THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

National Guidelines on Post-Exposure Prophylaxis Following Occupational and Non-Occupational Exposures to Blood and Other Body Fluids

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CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Jhpiego
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FOREWORD

Each day around the world, a large number of people experience accidental exposures to blood and other body fluids or tissues while performing their work duties or outside the work setting. These accidental exposures pose a significant risk to the transmission of blood-borne infections or development of such diseases.

The vast majority of accidental occupational exposures to pathogens, such as HIV and Hepatitis B and C viruses, occur in health care settings, and, as such, much emphasis has been placed on post-exposure management of such exposures among health care workers. However, there are other occupations in which people are at risk of accidental exposure, for example, law enforcement personnel, emergency and rescue workers, fire fighters, prison guards, and social service staff who work with intravenous drug users. Furthermore, non-occupational exposures, such as those from sexual assault, needle-sharing among intravenous drug users, human bites, and potential exposure through consensual sex, also have been poorly addressed, but they also bear a significant risk.

For provision of proper and timely post-exposure management, there has to be a functional system that ensures: timely identification and documentation of exposures, appropriate counselling and testing, prompt management in accordance with the national guidelines, continued follow-up and support, and data utilization for improving quality of post exposure prophylaxis (PEP) services.

Since 2004, the Ministry of Health and Social Welfare (MoHSW) in Tanzania has engaged in activities to improve the quality of PEP services as an integral component of infection prevention and control strategies. Despite some improvements, there remain some major challenges, including under-reporting of exposures, absence of a structured reporting system, inadequate record keeping and documentation practices, and failure to comply with the recommended guidelines. Therefore, taking into account the broad PEP definition as outlined in the World Health Organization (WHO)/International Labour Organization (ILO) PEP guidelines (2007), and realizing the gaps in the current practices in Tanzania, the MoHSW has developed this document to guide safe and high-quality provision of PEP services.

The main purpose of these guidelines is to provide the best practices in occupational and non-occupational PEP management at all levels of service provision so that outcomes for health care workers and external clients exposed to blood and other body fluids will be improved.

The MoHSW, in collaboration with development partners, is dedicated to supporting the implementation, monitoring, and evaluation of PEP best practices in health care settings. Therefore, it is our expectation that health facility management teams, quality improvement teams, health care workers, and other stakeholders will play a pivotal role in improving the quality of PEP services both at the facility level and in the country at large.

Mr. Charles A. Pallangyo
PERMANENT SECRETARY

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The development of the National Guidelines for Post-Exposure Prophylaxis services is the result of extensive work involving consultations and collaborative efforts of various stakeholders, including a number of individuals, several institutions, organizations, development partners and professional associations, and other interested groups.

The Ministry of Health and Social Welfare (MoHSW) would like to take this opportunity to acknowledge all stakeholders who contributed in one way or another to the successful development of this document. In particular, the MoHSW wishes to recognize the invaluable contributions of the Centers for Disease Control and Prevention–Tanzania through the Jhpiego Infection Prevention Program for its financial and technical support during the development and printing of the document.

Special thanks also go to Ms. Natalie Hendler (Infection Prevention Project Director), for her outstanding leadership and commitment in ensuring that post-exposure management services are strengthened in the country. The MoHSW wishes to recognize remarkable contributions by Dr. Albert Komba (Infection Prevention Advisor) and Dr. Chandrakant Ruparelia (Senior Technical Advisor), who spearheaded the technical review process and the production of the final draft of these guidelines. Thanks also go to other Jhpiego team members, including Valentina Msechu (Infection Prevention Officer), Steven Chombo (Quality Improvement Advisor) and Lemmy Mabuga (HIV Programme Officer), for their tremendous participation.

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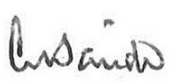
Lastly, we would like to extend our sincere appreciation in advance to all those who, after being introduced to this document, will be positively influenced to join the MoHSW's efforts to improving the quality of PEP services in Tanzania.



Dr. Donan W. Mmbando
CHIEF MEDICAL OFFICER

ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ARV	Antiretroviral
AZT	Zidovudine
CHMTs	Council Health Management Teams
DNA	Deoxyribonucleic Acid
EFV	Efavirenz
EIA	Enzyme Immunoassay
ELISA	Enzyme-Linked Immunosorbent Assay
HBIG	Hepatitis B Immunoglobulin
HBV	Hepatitis B Virus
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HF	Health Facility
ILO	International Labour Organization
IPC	Infection Prevention and Control
MMWR	Morbidity and Mortality Weekly Report
MoHSW	Ministry of Health and Social Welfare
NACP	National AIDS Control Programme
NRTI	Nucleoside Reverse Transcriptase Inhibitors
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
PEP	Post-Exposure Prophylaxis
PMTCT	Prevention of Mother-To-Child Transmission
QIT	Quality Improvement Team
RHMTs	Regional Health Management Teams
RNA	Ribonucleic Acid
RTI	Reproductive Tract Infections
STI	Sexually Transmitted Infection
TT	Tetanus Toxoid
WHO	World Health Organization

DEFINITIONS AND INTEPRETATIONS OF TERMS€

Child: According to the Tanzania constitution and the Law of the Child Act, a child is a person (male or female) who is less than 18 years of age.

Consent: Making an informed choice freely and voluntarily to do something. There is no consent when agreement is obtained through the use of threat, force, or other forms of coercion, abduction, fraud, deception, or misrepresentation.

Drop-in centre: A place for information, safety, referral, first aid, and other immediate needs of survivors of gender based violence (including victims of rape and sexual assault) who need a safe and confidential place for a limited period of time.

Exposed person: A person who has been exposed to potentially infected blood and other body fluids that can result in infection with blood-borne infections, such as HIV and hepatitis.

Female genital mutilation: Comprises all procedures that involve partial or total removal of the external female genitalia, or other injury inflicted to the female genital organs for non-medical reasons.

Gender-based violence (GBV): Umbrella term for any act, omission, or conduct that is perpetuated against a person's will and that is based on socially ascribed differences (gender) between males and females. In this context, GBV includes but is not limited to sexual violence, physical violence, and harmful traditional practices, and economic and social violence. The term refers to violence that targets individuals or groups on the basis of their being female or male.

Illicit sexual intercourse: Sexual intercourse between persons who are not married.

Man: A male more than 18 years of age.

Perpetrator: A person, group, or institution that directly or indirectly inflicts, supports, and condones violence or other abuse against a person or a group of persons. Perpetrators are in a position of real or perceived power, decision making, and/or authority and can thus exert control over their victims/survivors.

Rape: According to the Special Offenses Provisional Act, 1998, Section 130 of the penal code was repealed and replaced by the following: Rape 130-(1) It is an offence for a man to rape a child or a woman. (2) A man commits the offence of rape if he has sexual intercourse with a child or woman under circumstances falling under any of the following descriptions: not being his wife, or being his wife who is lawfully separated from him without her consenting to it at the time of the sexual intercourse; with her consent when the consent has been obtained by the use of force, threats, or intimidation or by putting her in fear of death or of injury or while she is in unlawful detention; with her consent when her consent has been obtained at a time when she was in a state of intoxication induced by alcohol or any drugs, matter or thing, administered to her by the man or by some other person; with her consent when the man knows that he is not her husband, and that her consent is given because she has been made to believe that he is another man to whom she is or believes herself to be lawfully married; with or without her consent when she is under 18 years of age, unless the woman is his wife who is 15 or more years of age and is not lawfully separated from the man. (3) For the purposes of proving the offence of

rape, penetration is sufficient to constitute the sexual intercourse necessary to the offence; and evidence of resistance such as physical injuries to the body is not necessary to prove that sexual intercourse took place without consent.

Safe house: A place of temporary refuge, suitable for hiding or keeping safe GBV victims/survivors, witness, or other persons perceived as being in danger; a place where trusted adult, family, or a community or charity organization provides a safe haven for GBV survivors/victims.

Sexual abuse: Illegal sexually-oriented acts or words done or said in relation to any person for gratification or for any other illegal purposes.

Sexual assault: A sexual act or attempt to obtain a sexual act against the victims' will, using threats, intimidation, or physical force by any person, regardless of their relationship to the victim.

Sexual intercourse: Whether natural or unnatural, shall, for the purpose of proof of a sexual offence, be deemed to be complete upon proof of penetration only, not by completion of the intercourse by the emission of semen.

Sexual offence: Any of the offences created in Parts XV and XVI of the Penal Code.

Source person: Person who is (either identified or not identified as) the possible source of infection through potentially infectious blood or body fluid.. Theperson may be either a patient if a health care worker is exposed or may be a perpetrator in cases of sexual assault.

Vaccine responder: Person who has protective surface antibodies to hepatitis B virus.

Woman: Any female more than 18 years of age, married or unmarried.

Women's or children's institution: An institution for the reception and care of women or children, however described.

Window period: Is the length of time after infection that it takes for the microbes to become detectable by antibody-based diagnostic tests. The length of the window period varies depending on the type of diagnostic test used and the method it employs to detect the organism.

€Definitions adapted from the National Management Guidelines for the Health Sector Prevention and Response to Gender Based Violence (MOHSW/GBV 2013), and the HIV and AIDS Workplace Interventions Guidelines (MOHSW/OHU 2008).

SECTION 1.0: INTRODUCTION

1.1 BACKGROUND

Each day around the world, a large number of people experience accidental exposures to blood and other body fluids or tissues either while performing their work duties or outside the work setting. In health facility settings, health care workers are especially vulnerable. Moreover, throughout the world, there is increased potential for workplace accidents that may expose workers to HIV and other blood-borne pathogens, including hepatitis B (HBV) and hepatitis C (HCV) viruses.

Recognizing this important public health problem, the World Health Organization (WHO) and the International Labour Organization (ILO) convened an experts' consultation forum that met in Geneva, Switzerland, in 2005 (WHO 2007) to review scientific evidence and programmatic experience in relation to provision of post-exposure prophylaxis (PEP) in occupational and non-occupational settings, and, more importantly, to recommend a consensus approach to policy guidelines formulation. During this forum, it became evident that there was a significant increase in risk of acquiring blood-borne infections from non-occupational exposures, especially those arising from sexual assault, isolated or episodic intravenous drug use, and consensual sexual exposure. In many countries, antiretroviral (ARV) medicines have been prescribed for PEP following occupational exposure to HIV, but a significant number of non-occupationally related exposed individuals have been inadequately managed.

Although there is limited data on non-occupational exposures in Tanzania, it is necessary to prevent these exposures and, whenever they occur, to appropriately manage them. Furthermore, policymakers and health care providers have been raising questions about certain aspects of the use of HIV PEP, in particular, about the indications for PEP, the most suitable ARV 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 ARV therapy in more resource-constrained settings, including Tanzania, and has led to calls for clear operational guidance on providing PEP.

Since the choice of HIV PEP regimen is based on the country's first-line ARV regimen, as periodically revised by the Ministry of Health and Social Welfare (MoHSW) through the National AIDS Control Program (NACP), it is required of all health care providers responsible for providing PEP, to always make reference to the current National Guidelines for Management of HIV and AIDS, before they decide on the right combination of ARVs. These guidelines list the various acceptable ARV combinations for HIV PEP, but strongly recommend the use of potent, available, and well-tolerated combinations that are easy to take.

