- The occupational exposure occurred on intact skin.
- The source patient is HIV negative, unless there are clinical features to suggest seroconversion illness, or a history of a recent high-risk exposure. In these cases, PEP should be commenced until further tests are done. If in doubt, initiate PEP. Consult with a virologist or infectious diseases specialist as necessary.
- When the exposed individual is already HIV-positive. Assess the person for ART initiation if not already on ART.

Table 3.1 Eligibility for HIV PEP

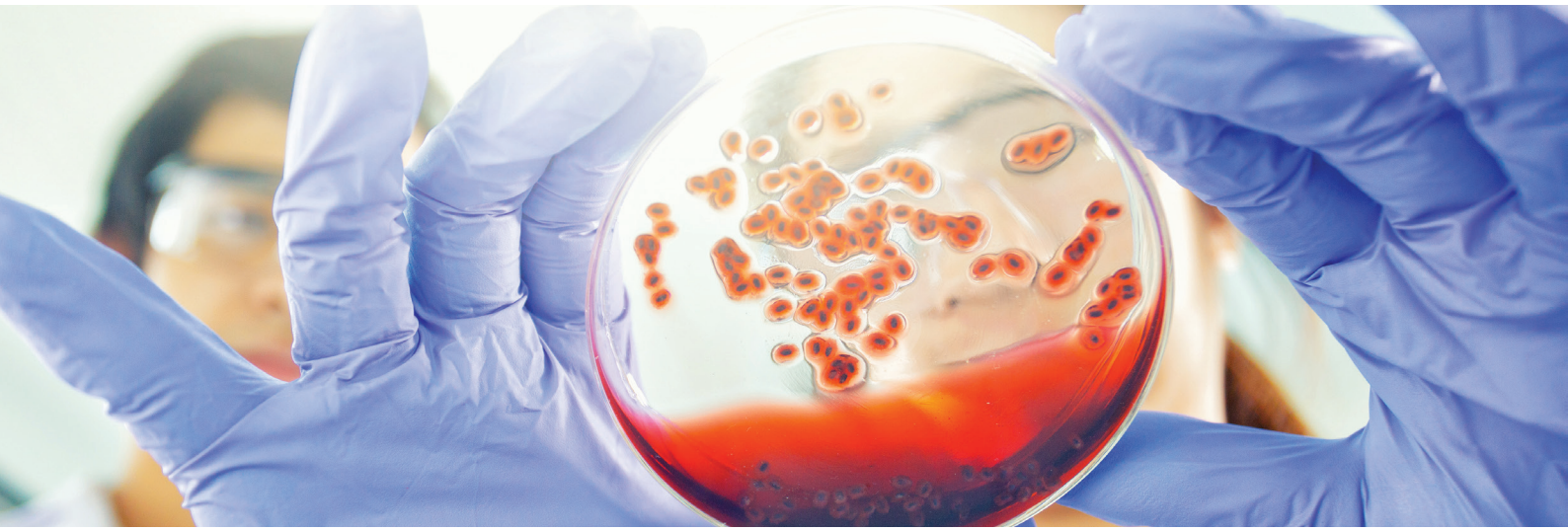
Types of Exposure	Status of the source	
	HIV-positive or Unknown	HIV-negative
Percutaneous exposure to blood or potentially infectious fluids	Give PEP to the exposed individual	No PEP
Mucous membrane exposure, including sexual exposure, mucocutaneous splash or open wound contact, with blood or potentially **infectious fluids**	Give PEP to the exposed individual	No PEP
Mucous membrane exposure including mucocutaneous splash or open wound contact, with **non-infectious fluids**	No PEP	No PEP
Intact skin exposure to infectious or non-infectious fluids	No PEP	No PEP

HIV testing for exposed adults and adolescents

Establishing the HIV status of the exposed individual and the source of the exposure is an important part of the clinical pathway but should not delay initiating PEP as quickly as possible.

The NDOH National HIV Testing Services (HTS) Policy: 2016 denotes that clients have the right to refuse HIV testing, without compromising their access to standard healthcare. Mandatory testing is not required, and all testing should be voluntary with informed consent, even when the testing services are provider-initiated. The only exception is in cases of sexual assault where the survivor may approach the court of law to request for the status of the perpetrator.[12]

In emergencies, where the exposed person refuses initial testing, PEP should be initiated, and HIV testing and counselling should be undertaken as soon as possible. However, it is the duty and responsibility of healthcare workers to inform the client about the risks of HIV so that they can make informed decisions about getting an HIV test. Healthcare providers need to approach exposed individuals with a non-judgmental and empathetic attitude. Provide counselling to the exposed person and then perform a rapid HIV test in line with the national HIV testing algorithm on *page 22*



HIV testing of the source person in sexual assault

All sexual assault victims should be given the option of reporting the assault. However, healthcare providers have a statutory obligation to report the sexual offence only if the victim is:

If the source person refuses an HIV test, the law makes provision for HIV testing of alleged offenders (Criminal Law; Sexual Offences and Related Matters. Amendment Act No. 32 of 2007 [Government gazette 31957, 6 March 2009]). The victim, or an interested person, can apply for this to be done within 90 days of the alleged offence.

If the source person of the exposure is known, the source person should be counselled and encouraged to consent for HIV testing. If the source of the exposure is unknown, that does not constitute a barrier for offering PEP. In many cases of sexual assault, the source persons are not known or are unwilling to consent.

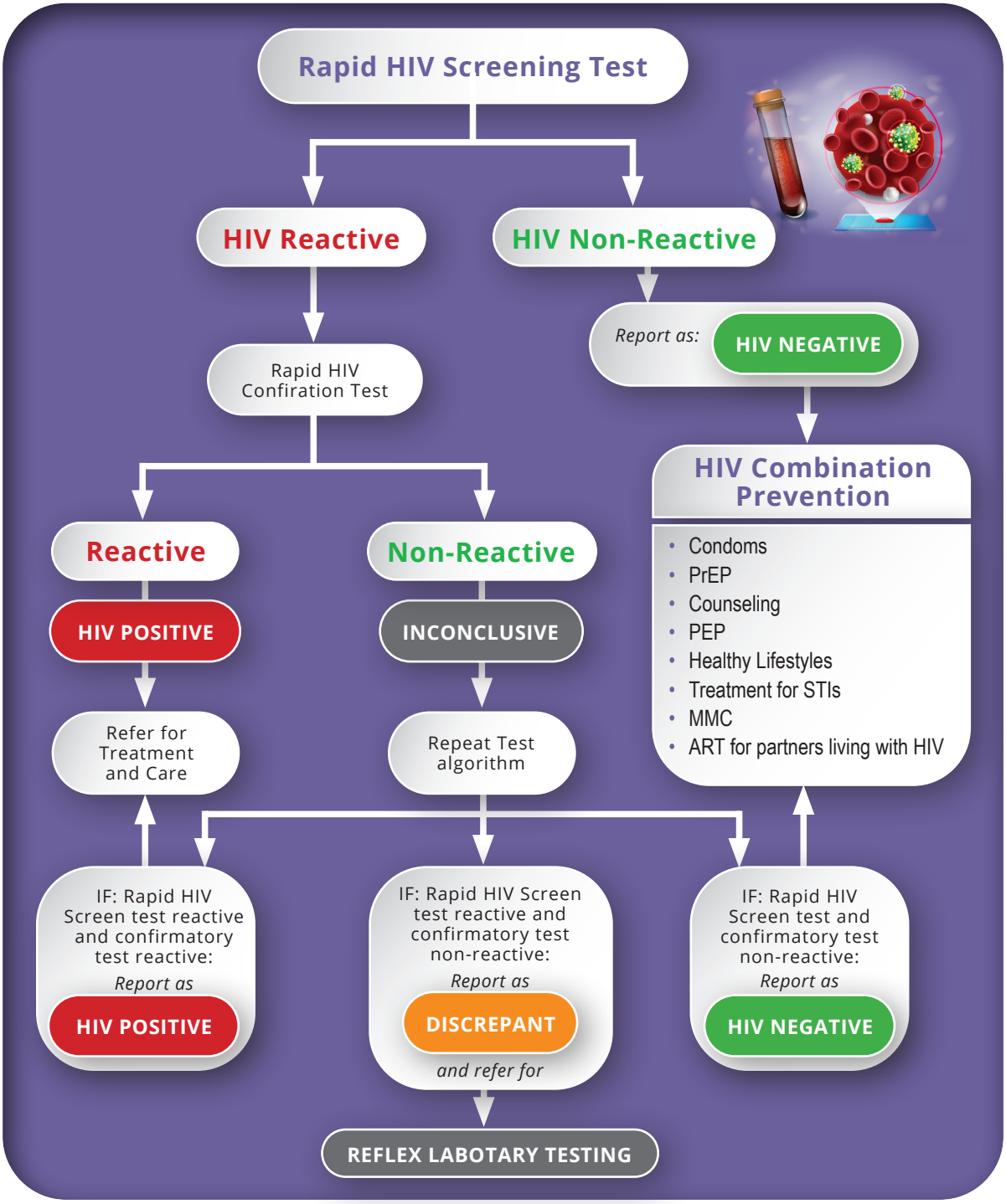
The healthcare provider must offer the alleged sexual offender pre-test counselling or ensure that such pre-test counselling has been done and must ensure that all necessary information concerning HIV/AIDS has been given. Systems must be put in place to provide both pre- and post-test counselling to the source person and to have blood results provided confidentially. Based on the outcome of the HIV testing, the source person should be managed in line with the standard of care; if positive, evaluate and initiate on ART as stipulated in the ART Clinical Guidelines (2019).

