NATIONAL GUIDELINES

PRE-EXPOSURE PROPHYLAXIS (PrEP)

AND

NON-OCCUPATIONAL POST EXPOSURE PROPHYLAXIS (nPEP)

MINISTRY OF HEALTH/

NATIONAL AIDS

PROGRAMME SECRETARIAT

(MOH/NAPS)-GUYANA

Contents

ABBREVIATIONS AND ACRONYMS

3TC	- LAMIVUDINE
AB/AG	- ANTIBODY/ANTIGEN
AIDS	- ACQUIRED IMMUNODEFICIENCY SYNDROME
ALT	- ALANINE TRANSAMINASE
ART	- ANTIRETROVIRAL THERAPY
ARV	- ANTIRETROVIRAL (DRUG)
ATV	- ATAZANAVIR
BMD	- BONE MINERAL DENSITY
CDC	- UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION
CR CL	- CREATININEE CLEARANCE
CT	- CHLAMYDIA TRACHOMATIS
DTG	- DOLUTEGRAVIR
DRV	- DARUNAVIR
ED-PREP	- EVENT-DRIVEN PRE-EXPOSURE PROPHYLAXIS
EIA	- ENZYME IMMUNOASSAY
ELISA	- ENZYME-LINKED IMMUNOSORBENT ASSAY
FDC	- FIXED-DOSE COMBINATION
FTC	- EMTRICITABINE
GC	- NEISSERIA GONORRHOEAE
HBEAG	- HEPATITIS B E ANTIGEN
HBSAG	- HEPATITIS B SURFACE ANTIGEN
HBV	- HEPATITIS B VIRUS
HCV	- HEPATITIS C VIRUS
HIV	- HUMAN IMMUNODEFICIENCY VIRUS
HIV-DR	- HIV DRUG RESISTANCE
HIVST	- HIV SELF-TESTING

ILO	- INTERNATIONAL LABOUR ORGANISATION
IPERGAY	- INTERVENTION PREVENTIVE DE L'EXPOSITION AUX RISQUES AVEC ET POUR LES GAYS.
IPREX	- PRE-EXPOSURE PROPHYLAXIS INITIATIVE
KP	- KEY POPULATIONS
NAT	- NUCLEIC ACID TEST
LGBTI	- LESBIAN, GAY, BISEXUAL, TRANSGENDER AND INTERSEX
LPV	- LOPINAVIR
M&E	- MONITORING AND EVALUATION
MSM	- MEN WHO HAVE SEX WITH MEN
NAT	- NUCLEIC ACID AMPLIFICATION TESTING
NNRTI	- NON-NUCLEOSIDE REVERSE-TRANSCRIPTASE INHIBITOR
NRTI	- NUCLEOSIDE REVERSE-TRANSCRIPTASE INHIBITOR
OPEP	- OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS
PAHO	- PAN AMERICAN HEALTH ORGANISATION
PI	- PROTEASE INHIBITOR
PEP	- POST-EXPOSURE PROPHYLAXIS
PREP	-PREEXPOSURE PROPHYLAXIS
PWID	- PERSON WHO INJECT DRUGS
RAL	- RALTEGRAVIR
RCT	- RANDOMISED CONTROLLED TRIAL
RDT	- RAPID DIAGNOSTIC TEST
RTV	- RITONAVIR /R
STI	- SEXUALLY TRANSMITTED INFECTION
SW	- SEX WORKERS
TASP	- TREATMENT AS PREVENTION
TDF	- TENOFOVIR DISOPROXIL FUMARATE
TG	- TRANSGENDER

UNAIDS	- JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS
CDC	- UNITED STATES CENTERS FOR DISEASE CONTROL AND
WHO	- WORLD HEALTH ORGANIZATION

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THE ORGANISATION OF THE GUIDELINES

These guidelines are organized in three main parts, as outlined in Figure 1 below.

Figure 1: Organization of the guidelines

1. Introduction	2. Pre-Exposure Prophylaxis (PrEP)	3. Non Occupational Post Exposure Prophylaxis (nPEP)
• HIV Epidemiology in Guyana • Rationale for PrEP and nPEP • Target Audience • Organisation of the guidelines	• Introduction to PrEP • Assessment for PrEP • Laboratory Testing • Precribing PrEP • Stafey of PrEP Medications • Stopping PrEP	• Definition • Carte Path Way • Precribing nPEP • Follow-up and Monitoring • Prevention Strategy

INTRODUCTION

HIV TO THE CARIBBEAN

At the end of 2018, the HIV prevalence in the Caribbean among adults aged 15-49 yearsis1.2% withan estimated 340,000 people living with HIV .The HIV epidemic remains mostlyconcentrated in key populations who are at significantly higher risk than the generalpopulation and are disproportionately affected. UNAIDS 2019 Global Update, reported thatthe risk of acquisition of HIV infection among key populations (KP) is significantly higherthan the general population- sex workers (21 times), men who have sex with men (22times), and transgender persons(12 times). [1] In 2018 key populations and their sex partners accounted for 47% new HIV infection in 2019. Among the KP groups, men who have sex withmen (MSM) accounted for the highest (22%) burden of new infections. Across the Caribbean, MSM communities are disproportionately affected by HIV prevalence as high a30% in Jamaica.