What is new in these guidelines?

These new guidelines recommend use of three-drug regimen for all exposed clients regardless of the degree of risk. The recommendation is based on evidence from Prevention of Mother-to-Child Transmission (PMTCT) of HIV data and other research studies that indicate that a three-drug regimen is more effective than a two-drug regimen, and providers' challenges in being able to appropriately classify the risk.

Furthermore, since source persons who are in a "window period" may not be identified, MoHSW recommends provision of a full course of HIV PEP for all exposed persons whom the clinician has ascertained that the source person could have exposed to HIV in the previous six weeks. In addition, since evidence shows that a non-reactive HIV test result at three months post

exposure excludes HIV infection related to the exposure event, these guidelines have omitted the need for routine testing at six months post exposure.

Recommendations on PEP management for HBV, HCV, tetanus, sexually transmitted infections, and pregnancy have also been updated.

1.2 PURPOSE AND SCOPE

These guidelines outline the best practices in occupational and non-occupational management of people exposed to blood and other body fluids by providing PEP and other measures for preventing the transmission of blood-borne infections. This document is intended for all levels of health care providers and other service providers, as well as the general community.

1.2.1 Objectives

Specifically, these guidelines aim to:

- Increase knowledge and awareness of the risks associated with occupational and non-occupational exposure to blood and other body fluids,
- Improve outcomes for health care workers and clients who are accidentally exposed to blood and other body fluids,
- Increase providers' confidence, safety, and comfort in working at health care facilities in Tanzania, and
- Increase confidence and safety of external clients in receiving health services at Tanzanian health facilities.

1.2.2 Target Audience

This document is for:

- All health care workers in both the public and private health care facilities, including those involved in home-based care
- Trained health care providers responsible for PEP, including the PEP focal person, the facility quality improvement team (QIT) members, and the health facility management team
- Council Health Management Teams (CHMTs) and Regional Health Management Teams (RHMTs)
- Procurement officials
- Students and faculty members in health-related courses
- Other related sectors
- The general community

SECTION 2.0: TYPES AND RISKS OF EXPOSURES TO BLOOD-BORNE PATHOGENS

2.1 DEFINITIONS

Post-exposure prophylaxis is generally understood to mean the medical response to prevent the transmission of blood-borne pathogens, including HIV, after exposure to blood and other body fluids (WHO 2007).

2.1.1 Types of Exposures

Exposures to blood and other body fluids or tissues can be categorized as occupational or non-occupational. Table 1 lists the individuals who are potentially at risk for each type of exposure.

Table 1. Individuals at Risk by Types of Exposures

OCCUPATIONAL	NON-OCCUPATIONAL
Health care workers	Victims of sexual assault
Emergency rescuers	People who share needles or sharps (e.g., intravenous drug users, females who have undergone genital mutilation, and males who have undergone unsafe circumcision procedures)
Waste disposal workers	Individuals who have consensual sex
Law enforcement personnel	Victims of human bites
Fire fighters	Victims of accidents (e.g., road traffic accidents)

2.1.2 Types of Body Fluids

Various types of body fluids have a potential risk for transmission of infections. Table 2 lists the types of body fluids and their respective infectivity potential according to the currently available scientific evidence.

Table 2: Body Fluids Known, Presumed and Known Not to Be Infectious[¥]

Body Fluids *Known* to Be Infectious	Body Fluids *Presumed* to Be Infectious	Body Fluids Known *Not* to Be Infectious (If Not Visibly Bloody)
• Blood • Any fluid with blood • Semen • Vaginal secretions • Breast milk[a]	• Cerebral spinal fluid • Pleural fluid • Pericardial fluid • Peritoneal fluid • Amniotic fluid • Synovial fluid	• Tears • Saliva • Urine • Faeces • Sweat • Emesis

[¥]Adapted from the National Infection Prevention and Control Guidelines for Healthcare Services in Tanzania (MOHSW/IPC 2007) and Quality Improvement – Infection Prevention and Control Orientation Guide for Participants (IPC 2009)

[a] Although small amounts of HBV and HCV have been found in breast milk, there is no documented risk of transmitting infections by breastfeeding, unless nipples are cracked.

Note: Assume any body fluid is infectious unless proven otherwise. The risk of transmission increases with larger volumes of fluid and more severe injuries.

2.2 COMMON PROCEDURES AND EVENTS LEADING TO OCCUPATIONAL EXPOSURES AND THEIR ASSOCIATED RISKS FOR BLOOD-BORNE PATHOGEN TRANSMISSION

2.2.1 Common Procedures and Events Presenting Risk of Occupational Exposure to Blood and Other Body Fluids

The most common procedures, events , or activities presenting the risk of exposure to blood and other body fluids include the following:

- Taking blood samples from veins and samples of other body fluids
- Inserting an intravenous line and handling drips, especially in emergency situations
- Providing intravenous medications
- Performing activities related to surgery, particularly during major surgical interventions of long duration or where haemorrhage may occur
- Performing rescue procedures in the event of disasters, emergencies, fire, or accidents
- Handling blood or other potentially infectious body fluids by health care workers (e.g., laboratory staff, labour ward staff, home-based care providers)
- Performing activities related to handling, pre-disinfection/cleaning of contaminated medical devices
- Sorting, separating, transporting, and cleaning hospital linens
- Caring for patients with mental illness
- Imbedding dead bodies in the mortuary
- Handling of infectious waste, which includes collecting, transporting, storage, and final disposal or treatment of waste

2.2.2 Risk Classification Associated with Different Types of Occupational Exposures to Blood and Other Body Fluids

Different types of occupational exposures are associated with different levels of risk of transmission of blood-borne pathogens (see Table 3).

Table 3. Levels of Risk According to Type and Severity of Occupational Exposure[a]

RISK CLASSIFICATION	TYPES OF EXPOSURES
High-Risk Exposures (Occupational post-exposure prophylaxis should be recommended)	• Exposure to a large volume of blood or potentially infectious fluids • Exposure to blood or body fluid contaminated with HIV from a source with high viral load • Injury with a large-bore hollow needle • Injury with device used in artery or vein • Injuries with blood-stained device • Deep and extensive injuries • Confirmed drug resistance in source person • Source person has symptomatic HIV infection, AIDS, known high viral load, or is in a window period

RISK CLASSIFICATION	TYPES OF EXPOSURES
Low-Risk Exposures (Occupational post-exposure prophylaxis should be recommended)	• Exposure to small volume of blood or potentially infectious fluids • Injury with a solid needle • Injury with small size needle • Any superficial injury or mucocutaneous exposure • Bite from a patient with visible bleeding in the mouth that causes bleeding in the exposed worker • Exposure to non-intact skin (e.g., dermatitis, chapped skin, abrasion, or open wound) with blood, visibly bloody fluid, or any other potentially infectious material • Source has asymptomatic HIV infection or known low viral load (< 1,500 RNA copies/mL), in the absence of other risks (for example, high risks)
	Below is a list of factors that increase risk for the above exposure events • Source person is known to be HIV-infected with high viral load • Source person has drug-resistant HIV and AIDS • Source person is in a window period • Deep skin penetration
No Risk (Occupational post-exposure prophylaxis not warranted)	• Exposure to solid-bore needles or sharps not in recent contact with blood[b] • Bite from a patient with visible bleeding in the mouth that causes bleeding in the exposed worker[c]

[a] Modified from New York State Department of Health AIDS Institute: HIV Prophylaxis Following Occupational Exposure, Updated in October 2012. Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-occupational-exposure.pdf (NYS-DOH-AI 2012)
[b] Examples of solid-bore needles include tattoo needles and lancets used by diabetes patients to measure blood-sugar levels
[c] When bite wounds result in blood exposure, the risk could be to the person bitten, the bitter, or both

2.3 COMMON INCIDENCES LEADING TO NON-OCCUPATIONAL EXPOSURES AND THEIR ASSOCIATED RISKS FOR BLOOD-BORNE PATHOGEN TRANSMISSION

2.3.1 Common Incidences Presenting Risk of Non-Occupational Exposure to Blood and Other Body Fluids

Various types of events that are associated with non-occupational exposure to blood and other body fluids include the following:

- Needle sharing among drug users wherein the risk is high if the source is known to have an acute and active infection or is at risk of blood-borne infection (e.g., HIV, HBV or HCV)
- Consensual sex or assault, wherein the risk becomes higher in the following circumstances
  - Receptive vaginal or anal intercourse without a condom or with a condom that broke or slipped
  - Contact between the perpetrator's blood or ejaculate and mucous membrane or non-intact skin during the assault
  - Receptive oral sex with ejaculation
  - Oral sex where there is blood exposure

- Presence of other sexually transmitted infections (STIs), particularly genital ulcer disease

- Other non-occupational injuries, including needle sticks, human bites, accidents, wherein the risk is high if a source person is known to have an active infection or is at risk of blood-borne infection (e.g., HIV, HBV or HCV).

2.3.2 Risk Classification Associated with Different Types of Non-Occupational Exposures to Blood and Other Body Fluids

For non-occupational exposures, such as injuries or accidents that involve contact of blood and other body fluids to skin, the risk categorization is similar to that for occupational exposures, as presented in Table 3. However, for other types of non-occupational exposures, Table 4 summarizes the risk classification.

Table 4. Levels of Risk According to Type and Severity of Non-Occupational Exposure[a]

RISK CLASSIFICATION	TYPES OF EXPOSURES
High-Risk Exposures (Non-occupational post-exposure prophylaxis should be recommended)	• Unsafe receptive and insertive vaginal or anal intercourse • Rape or assault involving multiple perpetrators • Rape or assault involving anal penetration • Rape or assault in which there is obvious trauma to the genital areas • Rape or assault in which one of the perpetrators is known to be HIV-positive • Sharing of needles in intravenous drug users (who never shared needles)[b] • Condom spillage or breakage during consensual sex • Rape or assault with no obvious trauma to genital areas • Injuries with exposure to blood or other potentially infected fluids from a source person known to have symptomatic HIV infection, AIDS, high viral load, unknown HIV status (including needle sticks with a hollow-bore needle, human bites, accidents), or is in a window period. • Injury in which source person has drug-resistant HIV strain
Low-Risk Exposures (Non-occupational post-exposure prophylaxis should be recommended)	• Oral-vaginal contact (receptive or insertive) • Oral-anal contact (receptive or insertive) • Receptive penile-oral contact with or without ejaculation • Insertive penile-oral contact with or without ejaculation • Rape or assault involving vaginal or mouth penetration (with no obvious injuries/trauma) • Bite from a person with visible bleeding in the mouth that causes bleeding in the exposed person[c] • Injuries resulting from trauma cases involving mass casualties--when there is significant cross-contamination with blood and other body fluids (e.g. motor traffic accidents) • Injury in which source has asymptomatic HIV infection or known low viral load (< 15000 RNA copies/mL), in the absence of other risks (e.g., high risks)
	Below is a list of factors that increase risk for the above exposure events • Source person is known to be HIV-infected with high viral load