HIV counselling and testing (HCT) is now referred to as HIV testing services (HTS) to embrace the full range of services that should be provided together with HIV testing. These services include:

- Counselling (pre-test information and post-test counselling)
- Linkage to appropriate HIV prevention, treatment and care services and other clinical and support services
- Coordination with laboratory services to support quality assurance and the delivery of correct results.

National HIV Testing Algorithm

Figure 3.1 South African National HIV testing algorithm



If **NEGATIVE**: initiate PEP if within 72 hours of exposure and send blood for HIV ELISA and baseline tests (Table 5)

If **POSITIVE**: repeat rapid antibody test. If both tests positive, send blood for HIV ELISA test, pre- ART tests and other baseline tests (Table 5). Assess eligibility for HBV prophylaxis.

If screening test is POSITIVE and confirmatory NEGATIVE: do baseline tests, initiate PEP, and send blood for HIV ELISA. If ELISA test result also positive, switch to ART regimen. If negative, continue PEP.

HIV PEP regimens for adults and adolescents

PEP is indicated for those who present within 72 hours of exposure. The WHO recommends three drugs as the preferred option for PEP, and no differentiation in regimen according to the type of exposure (occupational versus non-occupational exposure). These new recommendations promote simplification of prescribing to improve the availability of PEP and to reduce the time to PEP initiation. There is no danger of resistance, even if they have had previous PEP courses.

Side effects relating to antiretrovirals are common, especially in HIV-negative people. The inability to cope with the side effects of medication is often the main reason for discontinuing the medication. Therefore, attention must be given to:

- the appropriate selection of regimens
- the therapeutic management of the side effects (see also *page 26*), and
- close management of the patient through the PEP process

An updated review of the tolerability and completion rates of various ARV regimens for HIV post-exposure prophylaxis supports the use of DTG together with TDF + 3TC (or FTC) for HIV post-exposure prophylaxis, as 90% of individuals receiving this regimen complete post-exposure prophylaxis.[4]

Regimen selection

Preferred regimen
Tenofovir 300 mg / Lamivudine 300 mg / Dolutegravir 50 mg once a day x 4 weeks as a fixed-dose combination

TLD should be considered as the gold standard and should be readily available at all facilities. Alternatives should only be be considered in exceptional circumstances if TLD is not suitable or not tolerated.

Alternative regimen in women who are actively planning a pregnancy, pregnant women < 6 weeks gestation, or where DTG is not tolerated
Tenofovir 300 mg once daily + Emtricitabine 200 mg once daily + Atazanavir/r 300/100 mg once daily or Lopinavir/r 200/50 mg, oral, 2 tablets 12 hourly for 4 weeks.

- DTG may pose a small risk of neural tube defects and should be avoided peri-conception and in the first six weeks of pregnancy. For women and adolescent girls who do not want to take DTG or do not want to use emergency contraception (after unprotected intercourse), an alternative ARV drug to DTG (such as a boosted PI) should be provided (see also *page 19*).
- Efavirenz is not recommended as it is very poorly tolerated in PEP.
- Before initiating a client on PEP, it is important to take a thorough medication-related history to identify any potential drug-drug interactions. Drug interactions can result in suboptimal drug levels, which can affect the efficacy of prophylaxis. See *page 38* for more information on comorbidities and drug interactions that affect PEP regimen selection.
- If tenofovir is contraindicated or if source patient is known to be failing a tenofovir based regimen, replace tenofovir and emtricitabine with:
    - Zidovudine, oral, 300 mg 12 hourly for 4 weeks.
    - Lamivudine, oral, 150 mg 12 hourly for 4 weeks.

- Patients failing 2nd line ART usually have no resistance to protease inhibitors, so lopinavir/ritonavir should still be effective, but consultation with a virologist or infectious diseases physician is recommended for advice on which ARVs to use for PEP in this setting.

- There may be implications for clients receiving TDF-containing HIV PEP if they are also HBsAg positive. Stopping TDF on completion of the PEP regimen should be discussed with an expert.

Management of side effects

PEP is generally not well tolerated. Adverse effects occur in about half of cases and can lead to defaulting or non-completion of PEP in about a third of cases. It is, therefore, critical to **proactively manage possible side effects**. However, the serious side effects that can develop from long term use of ARVs are rarely a problem with a short course.

It is important to appropriately explain to the exposed individual the side effects of each medication and how to manage them. It is also a good practice to routinely prescribe medication that will help to manage common side effects, e.g. anti-emetic and analgesic. The next table provides the side effects most commonly associated with each antiretroviral.

Table 3.2 Common and severe side effects of antiretroviral drugs

Drug	Dose
Tenofovir (TDF)†	**Well tolerated. Nephrotoxicity: avoid in individuals with pre-existing renal disease.**
Lamivudine (3TC) †	**Well tolerated**
Dolutegravir (DTG) †	**Well tolerated. Occasional insomnia**
Emtricitabine (FTC) †	Well tolerated
Zidovudine (AZT)	Not well tolerated. Common side effects include nausea, vomiting, headache, insomnia and fatigue.
Atazanavir (ATV)	Unconjugated hyperbilirubinaemia (visible jaundice in some patients), rash, hepatitis (uncommon) § ‡
Lopinavir/ritonavir (LPV/r)	Gastrointestinal intolerance, nausea, vomiting, and diarrhoea are common § ‡

† Preferred antiretrovirals for PEP and available as a fixed-dose combination (TLD);

‡ drug interactions need to be considered;

§ must be boosted with ritonavir.

Source: Guideline on the management of occupational and non-occupational exposure to the human immunodeficiency virus and recommendations for post-exposure prophylaxis: 2015 Update.[11]

- If zidovudine is not tolerated, switch to tenofovir (check baseline eGFR as above).

- If lopinavir/ritonavir is not tolerated switch to atazanavir/ritonavir or dolutegravir.

- Atazanavir/ritonavir often causes unconjugated jaundice, which is benign but may not be tolerated, in which case switch to lopinavir/ritonavir or dolutegravir.

SECTION 4

POST-EXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV IN CHILDREN

This chapter addresses the management of children who have been exposed to HIV by means other than vertical transmission from a mother known to be living with HIV. However, HIV negative mothers exposed to HIV remain eligible for HIV PEP to protect herself and her unborn infant.

For prevention of vertical transmission, please see the 2019 Guideline for the Prevention of Mother to Child Transmission of Communicable Infections available at ***http://bit.ly/2019-PMTCT-Guidelines***

Management of specific exposures

Sexual assault

Sexual assault victims must be regarded as medical emergencies and provided PEP regardless of clinical findings. All cases of suspected or alleged sexual abuse involving a child must be reported to the relevant authorities (South Africa Police Service - SAPS), and a case must be opened. Adequate documentation in medical notes must be ensured.[15] Counsel the caregiver and child (if age-appropriate) on the risks of the exposure and obtain consent for HIV test unless known to be HIV infected.

Inadvertent exposure

If the individual is eligible for PEP, counsel caregiver and child (if age-appropriate) on the risks of acquiring HIV infection from the exposure and obtain consent for HIV test unless known to be HIV infected. If possible, establish whether the child has received HBV vaccination.