RISK CLASSIFICATION	TYPES OF EXPOSURES
	• Source person is in a window period • An oral mucosa that is not intact (e.g., oral lesions, gingivitis, wounds) • Oral mucosa is not intact (e.g., oral lesions, gingivitis, wounds)--for oral sex exposure • Lack of male circumcision[d] • Cervical ectopy[d] • Blood exposure--it is important to note that blood exposure can be minimal and therefore not recognized by exposed person. If the exposed person reports frank blood exposure, PEP would be indicated • Presence of genital ulcer disease or other STIs[e] • Lack of condom use[e]
No Risk (Non-occupational post-exposure prophylaxis not warranted)	• Kissing[f] • Oral-to-oral contact without mucosal damage (mouth-to-mouth resuscitation) • Human bites not involving blood • Exposure to solid-bore needles or sharps not in recent contact with blood[g] • Mutual masturbation without skin breakdown or blood exposure

[a] Modified from New York State Department of Health AIDS Institute: HIV Prophylaxis Following Non-Occupational Exposure, Updated in July 2013. Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf (NYS-DOH-AI 2013)
[b] With source known to be HIV-positive or HIV status is unknown
[c] When bite wounds result in blood exposure, the risk could be to the person bitten, the biter, or both
[d] For sexual exposure
[e] Correct condom use is highly effective in preventing transmission of HIV; however, during the post-exposure evaluation, it is often not possible to reliably ascertain whether condoms were used correctly or whether breakage, slippage, or spillage occurred
[f] There is no risk associated with close-mouthed kissing. There is remote risk associated with open-mouthed kissing if there are sores or bleeding gums and blood exchanged
[g] Examples of solid-bore needles include tattoo needles and lancets used by diabetes patients to measure blood-sugar level

Tables 5 and 6 summarize the estimated risks of HIV, HBV and HCV transmission depending on exposure type.

Table 5. Risk of HIV Transmission after Occupational and Non-occupational Exposure to Blood and Other Body Fluids, According to Type of Exposure[a]

TYPES OF EXPOSURE (FROM AN HIV-POSITIVE SOURCE)	RISK OF INFECTION PER EXPOSURE
Blood transfusion	90%
Percutaneous (needle stick)	0.3%
Mucous membranes	0.03–0.09%
Receptive oral sex with ejaculation	0–0.04%
Insertive vaginal sex	0.03–0.09%
Receptive vaginal sex	0.1–0.3%
Insertive anal sex	0.03%
Receptive anal sex	0.5–3%
Insertive oral intercourse	Low[b]
Receptive oral intercourse	Low[b]
Biting	Negligible[c]
Spitting	Negligible[c]
Throwing body fluids (including semen or saliva)	Negligible[c]
Sharing sex toys	Negligible[c]

Factors Associated with Increased Risk of HIV Transmission from Needle Sharing/Needle Stick Injuries

- Source person is known to be HIV-infected and is not receiving ARVs or has incomplete viral suppression; the risk of transmission increases with higher viral load levels in the source person
- Hollow-bore needle
- Deep skin penetration
- Presence of blood on needle; however, risk through exposure to dried blood on discarded needles is extremely low

Factors Associated with Increased Risk of HIV Transmission from Sexual Exposure

- Source person is known to be HIV-infected and is not receiving ARVs or has incomplete viral suppression; the risk of transmission increases with higher HIV viral load levels in the source person, most notably during acute HIV infection when the probability of transmission has been shown to be 8 to almost 12-fold higher than exposure that take place after the viral set point
- Lack of use of barrier protection, such as male or female condoms
- Presence of genital ulcer disease or other STIs
- Trauma at the site of exposure
- Blood exposure--it is important to note that blood exposure can be minimal and therefore not recognized by the exposed person. If exposed person reports frank blood exposure, PEP should be indicated
- Lack of male circumcision
- Cervical ectopy
- Oral mucosa is not intact (e.g., oral lesions, gingivitis, wounds) for oral sex exposure

Factors Associated with Increased Risk of HIV Transmission from Otherwise Negligible-Risk Exposures

- Source person is known to be HIV-infected with high HIV viral load
- Activity involved exposure to blood

[a] This table is modified from MMWR CDC (Panlilio, Cardo et al. 2005, Smith, Grohskopf et al. 2005), CDC HIV Transmission Risk, fact sheet; July 2012. Available at http://www.cdc.gov/hiv/law/transmission.htm

[b] HIV transmission through oral sex has been documented, but rare. Accurate estimates of risk are not available. It is prudent to recommend PEP for receptive oral sex with ejaculation, although discussion about the low risk should always occur

[c] HIV transmission through these exposure routes is technically possible but extremely unlikely and cases are not well documented

Table 6. Risk of HBV and HCV Transmission after Percutaneous Exposure[a]

TYPES OF EXPOSURE	RISK OF INFECTION PER EXPOSURE
Percutaneous (needle stick) from HBV-positive patient	
›› HBeAg+	30–40%
›› HBeAg-	1–6%
Percutaneous (needle stick) from HCV-positive patient	0–10% (average 1.8%)

[a] Modified from New York State Department of Health AIDS Institute: HIV Prophylaxis Following Occupational Exposure, Updated in October 2012. Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-occupational-exposure.pdf (NYS-DOH-AI 2012)

SECTION 3: MANAGEMENT OF ACCIDENTAL EXPOSURE TO BLOOD-BORNE PATHOGENS (HIV, HBV, HCV)

After accidental contact with blood and other body fluids, exposed individuals may be at risk of infection with HIV, HBV and HCV. In addition, depending on the type of exposure, other infections, such as tetanus or STIs, or conditions, such as pregnancy, may also occur. This section outlines both general and specific actions that need to be taken to reduce these risks.

3.1 GENERAL MANAGEMENT OF ACCIDENTAL EXPOSURES

After accidental exposures occur, whether occupational or non-occupational, the following post-exposure management steps should be performed in order:

1. Step 1: Treat the exposure site
2. Step 2: Report and document the exposure
3. Step 3: Evaluate the significance of the exposure
4. Step 4: Evaluate the exposed person
5. Step 5: Evaluate the source person
6. Step 6: Prevent HIV transmission
7. Step 7: Prevent HBV transmission
8. Step 8: Prevent HCV transmission
9. Step 9: Prevent transmission of other infections and prevent pregnancy
10. Step 10: Conduct follow-up testing and care

3.1.1 Post-Exposure Management Step 1: Treat the Exposure Site

- All exposed individuals, regardless of the cause of exposure, must first undergo first aid procedures in order to reduce the contact time with the source person's blood, body fluids or tissues and to clean the site of exposure, so as to minimize the risk of blood-borne pathogen transmission.

- Specifically to post-exposure HIV transmission, experimental models have demonstrated the following sequence of events: After percutaneous or mucosal exposure to HIV, local replication of the virus occurs in tissue macrophages or dentritic cells; host cytotoxic T cells will kill the productively infected target cells.

- However, if the infection cannot be contained at this stage, it is followed with 2 to 3 days by replication of the virus in regional lymph nodes; viremia then follows within 3 to 5 days of the virus inoculation. This sequence of events carries significant implications, one of which is the need for prompt treatment of the exposure site, among other interventions. Table 7 and Table 8 lists the specific steps according to exposure type.

3.1.1.1 Occupational Exposures[€]

Table 7. Steps for Initial Management of Occupational Exposures after Contact with Blood and Other Body Fluids

DO'S	DO NOT'S
Injury with a used needle or sharp instrument	
• Wash the site immediately using soap and running water.[$]	• Do NOT squeeze or rub the injury site. • Do NOT use strong solutions, such as bleach or iodine, to clean the site because these may irritate the wound and make the injury worse. • Do NOT use alcohol-based hand rub solutions to clean non-intact skin because it may irritate the wound and increase the risk of transmission.
Splash on unbroken skin	
• Wash the site immediately using soap and running water.[$]	• Do NOT use strong disinfectants, such as chlorine (e.g., JIK). • Do NOT use alcohol-based hand rub solutions.
Eye splash	
• Irrigate the exposed eye immediately with a litre of water or normal saline: – Sit in a chair, tilt the head back, and have someone 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 protective barrier over the eye. Once the eye has been cleaned, remove the contact lenses and clean them in the normal manner to make them safe to wear again.	• Do NOT use soap or disinfectant on the eye.
Mouth splash	
• Spit the fluid out immediately. • Rinse the mouth thoroughly, using water or saline, and spit again. • Repeat this process several times.	

[€] This table is adapted from the Joint WHO/ILO Guidelines on Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection (WHO 2007).

[$] Besides soap, if readily available, non-alcohol containing antiseptics, such as chlorhexidine gluconate (2–4%), (e.g., Savlon®, Hibiclens®, Hibiscrub® or Hibitane®), or normal saline may be used for cleaning.

3.1.1.2 Non-Occupational Exposures[€]

Table 8: Steps for Initial Management of Non-Occupational Exposures after Contact with Blood and Other Body Fluids

DO'S	DO NOT'S
Rape or sexual assault[¥]	
• Immediately obtain informed consent, then conduct a forensic clinical examination, and thereafter, collect forensic evidence. • After collection of forensic evidence, cleaning of the exposure site can proceed as appropriate: – Use a vaginal wash (and or anal wash for anal rape/sexual assault) with soap and water (warm saline or other appropriate antiseptics as per the current National Infection Prevention and Control (IPC) Guidelines, may be used) – Clean all visible abrasions, bruises, and superficial lacerations using soap and water[$] • Repair or refer high vaginal vault, anal, and oral tears, third/fourth degree perineal injuries and confirmed or suspected perforations to qualified personnel accordingly **Note:** Victims of rape or sexual assault have the right to medical care even if they do not consent to forensic evidence collection and police involvement. Therefore, after an exposure from rape/sexual assault, the medico-legal and forensic-related procedures should not delay the first aid procedure and subsequent management, if it is upon the decision of the victim to do so.	• In order not to destroy any evidence that needs to be collected, advise the victim NOT to: – Bathe/shower/douche (applicable for all types of rape/sexual assault) – Pass urine and/or defecate. If the victim cannot wait, then clean containers should be used to collect urine and stool samples (applicable for vaginal and anal rape/sexual assault) – Wipe the genital/anal area (applicable for vaginal and anal rape/sexual assault) – Brush teeth or use mouthwash (applicable for oral rape/sexual assault) – Change clothes. If changing is necessary, then the victim should place soiled clothes in a paper bag or wrap them in a newspaper, **BUT NOT** in a plastic bag. • Do NOT use strong solutions, such as bleach or iodine, to clean the site as these may irritate the wound and make the injury worse. • Do NOT use alcohol-based hand rubs or other chemicals to clean any wounds because it may irritate the wound and increase the risk of transmission of blood borne infections.
After unsafe procedures, such as traditional male circumcision or female genital mutilation, human bites, or accidents resulting in spills of blood and other body fluids to sustained cut wounds	
• Wash the site immediately using soap and running water.[$]	• Do NOT squeeze or rub the injury site. • 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. • Do NOT use alcohol-based hand rubs and other chemicals to clean the wound because it may irritate the wound and increase the risk of transmission.

[€] This table is adapted from the Joint WHO/ILO Guidelines on Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection (WHO 2007).

[¥] MoHSW requires health facilities of all levels in the country to provide comprehensive management of victims of rape or sexual assault. These services include provision of high-quality medical and psychological care and support services, with clear linkages to the community and police and legal systems. In addition, the services need to be integrated into the existing services at the health facilities and in the community. Therefore, providers are required to make reference to the current National Management Guidelines for the Health Sector Prevention and Response to Gender Based Violence.

[$] Besides soap, if readily available, non-alcohol containing antiseptics, such as chlorhexidine gluconate (2–4%) (e.g., Savlon®, Hibiclens®, Hibiscrub® or Hibitane®), or normal saline may be used for cleaning.

3.1.2 Post-Exposure Management Step 2: Report and Document

The MoHSW requires that both occupational and non-occupational exposures be properly documented at the facility using MoHSW standardized tools. Thus, it is critical to ensure that all exposed individuals immediately report their exposure to health facilities to obtain appropriate post-exposure management. These guidelines recommend the following:

- Health care workers who sustain exposures while providing health care services should report the exposure to their respective senior supervisors or any other person designated for coordinating post-exposure management at the facility.
- Individuals with non-occupational exposures and those exposures related to other occupations besides health care should immediately seek care for appropriate post-exposure management.
- Non-occupational exposures, such as rape/sexual assault, human bites, and accidents, should notify the local authorities in accordance with Tanzanian law and legislation.
- Health service providers should encourage and support victims of rape or sexual assault to first report the events to police. This can be through a physical visit or calling a police hotline (Phone Number 112).
- **In case the victim reports to a health facility first, he/she should be treated without making a prior police statement and later report to a police station/post. Police Form (PF3) can always be obtained and completed later.**
- Victims have a right to decline police investigation or legal justice procedures, and therefore, under no circumstances, should they be coerced to do so, and the reporting should never be a precondition for receiving post-exposure services.
- Workers at drop-in centres, safe houses, and social welfare offices who directly receive victims of rape and sexual assault should refer them immediately to health facilities for prompt PEP management.
- Care of children after rape or sexual assault should follow the protocols governing the reporting of those cases, in accordance with the Tanzanian legislation.

The overall management of these cases involves a complex interaction requiring efficient coordination and communication between health care providers and legal, investigative, and social support services. In addition to providing high-quality medical services, health care providers are required to link the exposed individuals with other areas of care and support, as described above. The National Management Guidelines for the Health Sector Prevention and Response to Gender Based Violence must be referred to (MOHSW/GBV 2013).

Note: Although post-exposure management steps 1 and 2 (treat the exposure and report, and document the exposure) are listed separately, ideally, they should be conducted concurrently. At health care facilities, there is usually someone to assist in providing care and support. Staff are encouraged to use phones for reaching supervisors or providers responsible for post-exposure management. However, if no one is available, the exposed person should report the exposure and perform the first aid themselves.

3.1.3 Post-Exposure Management Step 3: Evaluate the Significance of the Exposure

To determine the type of management the exposed person should receive, the health care provider should conduct a thorough risk assessment of every exposed individual and evaluate the severity and extent of the exposure using the information in Tables 2, 3, and 4.

Since the goal of PEP is to minimize the risk of potential infection due to exposure by preventing multiplication of blood-borne pathogens in the body and therefore enable host immune system to prevent or abort early infection, these guidelines recommend the same approach to starting PEP irrespective of high or low risk exposure.

An exposure is considered significant if those body fluids that are either known (e.g., blood, blood-stained fluids, or semen) or presumed (e.g., tissue fluids) to transmit blood-borne pathogens come into contact with the tissue or blood of the exposed person.

Faeces, nasal secretions, tears, urine, and vomitus do not transmit blood-borne pathogens (i.e., HIV, HBV and HCV) unless visibly contaminated with blood.

When a significant exposure occurs, further investigations (See 3.1.4 and 3.1.5) to evaluate the exposed and source persons need to be conducted.

Table 9 lists examples of factors or behaviours that should be considered when assessing the source person's risk of infection, according to the type of blood-borne pathogen.

Table 9: Risk Factors for Blood-borne Pathogens for Source Person

SOURCE PERSON HAS THE FOLLOWING	HIGH RISK OF INFECTION WITH THE FOLLOWING BLOOD-BORNE PATHOGENS		
	HIV	HBV	HCV
High-risk sexual behaviour (e.g., men having sex with men, sexual partner who is an intravenous drug user, multiple sexual partners)	√	√	√
Involved with sexual partner from above groups	√	√	√
History of intravenous drug use	√	√	√
History of blood transfusion (especially before screening of HIV, HBV and HCV were strengthened by MoHSW)	√	√	√
Born to HIV-infected mother (infant)	√		
Clinical features suggestive of HIV/AIDS, such as lymphadenopathy, pruritic purpura eruptions, Kaposi sarcoma lesions, etc.	√		

The ultimate aim of evaluating the significance of the exposure is to decide whether to administer PEP or not. However, specifically for HIV, as discussed in Section 3.1.4, carefully evaluate the exposed person to determine whether there are chronic exposures because it has implications on how specific post-exposure management (PEP provision) will be handled.

Repeated Exposures

Some individuals are prone to getting repeated exposures. These incidences can happen both in occupational (e.g., a medical-waste worker experiencing repeated sharps injuries) and non-occupationally related exposures (e.g., sexual abuse of children). Irrespective of whether the exposure is episodic (occurring occasionally) or repeated (occurring regularly), an assessment of the significance of each exposure event and provision of appropriate PEP management is required. In addition to provision of PEP, providers are required to focus on reducing on-going risk.

3.1.4 Post-Exposure Management Step 4: Evaluate the Exposed Person

To date, available PEP regimens can effectively prevent HIV, HBV, tetanus, and STIs, however, for effective delivery of PEP, prompt evaluation is critical for reducing possible side effects to the PEP regimens, drug waste, and potential for resistance to develop. Therefore, within two hours of the exposure, evaluate the exposed individual's general health status, conduct pre-test counselling for HIV, and other relevant tests as applicable. For HIV testing procedures, refer to the current national HIV testing and counselling guidelines (NACP 2009).

Since laboratory capacity is limited in some Tanzanian health care facilities, PEP providers should refer to MoHSW recommendations (listed in Table 10) as to the laboratory tests that MUST be done for all exposed persons, and those which should be done depending on the availability.

Table 10. Recommended Laboratory Tests for Exposed Individuals

TYPE OF TEST	MoHSW RECOMENDATIONS
HIV antibody test[a]	Must do
Haemoglobin (for zidovudine-containing PEP regimen)	Must do
HBV screening (Hepatitis B surface antigen, [HBsAg])	Do, if available
Anti-HBs (antibody to Hepatitis B)	Do, if available
HCV screening	Do, if available
Pregnancy test	Must do for all reproductive-age women, unless otherwise indicated

[a] Baseline HIV testing is recommended for all exposed individuals, even for those who decline PEP

Note: There is no vaccine or effective antiviral agents and immune globulins for Hepatitis C PEP. Therefore, the screening is only important for identification of early infection and, if positive, referral for evaluation of treatment options.

- According to current Tanzanian protocol, the diagnosis of HIV infection in adults and children older than 18 months is commonly done by detection of antibodies to HIV using two separate rapid tests, but enzyme immunoassays (EIA) can also be used.

- The rapid tests can be done using whole blood, serum, or plasma samples. Whenever possible, rapid testing will be done with a finger prick sample.

- A positive test (rapid test or EIA) in infants under 18 months of age does not confirm HIV infection, but rather mere exposure to HIV. For this age group, laboratory diagnosis is done by

detection of viral ribonucleic acid (RNA) or pro-viral deoxyribonucleic acid (DNA) or viral protein-24 (p24) antigen.

In the context of HIV PEP, MoHSW recommends the use of rapid antibody testing for all exposed persons. After conducting testing, perform post-test counselling according to the current national HIV testing and counselling guidelines (NACP 2009).

Note: Post-test counselling includes giving the HIV test result to the patient, whether it is positive, negative, or inconclusive, and discussing positive living.

If HIV results cannot be obtained within the first two hours of testing, then provide a starter pack (as discussed in section 3.2.1). Lack of test kits should not delay or discourage an exposed individual from obtaining appropriate post-exposure management.

3.1.5 Post-Exposure Management Step 5: Evaluate the Source Person

Whenever possible, evaluate the source person immediately and concurrently with the exposed person to quickly determine whether to initiate PEP, but always give the exposed person the priority.

- If the source person is available, obtain consent to perform testing. HIV testing is not mandatory, so patients, clients, or perpetrators of rape or sexual assault may decline testing. Conduct pre-test counselling with the individual.
- If consent is obtained, except for pregnancy testing, conduct HIV antibody test, haemoglobin estimation (if zidovudine–containing PEP regimen is to be used), and other tests, if available (see Table 10).
- When the source person is not available, never attempt to test the discarded needles or syringes because of possible cross-contamination of samples.
- However, if the source person is available later, a PEP provider should still evaluate the source person and decide whether to continue PEP or adjust the regimen depending on the actual risk classification.
- Lastly, conduct proper post-test HIV counselling according to the current national HIV testing and counselling guidelines (NACP 2009).

Window Period

The "window period" also referred to as "acute HIV infection" is the length of time after infection that it takes for the virus to become detectable by the traditional antibody-based diagnostic tests (Cohen, Gay et al. 2010, Branson and Stekler 2012). This period is usually associated with high-titre viral replication and hence individuals carrying the virus are very infectious (Kahn and Walker 1998). When the person becomes infected, HIV multiplies in the blood and the body develops antibodies against the virus. There can be some variation in the length of the window depending on the type of diagnostic test used and the method employed to detect the virus.

When the source person's HIV screening test result is negative but there has been a risk for HIV exposure in the previous 6 weeks, plasma RNA testing is currently the only ideal test for confirming the diagnosis of HIV infection. However, this test is not readily available, particularly in resource-limited countries such as Tanzania. An alternative to this method is a qualitative HIV DNA along

with a negative or indeterminate HIV serology, followed by a subsequent positive ELISA in the following weeks. The challenge with this latter test is that its reliability is highly questionable. Similarly, the clinical diagnosis of "acute HIV infection" also poses lots of challenges as its associated symptoms are very non-specific, and can simulate a number of differential diagnoses that are common in tropics, such as malaria or viral flu.

Due to these challenges, and the importance of prompt initiation of PEP management, MoHSW recommends HIV PEP provision for all exposures by which there is a high index of clinical suspicion that the source person is in the window period.

Note:

- Clinicians should raise a high index of suspicion for cases by which a source person presents with fever, fatigue, or malaise, joint pain, headache, loss of appetite, rash, night sweats, myalgia, nausea or diarrhoea, and pharyngitis, following a recent high risk exposure, e.g., unprotected sex, or blood transfusion.
- If unsure, inexperienced clinicians should initiate PEP and immediately seek further consultation from a provider experienced in HIV case management.
- Similarly, exposed persons suspected to be in the window period should also be given HIV PEP until a definitive diagnosis is established.

3.2 SPECIFIC POST-EXPOSURE MANAGEMENT OF INFECTIONS

According to WHO/ILO guidelines (2007), all health care facilities are expected to at least provide HIV PEP to all eligible exposed individuals presenting to the facilities, whether the individuals have sustained occupational or non-occupational exposures.