In the case of an infant being exposed to another mother's breastmilk in the post-natal period (excludes donor breastmilk via a milk bank), aspiration of the milk via a gastric tube should be performed immediately. Report the incident to the paediatric ward "on-call" doctor, the sister in charge, and the senior clinician. Counsel the mother of the child and the source breastfeeding mother about the small, but possible risk of HIV and HBV transmission and assure the source breastfeeding mother that confidentiality will be maintained.

HIV testing for exposed children

The *Children's Act*, Section 130, stipulates when and how a child may be tested for HIV.[15] The Act has distinguished HIV testing from other forms of medical treatment and has enforced conditions for HTS among children.

Children may only be tested for HIV in two circumstances:

- If testing is in their best interest and lawful consent has been given for the test
- If the test is needed to establish the child's HIV status in cases where a healthcare worker, caregiver, parent, or another person may have contracted HIV from the child's body fluids

Consent for HIV testing for children may be given:

- By a child, if he or she is older than 12 years.
- By a child younger than 12 years, if he or she has "sufficient maturity."
- By a parent, caregiver, or the provincial head of the Department of Social Development, if the child is younger than 12 years and is not sufficiently mature.

Counselling during HIV testing among children

- HIV testing must be accompanied by an accurate pre-information session and post-test counselling, and should be done by an appropriately trained person. This provision ensures that children and their caregivers make appropriate choices regarding HIV testing. For guidance on counselling children and caregivers, please reference the National HIV Testing Services Policy.
- No person may disclose a child's HIV status without consent
- Consent for the disclosure of HIV status can be given by the child if he or she is older than 12 years or is sufficiently mature. If the child does not have the capacity to give consent to the disclosure, consent can be given by a range of people, including a parent or caregiver. This provision aims to ensure that a child's right to confidentiality is protected.

Two different HIV testing technologies are used for children in South Africa.

Table 4.1 HIV testing methods for children < 18 months and ≥ 18 months of age

Child < 18 months of age and not known HIV-positive	Child ≥ 18 to 24 months of age
• Do PCR test and initiate HIV PEP if the exposure occurred within previous 72 hrs • Follow up on the results of the PCR test within 48 hours • If the PCR result is NEGATIVE, continue HIV PEP for 4 weeks • If the PCR result is POSITIVE, switch from PEP to ART regimen, and confirm the diagnosis with a second PCR on a different sample	• Do HIV rapid test. • If the HIV rapid test is negative, initiate HIV PEP if the exposure occurred within the previous 72 hrs • Continue PEP for 28 days • If the rapid result is POSITIVE, switch from PEP to ART regimen, and confirm the diagnosis with an HIV PCR or HIV viral load
	Child > 24 months of age
	• Follow normal adult testing algorithm

PEP regimen recommendations for children

Table 4.2 ARV PEP regimen for children < 10 years of age

Preferred regimens	
• Weight < 20 kg	• Zidovudine + Lamivudine + Lopinavir/ritonavir
• Weight ≥ 20 kg	• Zidovudine + Lamivudine + Dolutegravir

Remember that adolescents ≥ 10 years AND weighing ≥ 35 kg or more can use TDF, 3TC, and DTG

In children < 35 kg or unable to swallow tablets
• Substitute with d4T if AZT is poorly tolerated
• ABC + 3TC or TDF + 3TC (or FTC) can be considered as alternative NRTI backbones.[11]
• An age-appropriate alternative third agent can be identified among ATV/r, DRV, and EFV. Where RAL is available, it can be used in children over two years of age if LPV/r is poorly tolerated.
• A 28-day prescription of antiretroviral drugs should be provided for HIV PEP.
• It is imperative that the first dose of PEP is administered as soon as possible after exposure; if the three recommended drugs are not immediately available, use whatever suitable ARV medication is available to start.

AZT, zidovudine; 3TC, lamivudine; ABC, abacavir; TDF, tenofovir; FTC, emtricitabine; DTG, dolutegravir; LPV/r, lopinavir/ ritonavir; ATV/r, atazanavir/ritonavir; RAL, raltegravir; DRV/r, darunavir/ritonavir; EFV, efavirenz.

Source: Adapted from WHO Guideline 2014

Doses of ARVs in children are dependent on body weight or body surface area. The following guide should be followed for prescribing HIV PEP in children.

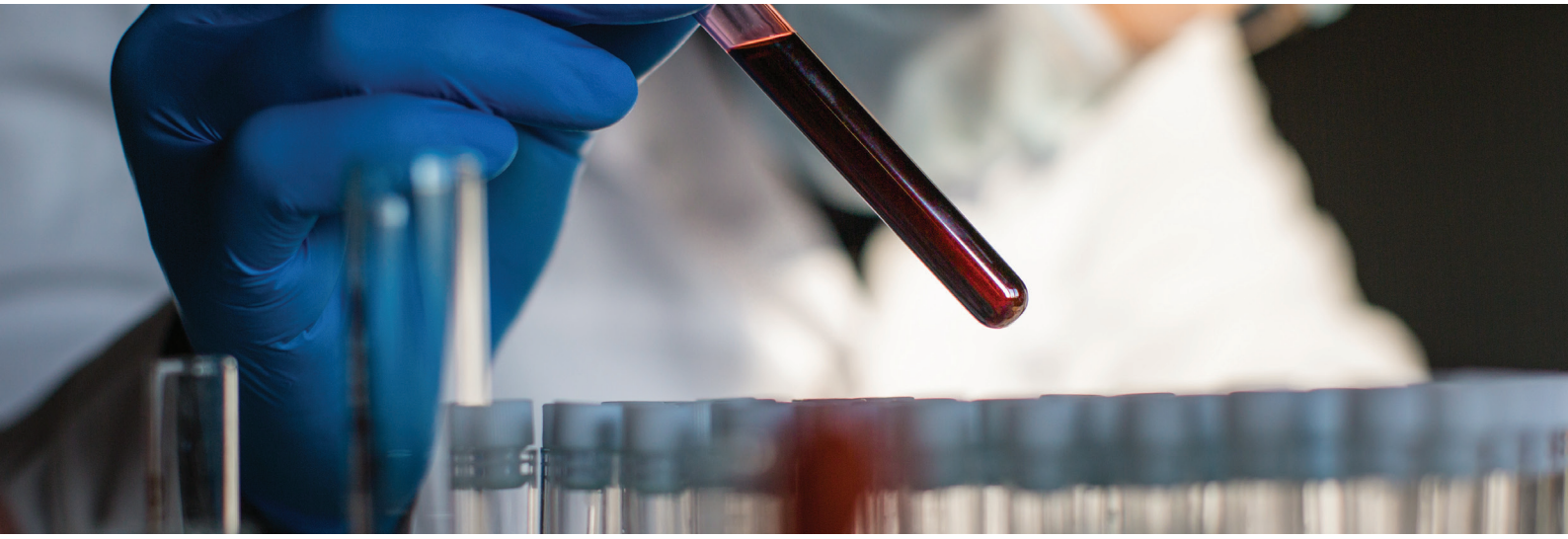


Table 4.3 Simplified dosing of child-friendly fixed-dose formulations

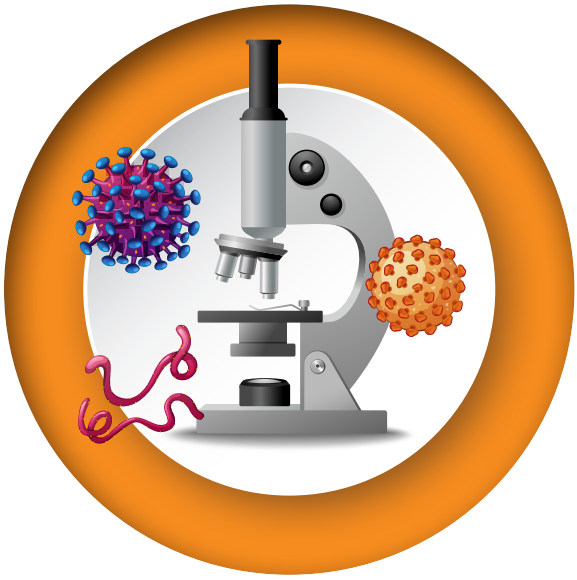
Drug	Strength of tablets (mg)	Number of tablets by weight band morning (AM) and evening (PM)										Strength of Adult tablet (mg)	Number of tablets by weight band	
		3,0 - 5,9 kg		6,0 - 9,9 kg		10,0 - 13,9 kg		14,0 - 19,9 kg		20,0 - 24,9 kg			25,0 - 34,9 kg	
		AM	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**		**AM**	**PM**
AZT/3TC	Tablet (dispersible) 60 mg / 30 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	300/150	1	1
Solid formulations														
3TC	Tablet (dispersible) 30 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	150	1	1
AZT	Tablet (dispersible) 60 mg	1	1	1,5	1,5	2	2	2,5	2,5	3	3	300	1	1
LPV/r < 20 kg	Tablet (heat stable) 100 mg / 25 mg	-	-	-	-	2	1	2	2	2	2	100/25	3	3
DTG ≥ 20 kg	Tablet 50 mg	-	-	-	-	-	-	-	-	1	-	50	1	
Liquid formulations														
AZT	10 mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	-	-	-	-	-	-	-
3TC	10 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	-	-	-	-	-	-	-
LPV/r*	80/20 mg/ml	1 ml	1 ml	1,5 ml	1,5 ml	2 ml	2 ml	2,5 ml	2,5 ml	3 ml	3 ml	-	-	-