Following this recommendation, the MoHSW requires that all facilities with HIV/AIDS care and treatment (including PMTCT) service capability provide HIV PEP to all eligible exposed individuals. Refer to section 3.2.1 and Table 11 to determine whether the exposed person is eligible for HIV PEP.

Depending on the facility's capabilities for testing for other infections, specific post-exposure management for other infections, such as HBV, tetanus and STIs, also needs to be provided. The steps for specific management are described in the subsequent sections.

3.2.1 Post-Exposure Management Step 6: Prevent HIV Transmission

Irrespective of occupational or non-occupational exposure, after successful completion of the general management as described in section 3.1, all eligible exposed individuals are equally entitled to receive quality HIV post-exposure management. The mainstay of this management is initiation of ARV medications within two hours of exposure and a full course for 28 days to prevent HIV transmission. To increase the likelihood of the exposed person completing the full drug regimen, the provider must conduct proper drug adherence counselling before and during the regimen.

Eligibility criterion is determined by both the HIV serostatus of the exposed and the source person, but also the duration of time after the exposure. Available data indicate that HIV PEP is less effective if initiated more than 24 to 36 hours after exposure and not effective if initiated more than 72 hours after exposure (Martin, Soike et al. 1994, WHO 2007, Landovitz and Currier 2009).

If initiation of PEP is delayed, the likely benefit may not outweigh the risks inherent in taking ARV medications. Hence, the MoHSW recommends that PEP be started as soon as possible after exposure, preferably within two hours of exposure, but not later than 72 hours after the exposure (Table 11). If any delays are anticipated that would prevent the initiation of PEP within two hours, provide a starter pack. Refer to the text "Use of HIV PEP Starter Packs."

Table 11. Eligibility Criteria for Providing HIV PEP to Exposed Individuals

EXPOSED PERSON'S HIV STATUS	SOURCE PERSON'S HIV STATUS	DURATION AFTER EXPOSURE (HOURS)	RECOMMENDATION FOR PROVIDING HIV PEP TO THE EXPOSED PERSON
Awaiting confirmation for HIV test results[£]	HIV-Positive **OR** Not known **OR** Awaiting confirmation **OR** Window Period (clinical suspicion)	<72	Yes
Awaiting confirmation for HIV test results[£]	HIV-Positive **OR** Not known **OR** Awaiting confirmation **OR** Window Period (clinical suspicion)	>72	No
HIV-Positive	HIV-Positive **OR** HIV-Negative **OR** Not known **OR** Window Period (clinical suspicion)	< 72 **or** >72	No
HIV-Negative	HIV-Positive **OR** Not known **OR** Window Period (clinical suspicion)	>72	No
HIV-Negative	HIV-Positive **OR** Not known **OR** Window Period (clinical suspicion)	<72	Yes
Window Period (clinical suspicion)	HIV-Positive **OR** HIV-Negative **OR** Not known **OR** Window Period (clinical suspicion)	< 72	Yes
Window Period (clinical suspicion)	HIV-Positive **OR** HIV-Negative **OR** Not known **OR** Window Period (clinical suspicion)	> 72	No
HIV-Negative	HIV-Negative (and no clinical suspicion of window period)	< 72 **or** >72	No

[£]Examples for this include, delayed HIV testing, discordant HIV test results, or delayed HIV test results

Note: Occasionally, clinicians responsible for PEP are faced with questions, such as: What should be done if an exposed person has reported in the 73rd hour? What if the patient thinks s/he is at risk of infection, but in reality s/he is at no risk? What should be done if the exposed person thinks that s/he has no risk, but the risk is significant? Could an exposed person who demands PEP be declined HIV PEP if there is no risk of infection? What if the patient declines baseline HIV testing?
Remember: These are guidelines, and although the MoHSW recommends these evidence-based decisions, clinicians may answer these questions about isolated events on a case-by-case basis using their clinical judgement and facility-specific protocols that are based on the available evidence. However, for exposed persons who decline HIV testing, HIV PEP is not recommended.

Recommended Drugs for HIV PEP

The ideal HIV PEP regimen is one that has a favourable side-effect profile, fewer potential drug-drug interactions, and expected efficacy equivalent to the existing PEP regimens, most of which contain zidovudine and protease inhibitors (PIs).

Evidence from countries with successful PEP programs has increasingly shown that tolerability is one of the most important factors for selection of PEP regimen. Furthermore, recent studies have shown increased rates of adherence and completion when tenofovir + emtricitabine/or lamivudine + raltegravir (an integrase inhibitor, not included in the national ARV drug list as of yet) are used in combination or as individual components of HIV PEP regimen (Mayer, Mimiaga et al. 2008, Tosini, Muller et al. 2010, Mayer, Mimiaga et al. 2012).

In addition, several systematic reviews carried out in support of the 2013 consolidated guidelines have given preference to an ARV regimen composed of a once daily fixed-dose combination of tenofovir + lamivudine (or emtricitabine) + efavirenz as a single preferred first-line therapy (WHO 2013).

Therefore, in view of these findings and in alignment with WHO guidance (i.e., choice of ARV regimen for PEP should be based on the country's available first-line ARV regimen), MoHSW recommends tenofovir + lamivudine + efavirenz as the preferred HIV PEP first choice regimen (Table 12). Zidovudine and PI-containing regimens are only reserved for special cases (Table 13). Despite the current evidence that has shown integrase inhibitors-containing PEP regimen (e.g., raltegravir in combination with two nucleoside reverse transcriptase inhibitors) to be the most efficacious and best tolerable, due to unavailability, this regimen has not been included in these guidelines.

As described in the earlier section, these guidelines recommend triple therapy for all significant (or substantial) risk exposures, irrespective of risk classification. Exposed individuals identified as having no risk to HIV infection should not be prescribed PEP. Refer to current NACP/MoHSW National Guidelines for Management and Care of HIV and AIDS for more details and updates on the ARV regimen for PEP, dosage, side effects, and management of ARVs (NACP 2012).

Note:
The two-drug PEP regimen as it appears in the current National Guidelines for Management and Care of HIV and AIDS (April 2012) is no longer recommended. The only indication for dual therapy is if the third drug has been stopped for tolerability purposes. Monotherapy of any kind is not recommended and is now obsolete.

Table 12. Recommended Regimen for HIV PEP Following Occupational and Non-Occupational Exposures[$]

HIV PEP (ARV) REGIMEN	CURRENT MOHSW RECOMMENDATIONS[$]	COMMENTS
Tenofovir[£] 300 mg PO od, lamivudine 300 mg PO od & efavirenz* 600 mg PO od	Preferred first option for HIV PEP	Compared to zidovudine-containing regimen, current evidence shows that this combination is better not only in terms of tolerability, but also efficacy in preventing post-exposure transmission of HIV infection. Studies have shown increased rates of adherence and regimen completion when tenofovir and lamivudine have been used as components of HIV PEP regimen.

[$] The recommended first-line ARV regimen as per the MoHSW's circular with reference number – GA. 16/209/01C/70 updating the current National Guidelines for Management of HIV and AIDS (NACP 2012), also adapted from New York State Department of Health AIDS Institute: HIV Prophylaxis Following Occupational Exposure, Updated in October 2012 – Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-occupational-exposure.pdf (NYS-DOH-AI 2012), and HIV Prophylaxis Following Non-Occupational Exposure, Updated in July 2013 – Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf (NYS-DOH-AI 2013)
[£] Tenofovir should always be used with caution in exposed individuals with renal insufficiency (baseline creatinine clearance <50mL/min). Under those circumstances, the dosing of emtricitabine should be adjusted accordingly. If ritonavir/lopinavir are to be used, it should be preferably taken with food, and boosting is necessary when co-administered.
* Due to central nervous system side effects, efavirenz should be avoided in exposed persons with active psychiatric illnesses.

Table 13. Preferred Alternatives Regimens for HIV PEP following Occupational and Non-Occupational Exposures

HIV PEP (ARV) REGIMEN	CURRENT MOHSW RECOMMENDATIONS[$]	COMMENTS
Zidovudine 300 mg bd, lamivudine 150 mg PO bd & efavirenz* 600 mg PO od	Acceptable alternative to the recommended first option above (Table 12). ***Note: This regimen is not recommended for routine HIV PEP***	Due to the treatment-limiting side effects of zidovudine, this regimen should only be reserved for cases in which tenofovir is contraindicated (e.g., renal insufficiency) or unavailable
Tenofovir[£] 300 mg PO od, lamivudine 300 mg PO od & ritonavir[¥] 100 mg PO od – boosted Lopinavir (400mg)	Acceptable alternative to the recommended first option above (Table 12). ***Note: This regimen is not recommended for routine HIV PEP***	Lopinavir/ritonavir–containing HIV PEP regimen has greater potential for side effects and drug interactions, (with little added efficacy as compared to the first choice regimen above (Table 12). Therefore this regimen should only be reserved for cases by which efavirenz is contraindicated or unavailable.

[$] The recommended first-line ARV regimen as per the MoHSW's circular with reference number – GA. 16/209/01C/70 updating the current National Guidelines for Management of HIV and AIDS (NACP 2012)
[£] Tenofovir should always be used with caution in exposed individuals with renal insufficiency (baseline creatinine clearance <50mL/min). Under those circumstances, the dosing of emtricitabine should be adjusted accordingly. If ritonavir/lopinavir is to be used, it should be preferably taken with food, and boosting is necessary when co-administered.
*Due to central nervous system side effects, efavirenz should be avoided in exposed persons with active psychiatric illnesses.
[¥] *If ritonavir/lopinavir is to be used, it should be preferably taken with food, and boosting is necessary when co-administered with TB drugs.*

Note:

- Clinicians should assess for potential drug interactions between various ARV agents and other medications, including prescription medications and over-the-counter drugs, such as H2-blockers and proton pump inhibitors. For instance, the drugs used to treat malaria (particularly sulpha-based drugs) and ARV drugs may share toxicities and may have clinically important pharmacokinetic interactions (especially artemesinins, lumefantrine, NNRTIs, and protease inhibitors). For this reason, people taking ARVs concomitantly with antimalarials should be monitored closely for adverse drug reactions, and people taking zidovudine, or efavirenz should, if possible, avoid amodiaquine-containing artemisinin-based combination regimens because of increased risk of neutropaenia in combination with zidovudine, and hepatotoxicity in combination with efavirenz.
- If possible, some ARVs should be avoided as PEP components. These include nevirapine (due to potential for severe hepatotoxicity), abacavir (due to potential for hypersensitivity reaction), stavudine, and didanosine (due to potential for toxicities), and nelfinavir and indinavir (due to poor tolerability)

For specific dosage information regarding paediatric and adult doses of HIV PEP, refer to Table 14.

Table 14. HIV PEP Dosing for Children and Adults Accidentally Exposed to Blood and Other Body Fluids[€]

DRUG (FORMULATION)	STRENGTH	CHILDREN 6 WEEKS OF AGE AND OLDER (BODY WEIGHT)					ADULTS (BODY WEIGHT)	FREQUENCY	DURATION (DAYS)
		3 – 5.9 kg	6 – 9.9 kg	10 – 13.9 kg	14 – 19.9 kg	20 – 24.9 kg	>25 kg		
Tenofivir **(oral powder scoops)**	40mg/scoop	-	-	3	-	-	1 tab (200mg or 300mg)	Once daily	28
Tenofovir **(tab)**	150/200mg	-	-	-	1 (150mg)	1 (200mg)	1 tab (200mg or 300mg)	Once daily	28
Zidovudine/Lamivudine **(tab/cap)**	60/30 mg	1	1.5	2	2.5	3	-	12 hourly	28
Zidovudine/Lamivudine **(tab/cap)**	300/150 mg	-	-	-	0.5 tab/cap	1 A.M. / 0.5 P.M.	1	12 hourly	28
Zidovudine **(liquid)**	10 mg/ml	6 ml	9 ml	12 ml	-	-	-	12 hourly	28
Lamivudine **(liquid)**	10 mg/ml	3 ml	4 ml	6 ml	-	-	-	12 hourly	28
Zidovudine **(tab/cap)**	300 mg	6 ml	9 ml	12 ml	0.5 tab/cap	1 A.M. / 0.5 P.M.	1	12 hourly	28
Lamivudine **(tab/cap)**	150 mg	3 ml	4 ml	6 ml	0.5	1 A.M. / 0.5 P.M.	1	12 hourly	28
Lopinavir/ritonavir **(tab/cap)**	100/25 mg	NR	NR	2	2	2	3	12 hourly	28
Lopinavir/ritonavir[a] **(liquid)**	80/20 mg/ml	1-1.5 ml	1.5 ml	2 ml	2.5 ml	3 ml	-	12 hourly	28
Efavirenz[b] **(tab/cap)**	200 mg	NR	NR	1	1.5	1.5	2	Once daily	28
Tenofovir/Lamivudine/Efavirenz **(tab/cap)**	75/75/150 mg	-	-	1.5	2	2.5	3-3.5	Once daily	28
Zidovudine/Lamivudine Lopinavir/ritonavir **(tab/cap)**	30/15/40/10 mg	2	3	4	5	6	-	12 hourly	28

[€] *Adapted from* National Guidelines for Management of HIV and AIDS (NACP 2012)
** NR = not recommended.*
[a] *Higher doses of lopinavir/ritonavir are usually required when co-administered with enzyme-inducing drugs, such as EFV.*
[b] *EFV is not recommended for children younger than 4 years and weighing less than 10 kg.*

Use of HIV PEP Starter Packs

After exposure, exposed individuals may be under considerable emotional stress, and, in particular, may experience fear of potential infection that may affect the ability to retain information relevant to making an informed decision about testing and starting PEP. In this case, it is highly recommended that clinicians provide a starter pack that contains a seven-day dose of ARV medications.

Similarly, in the event of potential delays in initiation of PEP within two hours, for any reason, such as non-availability of test kits or HIV counsellors/clinicians or forensic examination procedure, a starter pack should be given to all exposed individuals.

Prescribe a starter pack containing three drugs for all significant -risk exposures. Refer to current NACP/MoHSW–National Guidelines for Management and Care of HIV and AIDS for more details and updates on the ARV regimen for PEP (NACP 2012). For detailed information about the dosing, refer to Table 14.

After this initial prescription, health providers should schedule a follow-up visit within seven days.

Note: Because pre-packaged HIV PEP medications are not readily available, every health facility should have several starter packs with three-drug regimens readily available. The person preparing the starter packs should always write the expiry date on the packs and document the shelf life for the medications (i.e., the maximum time allowed for the medications to be used after removal from the original container). Furthermore, the starter packs need to be stored appropriately. The provider issuing the starter packs must examine the pack for stability of the drugs before giving it to the patient.

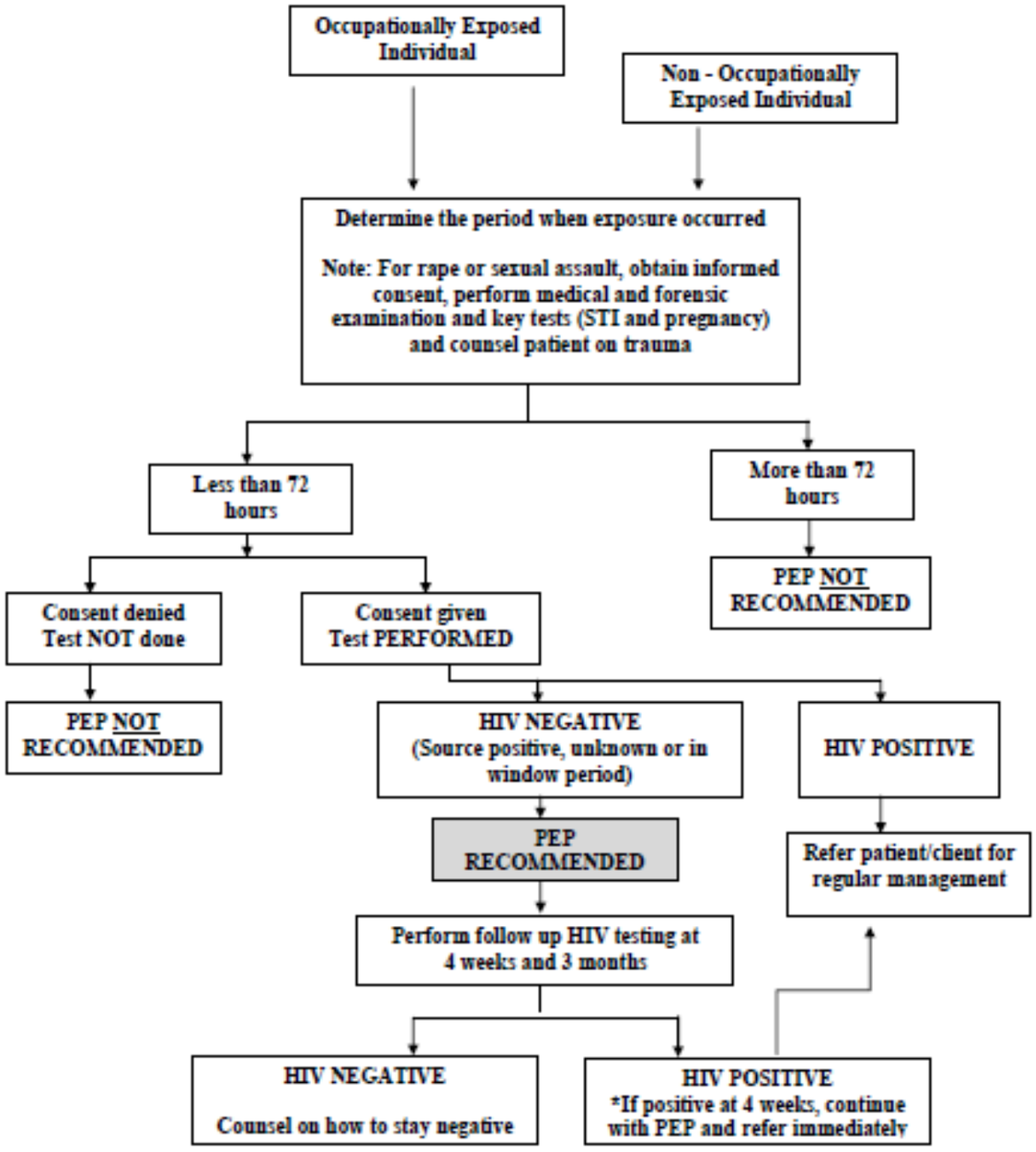
Side Effects

All ARV agents have associated side effects, including nausea, vomiting, malaise, fatigue, and headache. Many of these side effects can be managed symptomatically. Therefore, in addition to the pre-HIV PEP counselling, the provider has to conduct follow-up drug adherence counselling to increase the effectiveness of the regimen. If the side effects are intolerable, the provider should consider stopping, removing one drug, or changing the ARV drugs depending on the available current options.

Note:

- Exposed women who are breastfeeding should be educated about the risk of HIV transmission through breast milk, and properly counselled about exclusive breastfeeding for six months, or alternatives to breastfeeding if it is acceptable, feasible, affordable, sustainable, and safe.
- Based on the current body of evidence, providers should not provide a single drug regimen for HIV PEP.

Figure 1. HIV PEP Management Algorithm



Note: As discussed in section 3.1.3, for non-occupational exposures, if the exposure is chronic (e.g., results from repeated high-risk behaviour), the clinician should consider potential medication toxicity, adherence, potential resistance, and costs before proceeding with HIV PEP provision.

3.2.2 Post-Exposure Management Step 7: Prevent Hepatitis B Virus Transmission

To prevent transmission of HBV after exposure, both passive-active PEP with Hepatitis B immunoglobulin (HBIG) combined with the Hepatitis B vaccine series and active PEP with Hepatitis B vaccine alone have been demonstrated to be effective. Furthermore, data show that HBIG alone can also prevent HBV transmission. However, since the Hepatitis B vaccine became available, HBIG is typically used (and preferentially) as an adjunct to vaccination. For this reason, the MoHSW recommends that the two types of HBV PEP should be offered to all exposed individuals who are at risk of infection.

However, deciding whether to administer PEP and which type of regimen to administer depends on the HBsAg status of the source person and the vaccination history and vaccination response of the exposed person (see Table 15), as well as the health facility's ability to carry out HBV testing (i.e., HBsAg and anti-HBs).

Note: HBsAg is a protein on the surface of HBV that can be detected in high levels in serum during acute or chronic HBV infection. The presence of HBsAg indicates that the person is infectious. The body produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is used to make the HBV vaccine. Anti-HBs is an antibody that is present during recovery and immunity from HBV infection. Anti-HBs also develop in a person who has been successfully vaccinated against HBV.

The following recommendations should be used when deciding to administer HBV PEP:

- If the exposed individual has had natural HBV infection or has been vaccinated and is a known responder (has antibodies to HBV), then no investigation or PEP for HBV (i.e., neither HBV vaccine nor HBIG prophylaxis) is required.
- Persons with neither a reliable history of completed vaccination against HBV nor known contraindications to HBV vaccination should receive the first dose of HBV vaccination series as soon as possible, preferably within 24 hours and no later than seven days after the exposure.
- To prevent infection, the HBIG should also be given soon, preferable within 24 hours but not more than 14 days after exposure.
- Used together, the HBV vaccine and HBIG have an estimated efficacy of 85-95%, which is higher when either HBV vaccine or HBIG are used alone (i.e., 75% for each).
- Where capability to test HBsAg and/or anti-HBs is available, the options for management of unvaccinated individuals or those whose status is unknown and who are exposed to an HBsAg-positive source person are summarized in Table 15.
- If the source person tests HBsAg negative and the exposed individual is not vaccinated or does not know their vaccination/antibody status, the exposed person should be tested for the presence of antibodies and vaccinated accordingly. However, if antibody testing is not available, the individual should be vaccinated either way.
- If testing is not possible, determine if the source person has HBV by reviewing the clinical history, including presence of jaundice, hepatitis of any viral strain, and previous immunization status, then provide post-exposure management accordingly.