* LPV/r syrup should not be used for premature babies or infants younger than 2 weeks of age, NVP should be used instead at the following dose: 5 ml twice daily (3,0 – 5,9 kg), 8 ml twice daily (6,0 – 9,9 kg) and 10 ml twice daily (10,0 – 13,9 kg) if syrup is available; 1 tablet twice daily (3,0 – 5,9 kg), 1,5 tablets twice daily (6,0 – 9,9 kg) and 2 tablets twice daily (10,0 – 13,9 kg) if dispersible 50 mg tablets are available,

Source: WHO Guideline 2014

Special notes on dosing for children [16]:

- Children ≥ 28 days of age and ≥ 3 kg bodyweight should be dosed according to the ARV dosing chart (Annexes 1 and 2).
- For neonates (< 28 days of age) who are < 2 weeks of age or < 42 weeks gestational age (premature neonates), discuss drug selection and dosing with a paediatrician, as LPV/r is contraindicated.
- If the exposed infant is nil per mouth, start intravenous AZT early after discussion with the paediatrician. If at a lower-level facility, refer to a higher level.
- Older children who can swallow tablets should be prescribed a fixed-dose combination tablet (Lamzid) if dosages allow it.



SECTION 5

POST-EXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HEPATITIS

HBV PEP general principles

HBV exposure may occur in situations other than perinatal, sexual, or (occupational) healthcare settings. These include exposure as a result of wounds, human bites, exposure due to casualty events, or exposure following needle sharing. HBV transmission risk, if exposed, is high (30% transmission risk). PEP recommendations are the same for all types of exposure.

Previous HBV vaccination should be assessed and vaccination offered if required according to age-appropriate national immunisation schedules. Hepatitis B Immunoglobulin (HBIG) protects by passive immunisation if given shortly after exposure and should be given to unvaccinated or partly vaccinated individuals.

Since the risk of transmitting HBV and HCV is higher than the risk of transmitting HIV in most cases of exposure, investigating and managing concomitant exposures is a key part of the package of care.

Any client who tests HBsAg positive on follow-up testing should be referred for further assessment.

Indications for HBV PEP

PEP is indicated following exposure to blood or body fluids of a known or potential HBsAg-positive source if:

- the exposed individual does not have protective HBsAb ≥ 10 IU/mL, or
- if HBsAb status is unknown and testing will delay administration of HBV vaccination or HBIG by more than 24 hours.

There is NO need for investigation and therapeutic intervention if the exposed person:

- Has HBV infection at the time of exposure
- Was vaccinated with known good response
- If the source is HBsAg-negative, even if the exposed individual is not vaccinated or does not know their vaccination status. Refer these clients for testing and vaccination.

Timing and effectiveness of HBV PEP

The most important determinant of PEP effectiveness is the timing of administration of HBIG and the first HBV vaccine dose. HBIG to be given as soon as possible, preferably within 24 - 72 hours after exposure (within 7 days).

PEP effectiveness decreases with increasing delay in administration following exposure and is unlikely to be effective:

- > 7 days after perinatal and needle stick exposures
- > 14 days after sexual exposure

Box 5.1 Effectiveness of hepatitis B PEP

- A combination of HBIG and active HBV vaccination is highly effective in preventing transmission after exposure to HBV
- HBIG is approximately 75% effective in preventing clinical HBV infection if administered soon after HBV exposure
- HBIG provides passively acquired HBsAb, which is immediately protective and lasts for 3 - 6 months
- HBIG alone does not confer long-lasting protection against HBV
- HBIG is the primary means of protection of non-responders to vaccination

Management of individuals exposed to HBV

Table 5.1 Management of individuals with potential exposure to hepatitis B

Hepatitis B status of the source ↓	Vaccination status and antibody response of the exposed person	
	• Not vaccinated • Unsure if vaccinated • Vaccination incomplete • Vaccinated, but with HBsAb < 10 IU/mL, or level unknown	**Vaccinated with known response i.e.** **HBsAb > 10 IU/mL #**
• HbsAg positive, or • HbsAg unknown	• HBIG, IM, 500 units* • Hep B vaccine (3 doses at monthly intervals)	No treatment
HbsAg negative	• Initiate/complete/repeat HBV vaccination (month 0, 1 and 6)	No treatment

HBV, hepatitis B virus; HBIG, hepatitis B immunoglobulin; HBsAb, hepatitis B surface antibody. HBsAg, hepatitis B surface antigen.

* HBIG and the first dose of vaccine should ideally be given simultaneously, but at different sites. However, access to HBIG may require referral to a secondary level of care. If a facility does not have HBIG the client should still receive the HBV vaccine immediately and be referred as appropriate.

\# If the delay in obtaining HBsAb results is more than 24 hours initiate treatment as for vaccinated AND HBsAb < 10 units/mL.

After vaccination ensure the health care worker has a HBsAb > 10 units/mL 1 – 2 months after the last vaccine dose.

Source: National Department of Health, South Africa. Essential Drugs Programme. Hospital level (Adults) Standard Treatment Guidelines and Essential Medicines List. 5th ed. 2019.

Hepatitis C prevention

There is currently no vaccine for HCV.

If the source is known to be HCV-negative, the exposed person does not have to be followed up for HCV but may be tested at baseline to assess their HCV status.

If the source is HCV-positive or unknown, the exposed individual should be tested for HCV antibodies (HCVAb) at baseline with a follow-up HCV PCR at 6 weeks' post-exposure.

SECTION 6

POST-EXPOSURE PROPHYLAXIS FOR THE PREVENTION OF STIS AND PREGNANCY

STI prevention

In the case of sexual exposure, exposure to other STIs might have occurred. A thorough examination should be provided to the victim at baseline with a follow-up visit approximately one week after sexual exposure to allow sufficient time for infections to incubate. Similarly, to allow sufficient time for antibodies to develop, an additional follow-up visit at approximately 12 - 16 weeks after the last sexual exposure is necessary to collect blood for follow-up syphilis and HIV testing (after pre-test counselling with consent).

In line with the National Sexual Assault Policy, the NDOH Directives and Instructions for Conducting a Forensic Examination on Survivors of Sexual Assault, and the Comprehensive STI Clinical Management Guidelines, presumptive STI treatment should be provided at the first visit.

Table 6.1 Presumptive treatment for STIs in adults and adolescents

Drug	Dosage	Route	Frequency
Ceftriaxone	250 mg	IM	Stat
Azithromycin	1 g	orally	stat
Metronidazole	2 g	Orally	stat

Source: NDOH Comprehensive STI Clinical Management Guidelines 2017-2022

Other considerations

Treatment for pregnant women

- Cefixime 400 mg stat po (alternative: Ceftriaxone 250 mg IMI stat or Spectinomycin 2 g stat IMI)
- Erythromycin 500 mg qid for 7 days
- Metronidazole 2 g stat po (alternative: Metronidazole 400 mg bd po for 7 days). Metronidazole 400 mg bd po for 7 days should be used in the first trimester.