Note:

- Baseline testing is not necessary if vaccine response is known.
- If the first dose of HBV vaccine is not available but the exposed individual had received HBIG within seven days of exposure, repeat HBIG prophylaxis one month after the first dose.
- The recommended HBV vaccine series is a stat dose and repeat doses at one and six months.
- Neither pregnancy nor lactation should be considered a contraindication to HBV vaccination and/or provision of HBIG.

Preventing HBV infection for risky occupations:

- All exposed individuals are at an increased risk of HBV transmission, therefore MoHSW recommends a full course of HBV vaccination to all health providers.
- All health facility managers should ensure that all health service providers are routinely offered the HBV vaccine, and managers in other occupations whose employees carry a similar risk should do the same.
- Since the vaccine provides long-term immunity, in the event of exposures, the immune individuals do not need HBV PEP as they are primarily protected by the vaccination.

Table 15: Management of an Individual Exposed to an HBsAg---Positive or Unknown Source Person€

EXPOSED PERSON'S VACCINE STATUS	**PRESENCE OF ANTI-HBS IN EXPOSED PERSON (AS INFORMED BY LABORATORY TEST RESULTS OR PAST MEDICAL RECORDS)¥**	**HBV PEP**		**COMMENTS**
		HBIG (0.06 ml/kg)	**HBV Vaccine**	
Not vaccinated	Anti-HBs >10 mUl/ml (i.e. immune)	None	None	
Not vaccinated	Anti-HBs <10 mUl/ml (i.e. non-immune)	Give stat and repeat at 1 month	1st dose stat and proceed to complete full course	HBIG and HBV vaccine can be administered concomitantly at different injection sites
Previous vaccination and known responder	Documented in medical records as having Anti-HBs >10 mUl/ml (i.e. immune)	None	None	
Incomplete vaccination or unsure	Anti-HBs <10 mUl/ml (i.e. non-immune)	Single dose stat	Complete vaccination depending on documentation	HBIG and HBV vaccine can be administered

			or restart normal course as per guidelines	concomitantly at different injection sites
Incomplete vaccination or unsure	Anti-HBs >10 mUl/ml (i.e. immune)	None	None	
Vaccinated, but unknown response	Anti-HBs <10 mUl/ml (i.e. non-immune)	Single dose stat	Single booster stat	HBIG and HBV vaccine can be administered concomitantly at different injection sites
Vaccinated, but unknown response	Anti-HBs >10 mUl/ml (i.e. immune)	None	None	
Non-responder to primary vaccination	Documented in medical records as having Anti-HBs <10 mUl/ml (i.e. non-immune)	1st dose stat repeated after 1 month	1st dose stat, proceed to complete full course	HBIG and HBV vaccine can be administered concomitantly at different injection sites
Previously vaccinated but non-responder	Documented in medical records as having Anti-HBs <10 mUl/ml (i.e. non-immune)	1st dose stat repeated after 1 month	Consider alternative vaccine	

[€]**Table modified from European recommendations for the management of health care workers occupationally exposed to HBV and HCV (Puro, De Carli et al. 2005), New York State Department of Health AIDS Institute: HIV Prophylaxis Following Occupational Exposure, Updated in October 2012 – Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-occupational-exposure.pdf (NYS-DOH-AI 2012), and HIV Prophylaxis Following Non-Occupational Exposure, Updated in July 2013 – Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf (NYS-DOH-AI 2013). Also used in Republic of South Africa as detailed in a resource available at http://www.sahivsoc.org/upload/documents/guidelines_nov_2008.pdf.**

[¥]It is not recommended that decision-making be delayed while testing for anti-HBs at presentation

3.2.3 Post-Exposure Management Step 8: Prevent Hepatitis C Virus Transmission

Currently, there is no known PEP for preventing HCV infection and immunoglobulins are ineffective. The only effective prevention strategy is to avoid exposures to blood and other body fluids by proper compliance to standard precautionary measures.

Where diagnostic means are available, source persons should be tested for HCV. If the results are positive, the exposed person should also be tested.

Below is a list of the baseline tests for both the source and the exposed persons.

Exposed Person:

- HCV antibody, and if positive, HCV RNA test
- Liver panel, including liver enzymes

Source Person:

- HCV antibody test, e.g., enzyme immunoassay (EIA)/enzyme-linked immunosorbent assay (ELISA), and if positive, HCV RNA test

If EIA/ELISA test of the source person is reactive, then follow-up testing is necessary to confirm the source person's status. HCV RNA shall be used as a confirmatory test. When the HCV RNA test of the source person is reactive, then the exposed person should be managed as if the source has chronic HCV infection.

If the exposed person is a woman of reproductive age, counsel her about the need to avoid pregnancy and breastfeeding, but also about refraining from donating blood, plasma, organs, and tissues. Furthermore, despite the low risk of sexual transmission of HCV, the MoHSW recommends this exposed individual use a barrier method of contraception (e.g., condom) until six months after exposure.

3.2.4 Post-Exposure Management Step 9: Prevent Transmission of Other Infections and Prevent Pregnancy

Infections, such as tetanus and STIs may result from occupational and non-occupational exposures to blood and other body fluids. In addition, rape or sexual assault may lead to an unwanted pregnancy for women of reproductive age. Described hereunder are the steps to prevent these conditions.

3.2.4.1 Tetanus

For all tetanus-prone exposures (e.g., wounds from mass causalities, penetrating wounds, and any other type of injuries/wounds resulting in an anaerobic environment), if indicated, Tetanus Toxoid (TT) vaccine or booster must be provided (Chapman, Sullivent et al. 2008). MoHSW Tanzania Expanded Programme on Immunization guidelines recommends the following schedule:

1st TT dose – at first contact,
2nd TT dose – 1 month after 1st dose
3rd TT dose – 6 months after 2nd dose,
4th TT dose – 1 year after 3rd dose
5th TT – 1 year after 4th dose.

3.2.4.2 Sexually Transmitted and Reproductive Tract Infections

Following National Sexually Transmitted Infections/Reproductive Tract Infections (STI/RTI) guidelines, a presumptive supervised treatment for STIs/ RTIs should be provided to all victims of rape or sexual assault as follows:

Non-pregnant adults, male or female:

- Norfloxacin 800mg stat
- Doxycycline 100 mg bd X 7 days

Pregnant women:

- Spectinomycin 2g stat
- Amoxil 3g stat
- Probenecid 1g stat
- Erythromycin 500mg qds X 7 days

Children:

- Amoxil 15mg/kg tds X 7 days
- Erythromycin 10mg/kg qds 7 days

3.2.4.3 Pregnancy

All women of reproductive age should be tested for pregnancy as part of sexual assault care services. If they are not pregnant, offer them emergency contraceptives, which can be given up to 120 hours (five days) after the incident. Provision of an anti-emetic (Plasil 10mg stat) 30 minutes prior to the initiation of contraceptives and thereafter as needed should be considered. If the results of the initial pregnancy test were negative, test for pregnancy again after one month.

The options for emergency contraceptive intervention are:

- Progestin only pills; Postinor 2® (Levonogestrel) 1 tab bd stat (or 2 tabs stat)
- Combined oral contraceptive pills with high dose of oestrogen (50µg); Ovral ® 2 tabs every 12 hours (total 4 tabs per day)
- Combined oral contraceptive pills with high dose of oestrogen (30µg); Nordette ® 4 tabs every 12 hours (total 8 tabs per day)

Note: For guidance regarding the rights and procedures for compensation claims following the effects of occupational-related exposure to blood and other body fluids, refer to The Workers Compensation Act 2008 (section 22(1) and third schedule).

3.3 POST-EXPOSURE MANAGEMENT STEP 10: CONDUCT FOLLOW-UP TESTING AND PROVIDE CARE

Regardless of whether they are taking PEP or not, follow up of all exposed (occupational and non-occupational) individuals is necessary in order to:

- Evaluate them clinically for signs and symptoms of seroconversion and if necessary, do respective laboratory tests and provide appropriate support
- Counsel them on how to protect themselves and others from HIV, HBV, and HCV infections (e.g., not to donate blood, other blood products, or semen when using PEP within the follow-up time until confirmed seronegative for the potential infections mentioned above)
- Provide them with psychological support
- Counsel them on PEP medications and vaccines adherence
- Counsel them and provide contraceptive services (e.g., an exposed female of reproductive age should be counselled on family planning methods and avoiding pregnancy for up to six months after exposure); and
- Monitor them for drug toxicity and adverse side effects

Table 16 summarizes the recommended laboratory evaluations for both exposed and source persons.

Table 16: Recommended Laboratory Evaluation for Exposed (E) and Source (S) Persons[€]

TYPE OF TEST	MOHSW GUIDELINES	BASELINE	DURING PEP[++]	4-6 WEEKS AFTER EXPOSURE	3 MONTHS AFTER EXPOSURE	6 MONTHS AFTER EXPOSURE
HIV antibody test	Must do	E & S[£]	-	E	E	-
Haemoglobin *(especially for zidovudine-containing PEP regimen)*	Must do	E	E	E[¥]	-	-
Complete blood count with blood differential	Do, if available	E	E	-	-	-
Serum creatinine/Blood urea Nitrogen	Do, if available	E	E	-	-	-
STI screening (gonorrhoea, chlamydia, syphilis)	Do, if available	E & S	E[$]	E[$]		
HBV screening (HBsAg)	Do, if available	E & S		E[$]	E[$]	
Anti-HBs	Do, if available	E			E	E
HCV screening (including liver panel)[&]	Do, if available	E & S		E	E	E
Pregnancy test *(for all women of reproductive age)*	Must do, unless otherwise indicated	E[$]	E[$]			
HIV viral load	Do, if available	S		E**	E**	-
HIV resistance testing	Do, if available	S		E**	E**	-
CD4+ T-lymphocyte count	Do, if available	S		E**	E**	-

E = exposed person, S = source person

[€] Table modified from the New York State Department of Health AIDS Institute: HIV Prophylaxis Following Occupational Exposure, Updated in October 2012 – Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-occupational-exposure.pdf (NYS-DOH-AI 2012), and HIV Prophylaxis Following Non-Occupational Exposure, Updated in July 2013 – Available at http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf (NYS-DOH-AI 2013).

** If determined to be HIV infected on follow-up testing, perform as clinically indicated once diagnosed.

[$] Additional testing for pregnancy, STIs, and HBV should be performed as clinically indicated.

[£] HIV antibody testing of source patient is indicated for sources of unknown status.

[++] Other specific tests may be indicated depending on the type of ARV medications prescribed. In case of change of HIV/AIDS care and treatment guidelines, literature search pertaining to individual agents should be conducted.

[&] If any time the serum ALT levels is elevated, the clinician should repeat HCV RNA testing to confirm HCV infection. Also, if at any time the exposed person tests positive for HCV RNA, the clinician should refer for medical management and possible treatment.

[¥] If the exposed person's week 4 post-exposure HIV test results are indeterminate or the exposed person has symptoms suggestive of acute HIV infection, clinicians should continue ART beyond 28 days until a definitive diagnosis is established.