Treatment for children

- Ceftriaxone:
  - If child weighs < 25 kg: 125 mg IMI stat
  - If the child weighs ≥ 25 kg: 250 mg IMI stat
- Macrolide:
  - Azithromycin:
    - If the child weighs < 45 kg: 20 mg/kg/dose as a single dose
    - If the child weighs ≥ 45 kg: 1 gm orally as a single dose

    Or
  - Erythromycin:
    - If the child is < 12 years: 50 mg/kg body weight per day in 4 doses
    - If the child is ≥ 12 years: 250 mg qid for 7 days
- Metronidazole: (Only for female patients or males who were sexually assaulted by females):
  - If the child is 1 - 3 years: 50 mg tds for 7 days (alternative: 500 mg stat po)
  - If the child is 4 - 7 years: 100 mg bd for 7days (alternative: 600 - 800 mg stat po)
  - If the child 8 - 10 years: 100 mg tds for 7 days (alternative: 1 gm stat po)
  - In children > 10 years: Metronidazole 2 gm stat po (alternative: Metronidazole 400 mg bd po for 7 days). Metronidazole 400 mg bd po for 7 days is preferred for children.

Pregnancy prevention

Emergency contraceptive tablets must be taken as soon as possible and not later than five days. Emergency contraception can be used at any time in the menstrual cycle.

Unprotected intercourse includes the following scenarios:

- when methods fail (i.e. a condom slips or breaks, or an intrauterine device is expelled),
- situations when a method was used incorrectly (i.e. missed pills, late for injection), or
- where contraceptive methods were not used at all (i.e. failure to use a condom, as well as coercive sex or sexual assault).

Priorities as part of the standard of care are:

- Establishing whether there was a pregnancy before unprotected sexual exposure
- Preventing a pregnancy as a result of unprotected sexual exposure
- Providing options for a pregnancy resulting from unprotected sexual exposure
- Respecting a woman's right to choose whether to take active measures to prevent pregnancy or terminate a pregnancy conceived during unprotected sexual exposure

Emergency contraception should be offered to all women who have had unprotected intercourse and who are:

- not pregnant, and
- not covered by other means of contraception, including girls who have not yet started menstruating but have signs of breast development.

Two types of safe and effective emergency contraceptive methods are currently available in South Africa:

- Hormonal, emergency contraceptive pills (ECPs) taken within 120 hours (5 days) of unprotected intercourse, the sooner, the better
- Copper (Cu) IUD, inserted up to 120 hours (5 days) after unprotected intercourse

As the provision of ECPs is simpler and less invasive than emergency Cu IUD insertion, the **recommended regimen** is:

- Levonorgestrel 1,5 mg stat po
- Provide an anti-emetic to prevent nausea and vomiting: metoclopramide oral, 10 mg 8 hourly as needed.
- If vomiting occurs within two hours of taking ECPs, another dose should be taken
- Alternative regimens include combined pills including levonorgestrel and Ethinyl estradiol and in various dosing combinations. These have to be taken immediately and repeated in 12 hours.
- The use of Ovral is not recommended, except in exceptional circumstances where alternative options are not available.

CAUTION

Enzyme inducers (including efavirenz, carbamazepine) cause a significant reduction in levonorgestrel concentrations. Women on these medicines should double the dose of levonorgestrel, because of significant reduction of levonorgestrel.

Women > 80 kg or BMI ≥ 30 should also be given twice the standard dose.

Box 6.2 Considerations for emergency contraception

- If routine contraceptive use is well established, it is best to continue with it as normal after unprotected sexual exposure
- Emergency contraception is not 100% effective, so a repeat pregnancy test is needed if normal menstrual bleeding has not occurred within four weeks of unprotected sexual exposure.

SECTION 7

TETANUS PREVENTION

Tetanus prevention

Tetanus is a fatal infectious disease that is caused by the bacterium *Clostridium tetani*. The bacterium enters the body through a puncture, cut, or open wound. Tetanus leads to profound painful spasms of muscles, including 'locking' of the jaw so that the mouth cannot open, and death. Prevention involves immediately cleaning and covering any open wound and getting a tetanus vaccination. Regular boosters are necessary to ensure immunity.

Individuals who have wounds such as abrasions, cuts, or bites should be asked about their tetanus immunisation status, and be offered immunisation if appropriate.[17]

Table 7.1 Tetanus PEP requirements

Immunisation status	Clean, minor wound		All other wounds*	
	TT, IM 0,5mL	TIG‡	TT, IM 0,5mL	TIG‡
Not immunised in the last 5 years	Yes	No	Yes	Yes
Immunised in last 5 years	No	No	No	No

Abbreviations: TT = Tetanus toxoid vaccine
TIG = Tetanus immune globulin

* Such as, but not limited to, wounds contaminated with dirt, faeces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns, and frostbite.

‡ People with HIV infection or severe immunodeficiency who have contaminated wounds (including minor wounds) should also receive TIG, regardless of their history of tetanus immunisations.

Source: PHC EML, 2018 [20]

SECTION 8

MONITORING AND EVALUATION

Introduction

Programme monitoring and evaluation (M&E) is critical to implementation: it enables stakeholders to know if the implementation process is on course for achieving the designed goals and objectives; it helps in tracking progress in line with milestones, and it uses indicators to ascertain achievements.

This PEP M&E plan is not designed to cover the full management of all types of exposures, including sexual assault. It covers only the monitoring of the effective implementation of PEP for HIV, viral hepatitis, STIs, tetanus, and the prevention of unwanted pregnancy.

These indicators are not part of the routine indicators collected at primary care level. These may be collected using alternative means of collection, where funding mechanisms allow.

Logical framework

Table 8.1 PEP M&E logic framework

Purpose of the Guideline:	The purpose of this Guideline is to ensure healthcare providers at all levels of care have the most up-to-date recommendations on post-exposure prophylaxis for the prevention of HIV, HBV, STIs, tetanus, as well as preventing unintended pregnancy

Activities/ Input	Outputs	Outcomes	Impact
Provision of PEP service at the facility level	• Total number of individuals exposed to blood and body fluids seen at the facility disaggregated by type of exposure (occupational and non-occupational exposure: sexual vs inadvertent)	• The proportion of individuals exposed to blood and body fluids seen at the facility within 72 hours post-exposure	Reduced HIV infection (for all)
Provision of PEP (ARV prophylaxis) to eligible individuals for preventing HIV infection	• The proportion of individuals exposed to blood and infectious body fluids seen at the facility tested for HIV • The proportion of individuals exposed to blood and infectious body fluids eligible for PEP • Number of exposed individuals initiated on ARV prophylaxis	• The proportion of exposed individuals initiated on ARV prophylaxis that completed a 28-day regimen	
Activities/ Input	**Outputs**	**Outcomes**	**Impact**

	• The proportion of exposed individuals initiated on ARV prophylaxis within 72 hours post-exposure • The proportion of exposed individuals initiated on ARV prophylaxis and given 28-day regimen	• The proportion of exposed individuals initiated on ARV prophylaxis and HIV seroconvert at three months	
Provision of PEP (HBIG and HBV vaccine) to eligible individuals for preventing HBV infection	• Number of exposed individuals initiated on HBV prophylaxis	• The proportion of exposed individuals initiated on HBV prophylaxis that seroconvert at three months	
Provision of emergency contraception to women and eligible girls for the prevention of unwanted pregnancy	• Number of women/eligible girls that were given emergency contraception after sexual exposure	• The proportion of women/eligible girls that were given emergency contraception and tested positive on pregnancy test within one-month post sexual exposure	
Prophylactic treatment of STIs in the sexually exposed individual	• Number of healthcare workers trained on the implementation of PEP package of services	• Number of PHC facilities that can offer a minimum package of PEP care per district • The proportion of PHC facilities with healthcare workers skilled in offering PEP package of service	
Ensuring the availability of PEP medication	• PEP medication available (ARV prophylaxis as a marker)	• Number of patients that are eligible for prophylactic treatment but did not receive because of stock out	

Proposed PEP indicators

(Core indicators are highlighted in bold)

Health systems

- Number of PHC facilities that provide a minimum package of PEP care per district
- The proportion of PHC facilities per district that provide a minimum package of PEP care
- The proportion of PHC facilities with healthcare workers skilled in offering PEP package of services

The utilisation of services/burden of exposure

- Total number of individuals exposed to blood and body fluids seen at the facility disaggregated by type of exposure (occupational and non-occupational exposure)
- The proportion of individuals exposed to blood and body fluids seen at the facility within 72 hours post-exposure

- The proportion of individuals exposed to blood and body fluids that are as a result of sexual exposure

PEP stock management

- PEP medication available (ARV prophylaxis as a marker)
- Number of patients that are eligible for PEP prophylactic treatment but did not receive because of stock out (detail by type of PEP prophylaxis)

HIV PEP

- The proportion of individuals exposed to blood and body fluids seen at the facility tested for HIV
- Number of exposed individuals initiated on ARV prophylaxis
- The proportion of exposed individuals initiated on ARV prophylaxis within 72 hours post-exposure
- The proportion of exposed individuals initiated on ARV prophylaxis and given 28-day regimen
- The proportion of exposed individuals initiated on ARV prophylaxis that completed a 28-day regimen
- The proportion of exposed individuals initiated on ARV prophylaxis and HIV seroconvert at 3 months

Hepatitis B PEP

- Number of exposed individuals eligible for hepatitis B prophylaxis
- Number of exposed individuals initiated on hepatitis B prophylaxis
- The proportion of exposed individuals initiated on hepatitis B prophylaxis that seroconvert at 6 months

STI prevention

- Number of sexually exposed individuals that were eligible for STI prevention medication
- Number of sexually exposed individuals that were given STI prevention medication
- The proportion of sexually exposed individuals that developed an STI after 3 months of prophylactic treatment

Prevention of unwanted pregnancy

- Number of women/eligible girls that qualify for emergency contraception (EC) after sexual exposure
- Number of women/eligible girls that were given emergency contraception after sexual exposure
- The proportion of women/eligible girls that were given emergency contraception after sexual exposure

Tetanus

- Tetanus should be monitored in line with the PHC routine process. No indicator is necessary for this under PEP monitoring.

Activities/Input	Outputs	Rationale	Numerator	Denominator	Primary level of responsibility	Data collection tool	Frequency of reporting
Provision of PEP service utilisation at the facility level	Total number of individuals exposed to blood and body fluids seen at the facility disaggregated by type of exposure (occupational and non-occupational exposure)	Indication of the utilisation of PEP services at the facility level	N/A	N/A	Facility	DHIS	Monthly
	The proportion of individuals exposed to blood and body fluids that are as a result of sexual exposure	Monitor the frequency of sexual offence cases in relation to other exposures	Number of individuals sexually exposed to blood and body fluids seen at the facility	Total number of individuals exposed to blood and body fluids seen at the facility	Facility	DHIS	Monthly
	The proportion of individuals exposed to blood and body fluids seen at the facility within 72 hours post-exposure	Proxy indicator to access PEP services	Number of individuals exposed to blood and body fluids seen at the facility within 72 hours post-exposure	Total number of individuals exposed to blood and body fluids seen at the facility	Facility	DHIS	Monthly
Provision of PEP (ARV prophylaxis) to eligible individuals for preventing HIV infection	The proportion of individuals exposed to blood and body fluids seen at the facility tested for HIV	Monitor the HIV testing rate among exposures	Number of exposed individuals seen at the facility tested for HIV	Total number of individuals exposed to blood and body fluids seen at the facility			
	Number of exposed individuals initiated on ARV prophylaxis	Monitors ARV prophylaxis initiation among the exposed	N/A	N/A	Facility	DHIS	Monthly
	The proportion of exposed individuals initiated on ARV prophylaxis within 72 hours post-exposure	Monitors ARV prophylaxis initiation within the period of HIV PEP effectiveness (72 hours)	Number of exposed individuals initiated on ARV prophylaxis within 72 hours post-exposure	Number of exposed individuals initiated on ARV prophylaxis	Facility	DHIS	Monthly
	The proportion of exposed individuals initiated on ARV prophylaxis and given 28-day regimen	Establish an indication that exposed individual will not default treatment because of lack of medication	Number of exposed individuals initiated on ARV prophylaxis and given 28-day regimen	Number of exposed individuals initiated on ARV prophylaxis	Facility	DHIS	Monthly
	The proportion of exposed individuals initiated on ARV prophylaxis that completed a 28-day regimen	Monitors adherence to medication	Number of exposed individuals initiated on ARV prophylaxis that completed a 28-day regimen	Number of exposed individuals initiated on ARV prophylaxis	Facility	DHIS	Monthly
	The proportion of exposed individuals initiated on ARV prophylaxis and HIV seroconvert at 3 months	Monitors the performance of the HIV PEP intervention	Number of exposed individuals initiated on ARV prophylaxis and HIV seroconvert at 3 months	Number of exposed individuals initiated on ARV prophylaxis	Facility	DHIS	Monthly

Activities/Input	Outputs	Rationale	Numerator	Denominator	Primary level of responsibility	Data collection tool	Frequency of reporting
Provision of PEP (HBIG and HBV vaccine) to eligible individuals for preventing hepatitis B infection	Number of exposed individuals eligible for hepatitis B prophylaxis	Establish number eligible for hepatitis B prophylaxis	N/A	N/A	Facility	DHIS	Monthly
	Number of exposed individuals initiated on hepatitis B prophylaxis	Monitors hepatitis B prophylaxis initiation among the exposed	N/A	N/A	Facility	DHIS	Monthly
	The proportion of exposed individuals initiated on hepatitis B prophylaxis that seroconvert at 6 months	Monitors the performance of the hepatitis B prophylaxis intervention	Number of exposed individuals initiated on hepatitis B prophylaxis that seroconvert at 6 months	Number of exposed individuals initiated on hepatitis B prophylaxis	Facility	DHIS	Monthly
Provision of emergency contraception (EC) to women and eligible girls for the prevention of unwanted pregnancy	Number of women/eligible girls that qualify for emergency contraception (EC) after sexual exposure	Establish number eligible for EC	N/A	N/A	Facility	DHIS	Monthly
	Number of women/eligible girls that were given emergency contraception (EC) after sexual exposure	Establish the numbers of exposed individuals eligible for EC	N/A	N/A	Facility	DHIS	Monthly
	The proportion of women/eligible girls that were given emergency contraception and tested positive on pregnancy test within one-month post sexual exposure	Monitor the EC rate among the eligible	Number of women/ eligible girls that were given emergency contraception and tested positive on pregnancy test within one-month post sexual exposure	Number of women/eligible girls that were given emergency contraception (EC) after sexual exposure	Facility	DHIS	Monthly
Prophylactic treatment of sexually transmitted infections (STI) in sexually exposed individuals	Number of sexually exposed individuals that were eligible for STI prevention medication	Establish the number eligible for STI prevention medication	N/A	N/A	Facility	DHIS	Monthly
	Number of sexually exposed individuals that were given STI prevention medication	Monitors initiation on STI prevention medication	N/A	N/A	Facility	DHIS	Monthly
	The proportion of sexually exposed individuals that developed an STI after 3 months of prophylactic treatment	Monitor programme performance of STI prevention	Number of sexually exposed individuals that developed an STI after 3 months of prophylactic treatment	Number of sexually exposed individuals that were given STI prevention medication	Facility	DHIS	Monthly

Activities/Input	Outputs	Rationale	Numerator	Denominator	Primary level of responsibility	Data collection tool	Frequency of reporting
Training of healthcare workers on the implementation of PEP guideline	Number of healthcare workers trained on the implementation of PEP package of services	Monitors the capacity of the healthcare workers to deliver PEP services	N/A	N/A	National / Province	DHIS	Quarterly
	Number of facilities that can offer a minimum package of PEP care per district	Monitors the numbers of facilities that provide PEP services	N/A	N/A	National / Province	DHIS	Quarterly
	The proportion of PHC facilities with healthcare workers skilled in offering PEP package of service	Establish coverage of PEP services	Number of PHC facilities that can offer a minimum package of PEP care per district	Number of PHC facility in the district	National / Province	Survey	Annual
Ensuring the availability of PEP medication	PEP medication available (ARV prophylaxis as a marker)	Monitors the availability of PEP medication	N/A	N/A	Province / District / Facility	DHIS	Monthly
	Number of patients that are eligible for prophylactic treatment but did not receive because of stock out	Monitor stock out of PEP medication	N/A	N/A	Facility	DHIS	Monthly

Evaluation

A baseline assessment of the implementation of PEP in the country should be done to serve as a reference for tracking the performance of PEP implementation. This will serve as a reference guide for the periodic evaluation.

The PEP policy should be evaluated every three years to determine the following:

- The quality of implementation of the package of service
- The coverage of the PEP service
- The effectiveness of the prophylaxis among those that were offered PEP
- This evaluation could be conducted as part of overarching SRHR or as a stand-alone evaluation process

ANNEXURE 1
DRUG DOSING OF ARVS FOR PEP IN INFANTS

Zidovudine (AZT)

Use intravenous AZT if oral drugs are contraindicated (necrotising enterocolitis; intestinal obstruction; gut anomaly). Discuss with a paediatric infectious disease (ID) specialist.