SECTION 4: ROLES AND RESPONSIBILITIES OF VARIOUS STAKEHOLDERS REGARDING POST-EXPOSURE PROPHYLAXIS SERVICE PROVISION

4.1 PREAMBLE

For successful PEP services provision, stakeholders at all levels (national, regional, district, health care facility, and community) need to work cooperatively. The roles and responsibilities of the health facility management, facility quality improvement team (QIT), PEP Focal Person, and trained health care provider responsible for PEP and national, regional, and district level supervisors are listed below.

Supervision for PEP should be integrated into regular supportive supervision visits and should follow the principles outlined in the National Supportive Supervision Guidelines for Quality Health Services in Tanzania (2010). In addition, criteria for supervising PEP services are described in the National IPC Standards (2012).

4.2 ROLES AND RESPONSIBILITIES—adapted from the National Supportive Supervision Guidelines (MOHSW/SUP 2010), and Tanzania Quality Improvement Framework (MOHSW/TQIF 2011)

4.2.1 Roles and Responsibilities of Health Facility Management

To improve provision of quality PEP services, the health facility management should do the following:

- Inform all staff and the community served by the facility of the availability of PEP services
- Ensure that PEP services are available and accessible 24 hours a day and seven days a week by having a trained health care provider responsible for PEP services available at all times and communicate clearly where an exposed person should report immediately after exposure
- Ensure that PEP drugs (including starter packs) are consistently available and accessible by the trained health care provider responsible for PEP management
- Ensure the monitoring and evaluation of PEP service implementation is conducted according to the MoHSW guidelines
- Guarantee confidentiality and privacy to all exposed individual
- Provide financial, human resource, and physical working space to ensure proper PEP service provision
- Ensure availability of quality IPC equipment and supplies

4.2.2 Roles and Responsibilities of the Facility Quality Improvement Team in Management of Post-Exposure Prophylaxis Services

The facility QIT should do the following in managing PEP services:

- Disseminate the PEP guidelines and standards to each department/ward/unit
- Coordinate regular in-service training to orient and update staff on PEP
- Coordinate, monitor, and evaluate PEP services implementation as per the guidelines

- Review reports for both occupational and non-occupational exposure to blood and other body fluids and institute appropriate actions
- Ensure compliance to standard operating procedures for PEP reporting and management
- Ensure that PEP medicines are available and accessible at all times
- Review and recommend appropriate IPC supplies and equipment to the health facility management
- Conduct regular supportive supervision visits to ensure that IPC supplies and equipment are properly used
- Conduct monthly meetings on PEP (as a component of other IPC practices) and provide written minutes of the meetings and other activities to the health facility management;
- Ensure that all staff and the community served by the facility are aware of the availability of PEP services
- Designate a focal person for PEP management

4.2.3 Roles and Responsibilities of Post-Exposure Prophylaxis Focal Person

The PEP Focal Person has the following roles and responsibilities:

- Oversee the smooth implementation of PEP services
- Act as a liaison between the facility QIT and trained health care providers responsible for PEP
- Gather opinions from health care workers regarding PEP services
- Compile, analyse, and share all PEP data with the facility QIT, and organize regular in-service training to orient and update staff on PEP

4.2.4 Roles and Responsibilities of Trained Health Care Provider Responsible for Providing Post-Exposure Prophylaxis Services

A trained health care provider shall:

- Be available at all times to respond to emergency calls
- Assess the time of exposure; the risk of HIV, HBV, and HCV transmission following exposure; and conduct first aid measures;
- Document the assessment findings according to the MoHSW guidelines
- Where appropriate, initiate PEP drugs according to the guidelines
- Educate the exposed person on the post-exposure follow-up according to the guidelines

4.2.5 Roles and Responsibilities of Council-Level Supervisors

Council-level supervisors shall:

- Ensure that all staff at facilities are oriented to the PEP guidelines
- Conduct supportive supervision visits to all health facilities in the district, irrespective of ownership
- Ensure that PEP focal persons are appointed at all health facilities in the district

- Support health facilities to complete registers and submit PEP summary reports according to the MoHSW schedule
- Ensure integration of PEP services with other health-related programs in the district
- Ensure constant availability of PEP commodities to all facilities

4.2.6 Roles and Responsibilities of Regional Level Supervisors

Regional supervisors shall:

- Ensure that CHMT are implementing PEP policies and guidelines
- Conduct supportive supervision visits to regional and all district hospitals and other health facilities
- Ensure integration of PEP services with other health-related programmes in the region

4.2.7 Roles and Responsibilities of National Level Supervisors

National level supervisors should:

- Review and update guidelines
- Ensure that PEP policies and guidelines are being translated into achievable objectives
- Conduct supportive supervision visits to national, referral, and specialized hospitals
- Visit selected health facilities, irrespective of ownership, as the need arises
- Conduct monitoring and evaluation

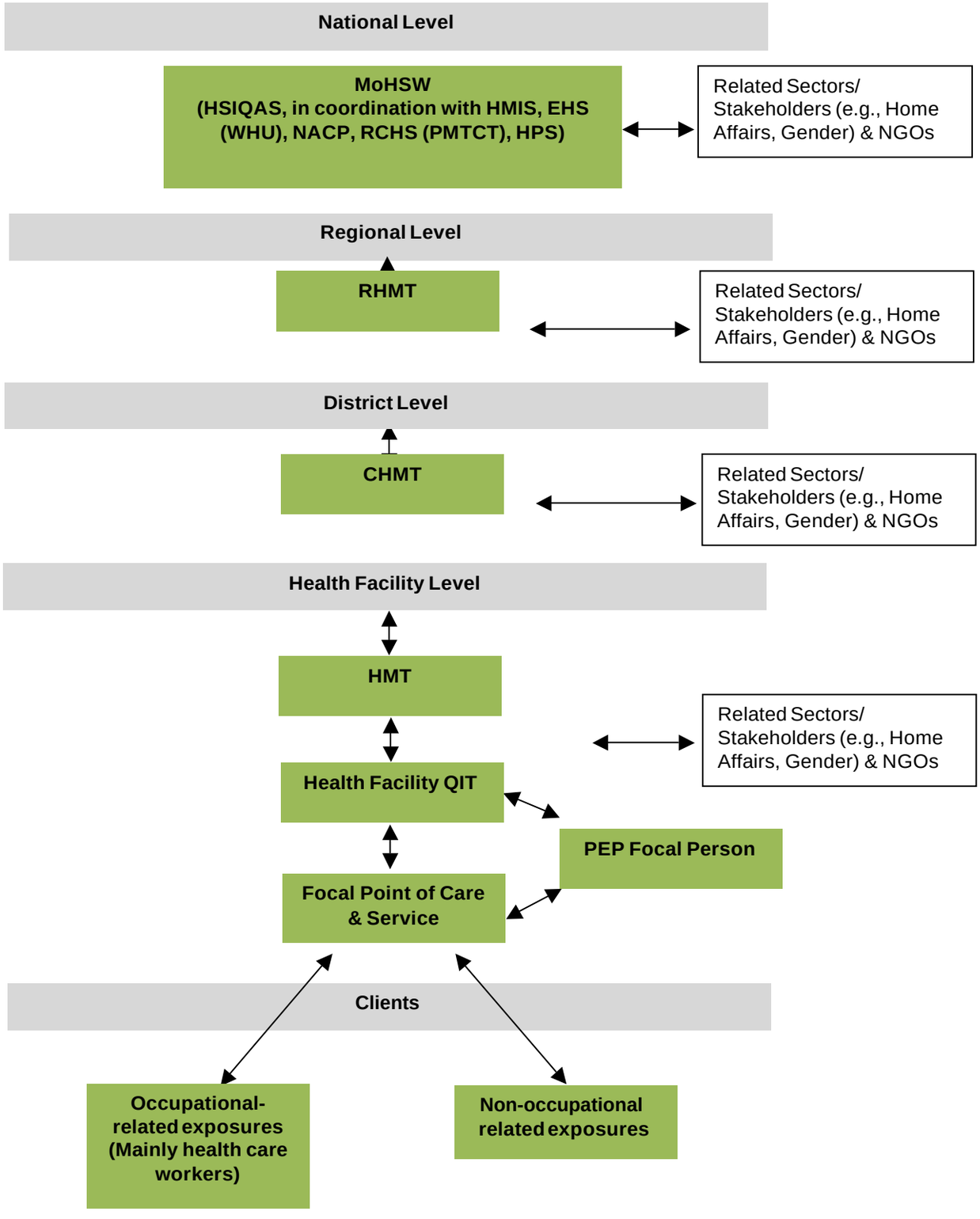
4.2.8 Roles and Responsibilities of Related Sectors/ Other Stakeholders:

- Speed up access to PEP services as early as possible after the incidents
- Adhere to the confidentiality and privacy during handling of the exposed clients
- Participate in advocacy of PEP services
- Avoid stigma and discrimination in handling the exposed cases

4.3 PEP SERVICES ORGANOGRAM

Figure 2 illustrates how facilities and other stakeholders shall plan, implement, supervise, monitor, and evaluate PEP services and shows the involvement of various levels.

Figure 2. Organogram on PEP services



ACRONMS
HSIQAS=Health Services Inspectorate and Quality Assurance Section; HMIS=Health Management Information System; EHS = Environmental Health, Hygiene and Sanitation Section; WHU = Workplace Health Unit; NACP=National Aids Control Programme; RCHS = Reproductive and Child Health Section; PMTCT = Prevention of Mother to Child Transmission; HEPS=Health Education Promotion Section; RHMT=Regional Health Management Team; CHMT=Council Health Management Team; HMT= Health facility Management Team; QIT = Quality Improvement Team

SECTION 5: MONITORING AND EVALUATION

5.1 PREAMBLE

Anecdotal reports in Tanzania indicate that the rate of exposures to blood and other body fluids is high. However, the rate of reporting is extremely low. Without accurate data on the number of exposures, it is difficult to plan, implement, and effectively manage a PEP program. Therefore, improved data collection and reporting for both occupational and non-occupational exposures is urgently needed in order to:

- Effectively plan PEP-specific interventions
- Prioritize and allocate resources
- Utilize data for decision making

Using a participatory approach, the MoHSW has developed standard tools for documenting and reporting exposures.

5.2 DATA COLLECTION AND ANALYSIS

To improve data collection and reporting, all health care facilities are encouraged to designate a focal person, as mentioned in the earlier section. This person, in coordination with the trained health service providers shall be responsible for overseeing all PEP documentation and reporting issues. The following steps shall be followed to collect, manage, and analyse data:

- Record information for all exposed individuals on case note forms (initial and follow-up) and file them appropriately
- Transfer all data from case notes forms to PEP register
- Use the register to complete the summary form. This report shall be used to inform indicators that are reportable both nationally and internationally to improve the quality of PEP services at all levels of service provision
- The designated focal person for PEP shall ensure that the summarized reports are submitted to the next level in a timely manner

(Please refer to the National PEP Data Collection Tools for details on all forms and registers.)

5.3 CONFIDENTIALITY

Lack of confidentiality on HIV test results and PEP medication usage could be one of the factors contributing to underreporting of exposures. For this particular reason, the MoHSW recommends that facilities comply with the following requirements:

- All information related to the exposed person should be kept confidential
- Access to the HIV-related information of exposed individuals should be strictly limited to health care personnel involved in prescribing and following up PEP
- Such information may only be disclosed if legally required or with the consent of the person concerned

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