Oral dosing of zidovudine (10 mg/mL syrup) for PEP in HIV-exposed infants

Birth weight / gestational age	Age at exposure	Dosage
If gestational age < 35 weeks	Birth to 6 weeks	2 mg/kg/dose 12 hourly (0,2 ml/kg/dose 12 hourly)
< 3 kg and ≥ 35 weeks	Birth to 6 weeks	4 mg/kg/dose 12 hourly (0,4 ml/kg/dose 12 hourly)
≥ 3 kg and ≥ 35 weeks	Birth to 6 weeks	12 mg 12 hourly (1,2 ml 12 hourly)
≥ 3 kg	> 6 weeks	Dose according to weight-based dosing chart (2019)

Lamivudine (3TC)

- < 28 days of age: 2 mg/kg/dose orally every 12 hours for 28 days
- ≥ 28 days of age: 4 mg/kg/dose orally every 12 hours for 28 days (if ≥ 3 kg, refer to the weight-based dosing chart

Lopinavir/Ritonavir (Kaletra®)

- 300 mg/m^2/dose orally 12 hourly for 28 days
- To calculate the surface area of the baby: BSA (m^2) = (0,05 x WT in kg) + 0,05
- **NOTE:** Serious adverse events have been associated with Kaletra use < 42 weeks gestational age. Discuss with a paediatric ID specialist, if any concerns.

ANNEXURE 2

ARV DRUG DOSING CHART FOR CHILDREN (2019)

	Abacavir (ABC)		**Lamivudine (3TC)**		**Zidovudine (AZT)**	**Lopinavir / ritonavir (LPV/r)**	
Target dose	8 mg/kg/dose **TWICE daily** OR **If ≥ 10 kg:** 16 mg/kg/dose **ONCE daily**		4 mg/kg/dose **TWICE daily** OR **If ≥ 10 kg:** 8 mg/kg/dose **ONCE daily**		180 - 240 mg/m²/dose **TWICE daily**	300/75 mg/m²/dose LPV/r **TWICE daily**	**LPV/r std dose + super-boosting with ritonavir (RTV)** solution **TWICE daily** (≥ 0,75 x LPV dose bd)
Available formulations	Sol. 20 mg/ml Tabs 60 mg (scored, dispersible), 300 mg (not scored), FDC: ABC/3TC 600/300 mg		Sol. 10 mg/ml Tabs 150 mg (scored), FDC: ABC/3TC 600/300 mg		Sol. 10 mg/ml Tabs 100 mg, 300 mg (not scored), FDC: AZT/3TC 300/150 mg	Sol. 80/20 mg/ml Adult tabs 200/50 mg, Paeds tabs 100/25 mg **TABLETS MUST BE SWALLOWED WHOLE**	Solution 80 mg/ml
Weight (kg)	Currently available tablet formulations of abacavir (except 60 mg), zidovudine, lopinavir/ritonavir, ritonavir, dolutegravir & efavirenz must be swallowed whole and NOT chewed, divided or crushed						
< 3	Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3 kg						
3 - 3,9	2 ml bd		2 ml bd		6 ml bd	*1 ml bd	1 ml bd
4 - 4,9							
5 - 5,9	3 ml bd		3 ml bd			*1,5 ml bd	1,5 ml bd
6 - 6,9					9 ml bd		
7 - 7,9	4 ml bd		4 ml bd				
8 - 8,9							
9 - 9,9							
10 - 10,9	**Choose only one option**		**Choose only one option**		12 ml bd OR 1 x 100 mg tab bd	2 ml bd OR 2 x 100/25 mg **paed tabs** am 1 x 100/25 mg **paed tab** pm	1,5 ml bd
11 - 13,9	6 ml bd OR 2 x 60 mg abs bd	12 ml od OR 4 x 60 mg tabs od	6 ml bd	12 ml od			
14 - 14,9	8 ml bd OR 2,5 x 60 mg tabs bd	5 x 60 mg tabs od OR 1 x 300 mg tab od OR 15 ml od	½ x 150 mg tab bd OR 8 ml bd	1 x 150 mg tab od OR 15 ml od	2 x 100 mg tabs am + 1 x 100 mg tab pm OR 15 ml bd	Choose only one option: 2,5 ml bd OR 2 x 100/25 mg **paed tabs** bd OR 1 x 200/50 mg **adult tab** bd	2 ml bd
15 - 16,9							
17 - 19,9							
20 - 22,9	10 ml bd OR 3 x 60 mg tabs bd	1 x 300 mg tab + 1 x 60 mg tab od	1 x 150 mg tab bd OR 15 ml bd	2 x 150 mg tab od OR 30 ml od	2 x 100 mg tabs bd OR 20 ml bd	Choose only one option: 3 ml bd OR 2 x 100/25 mg **paed tabs** bd OR 1 x 200/50 mg **adult tab** bd	2,5 ml bd
23 - 24,9		1 x 300 mg tab + 2 x 60 mg tab od					
25 - 29,9	1 x 300 mg tab bd	2 x 300 mg tabs od OR 1 x ABC/3TC 600/300 mg tab od	1 x 150 mg tab bd	2 x 150 mg tab od OR 1 x ABC/3TC 600/300 mg tab od	1 x 300 mg tab bd OR 1 x AZT/3TC 300/150 mg tab bd	Choose only one option: 3,5 ml bd OR 3 x 100/25 mg **paed tabs** bd OR 1 x 200/50 mg **adult tab** bd + 1 x 100/25 mg **paed tab** bd	3 ml bd
30 - 34,9						Choose only one option: 5 ml bd OR 4 x 100/25 mg **paed tabs** bd OR -2 x 200/50 mg **adult tabs** bd	4 ml bd
35 - 39,9							
≥ 40							

Lopinavir/ritonavir when on rifampicin (and for 2 weeks after stopping rifampicin) **Choose one of the 3 options below as appropriate**		**#Atazanavir (ATV) + ritonavir (RTV)**	**Dolutegravir (DTG)**	Dolutegravir when on rifampicin	Efavirenz (EFV)	
LPV/r std dose + super-boosting with ritonavir (RTV) powder **TWICE daily** (≥ 0,75 x LPV dose bd)	**Double-dose LPV/r tabs ONLY if able to swallow whole LPV/r tabs TWICE daily**	By weight band **ONCE daily**	By weight band **ONCE daily**	By weight band **TWICE daily**	By weight band **ONCE daily**	**Target dose**
Oral powder 100 mg/packet	Adult tabs 200/50 mg, Paed tabs 100/25 mg	ATV caps 150, 200 mg: RTV tabs 100 mg	Tabs 50 mg, FDC: TLD 300/300/50 mg	Tabs 50 mg	Caps/tabs 50, 200, 600 mg (not scored); FDC: TEE 300/200/600 mg	**Available formulations**
Currently available tablet formulations of abacavir (except 60 mg), zidovudine, lopinavir/ritonavir, ritonavir, dolutegravir & efavirenz must be swallowed whole and NOT chewed, divided or crushed						**Weight (kg)**
Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3 kg						**< 3**
100 mg (1 packet) bd	Do not use double-dose LPV/r tabs	Avoid ATV capsules when < 15 kg or < 6 years	Not currently recommended: dosing and formulations not available	Not currently recommended: dosing and formulations not available	Avoid using when < 10 kg or < 3 years	**3 - 3,9** **4 - 4,9** **5 - 5,9** **6 - 6,9** **7 - 7,9** **8 - 8,9** **9 - 9,9**
	3 x 100/25 mg tabs bd				1 x 200 mg caps/tabs nocte	**10 - 10,9** **11 - 13,9**
200 mg (2 packets) bd	4 x 100/25 mg tabs bd OR 2 x 200/50 mg tabs bd	ATV 1 x 200 mg cap od + RTV 1 x 100 mg tab od	1 x 50 mg tab od	1 x 50 mg tab bd	1 x 200 mg cap/tab + 2 x 50 mg caps/tabs nocte	**14 - 14,9** **15 - 16,9** **17 - 19,9** **20 - 22,9** **23 - 24,9**
300 mg (3 packets) bd	6 x 100/25 mg tabs bd OR 3 x 200/50 mg tabs bd				2 x 200 mg caps/tabs nocte	**25 - 29,9** **30 - 34,9** **35 - 39,9**
400 mg (4 packets) bd	4 x 200/50 mg tabs bd OR 8 x 100/25 mg tabs bd	ATV 2 x 150 mg cap od + RTV 1 x 100 mg tab od	1 x 50 mg tab od OR FDC: TLD if eligible od	1 x 50 mg tab bd OR FDC: TLD if eligible od + 50 mg 12 hours after TLD dose	1 x 600 mg tab nocte OR FDC: TEE if eligible od nocte	**≥ 40**

ANNEXURE 3
COMORBIDITIES AND DRUG INTERACTIONS AFFECTING THE CHOICE OF POST-EXPOSURE PROPHYLAXIS

Before initiating a client on PEP, it is important to take a thorough medication-related history to identify any potential drug-drug interactions. Ask about TB medications, treatment for NCDs, and any other prescribed medication. Also ask about over the counter (OTC) medications and traditional remedies. Drug interactions can result in suboptimal drug levels, which can affect the efficacy of prophylaxis.

Drug interactions with emergency contraception

Enzyme inducers (including efavirenz, carbamazepine) cause a significant reduction in levonorgestrel concentrations. Women on these medicines should double the dose of levonorgestrel, because of significant reduction of levonorgestrel.

Women > 80 kg or BMI ≥ 30 should also be given twice the standard dose.

Drug interactions with HIV PEP

Drug Interactions with dolutegravir

Interacting Drug	Effect of Coadministration	Recommendation
Rifampicin	↓ Dolutegravir	Double DTG dose to 50 mg 12-hourly. If on TLD FDC, add DTG 50 mg 12 hours after TLD dose
Polyvalent cations (Mg^{2+}, Fe^{2+}, Ca^{2+}, Al^{3+}, Zn^{2+}) e.g. antacids, sucralfate, multivitamin and nutritional supplements	↓ Dolutegravir	Calcium supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and calcium supplements can be taken at the same time if taken with food. Iron supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and iron supplements can be taken at the same time if taken with food. However, calcium and iron supplements must be taken at least 4 hours apart. Magnesium/aluminium containing antacids decrease DTG concentrations regardless of food intake and should be taken a minimum of 2 hours after or 6 hours before DTG
Anticonvulsants: • Carbamazepine • Phenobarbital • Phenytoin	↓ Dolutegravir	Avoid coadministration if possible. Alternative agents that do not interact with DTG include valproate, lamotrigine, levetiracetam, and topiramate. Remember that valproate is contra-indicated during pregnancy. Double DTG dose to 50 mg 12-hourly for carbamazepine if an alternative anticonvulsant cannot be used
Metformin/DTG	↑ Metformin	DTG increases metformin levels. Maximum metformin dose 500 mg 12-hourly

Comorbidities and drug interactions affecting the choice of antiretrovirals for HIV post-exposure prophylaxis

Comorbidity	Drug	Complication
Tuberculosis	LPV/r	Double the dose of LPV/r if patient is on rifampicin
Epilepsy	PIs	PIs increase the level of a number of commonly used anticonvulsants
Renal failure	NRTIs	Avoid TDF if creatinine clearance < 50 mL/min Dose adjust AZT, d4T and 3TC
Hypertension	PIs	PIs increase levels of calcium channel blockers. RTV increases beta blocker levels
Asthma	PIs	PIs decrease theophylline levels
DVT/PE	PIs	Increase warfarin levels, leading to risk of bleeding

LPV/r, lopinavir/ritonavir; PI, protease inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; TDF, tenofovir; AZT, zidovudine; d4T, stavudine; 3TC, lamivudine; RTV, ritonavir; DVT/PE, deep vein thrombosis/pulmonary embolus.

Source: Adapted from SAHCS Guideline on the management of occupational and non-occupational exposure to the human immunodeficiency virus and recommendations for post-exposure prophylaxis: 2015 Update.[11]

For more information, please refer to the following resources:

www.hiv-druginteractions.org/checker,

the Liverpool HIV iChart application for smartphones,

the SA HIV/TB Hotline application for android smartphones,

the EML-Antiretrovirals Interactions table available on www.mic.uct.ac.za,

or any of the following helplines:

- National HIV & TB Health Care Worker Hotline: 0800 212 506
- Right to Care Adult HIV Helpline: 082 957 6698
- Right to Care Paediatric and Adolescent HIV Helpline: 082 352 6642
- KZN Paediatric Hotline: 0800 006 603

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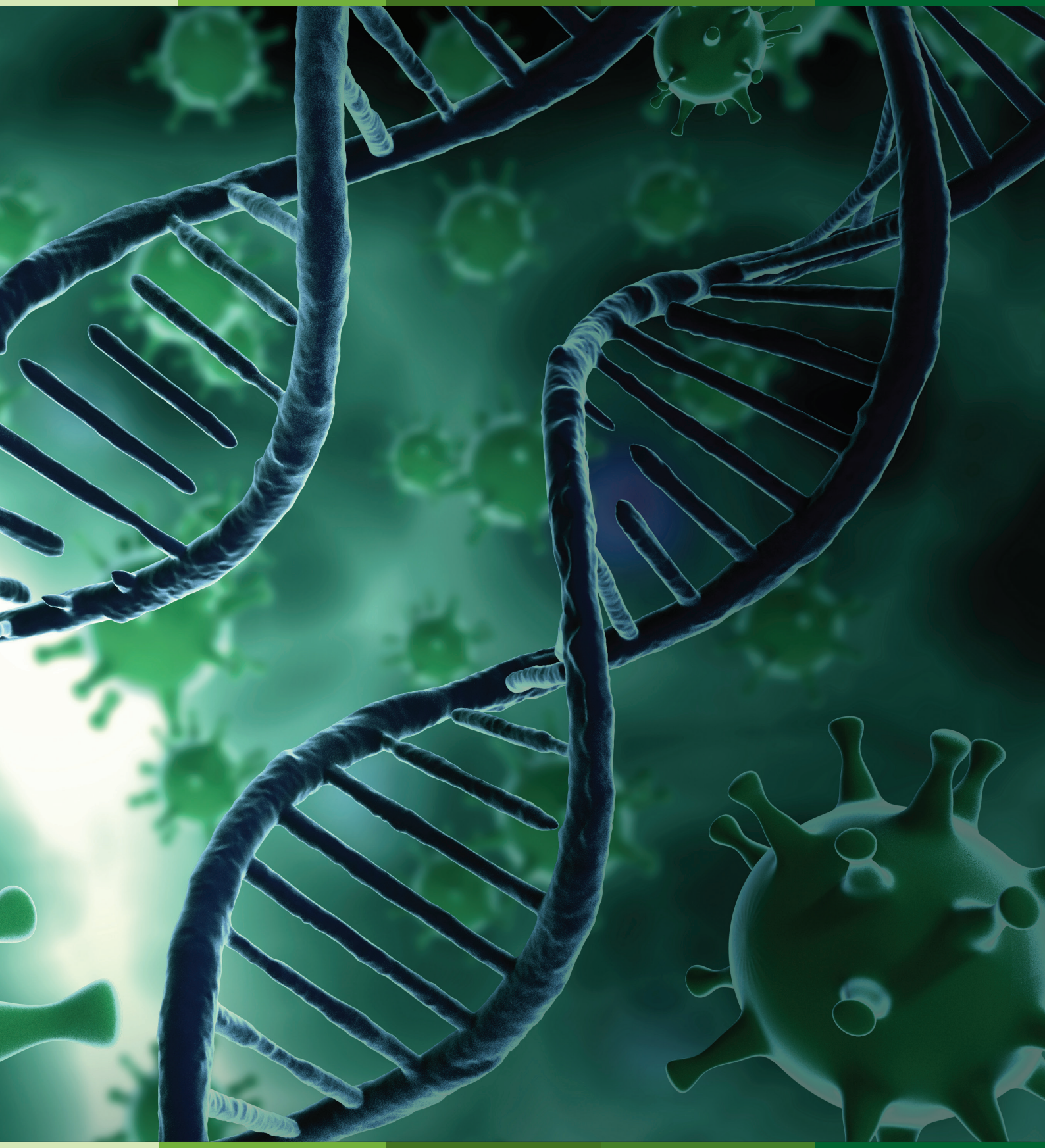

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Department:
Health
REPUBLIC OF SOUTH AFRICA

Civitas Building, 222 Thabo Sehume St,
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