The World Health Organisation (WHO) recommends a comprehensive package of servicesfor KPs includes prevention, diagnosis, treatment, and care for HIV and other sexuallytransmitted infections to meet the health needs of this community. In regards toprevention, WHO recommends combination prevention that is a person and communitycentred focus and includes biomedical, structural and behavioural interventions. HIV preand post-exposure prophylaxes are recommended as effective biomedical strategies forprevention of HIV infection.

HIV EPIDEMIOLOGY IN GUYANA

The HIV prevalence in Guyana has plateaued over the last ten years and is reported at 1.4% in 2018 among persons 15-49 years old. There is an estimated 8200 persons living with HIV (PLHIV), with 4100 men slightly higher compared 3800 women and less than 500 children 0-14 years of age. New infections have reduced by 20% from 2010 to 2018 with less than 500 new infections in 2018. AIDS related deaths have increased by 36% from 2010 to 2018[2]. Guyana has a mixed epidemic which disproportionately affects key populations and vulnerable groups.

[1] UNAIDS Data 2019: https://www.unaids.org/en/resources/documents/2019/2019-UNAIDS-data

[2]UNAIDS data 2019, https://www.unaids.org/sites/default/files/media_asset/2019-UNAIDS-data_en.pdf.

The evaluation of National Strategic Plan (NSP) 2021-2025 found that there was no change in the HIV epidemic in the past five years. The HIV prevalence among pregnant women was 1.9% (below the threshold of generalized epidemic which is above 2%). The prevalence has plateau at 1.4% in the last five years with the same being reported in 2020. Prevalence also differed slightly between males and females (15-49 years), with males at 1.4% and females at 1.3%. The number of persons estimated to be living with HIV for all ages increased by 7.9% from 7,600 in 2014 to 8,752 in 2020, of which 500 were children and 3,300 were women

HIV prevalence among Key Population groups

The HIV prevalence among men who have sex with men has decreased from 19.4% in 2008 to 5.5% in 2014 but remains significantly higher than that of the general population. Similarly, for female sex workers, the HIV prevalence decreased from 16.6% in 2008 to 4.1% in 2015. In 2014, prevalence among the transgender was 8.4%; male sex workers, 4.9% and loggers 1.3%.

Despite the decrease in HIV prevalence, the practices continue to place key populations at high risk for HIV acquisition and transmission. Guyana's fourth Biological and Behavioural Survey of HIV in Guyana in 2017 report on thepreferences for and likelihood of using PrEP among key groups of which the responsesdidn't vary widely across age groups. FSW have similar rates of reported PrEP use in thepast, but younger MSM report higher previous use (7.2 percent) compared to older MSM (1.2 percent). In terms of perceived chance of getting HIV, FSW and MSM who are 25 yearsor older are more likely to say that have "no chance" of getting HIV (6.1 percent and 3.5percent respectively) compared to those who are under 25 (3.7 percent and 1.8 percent respectively).

PrEP, FSW and MSM by age group

	FSW		MSM		
	<25	25+	<25	25+	Total
Ever taken PrEP	10.1	10.4	7.2	1.2	6.4
Likelihood of taking PrEP if available for free					
Very likely	52.7	52.8	56.2	53.7	53.8
Somewhat likely	19.0	20.5	19.7	19.1	19.6
Somewhat unlikely	15.4	18.2	21.5	22.3	20.0
Very unlikely	13.0	8.5	2.6	4.9	6.5
Likelihood of taking PrEP if available for a cost					
Very likely	35.3	38.3	35.1	39.5	37.6
Somewhat likely	22.2	27.4	25.0	24.2	25.0
Somewhat unlikely	24.3	23.9	34.0	27.6	27.4
Very unlikely	18.3	10.4	6.0	8.7	9.9
Perceived chance of getting HIV					
No chance	3.7	6.1	1.8	3.5	3.9
Low	25.7	33.4	33.6	29.4	31.0
Moderate	48.6	46.2	48.5	40.6	45.1
High	22.0	14.2	16.1	26.5	20.1
Weighted n=	179	375	278	456	1287

Source: Guyana BBSS 2017

The results of these clinical trials and studies have increased the understanding of who can use PrEP, what antiretroviral are effective ARVs, their dosing regimens and side effects. The results indicate that PrEP is effective in preventing HIV transmission, and hence, PrEP is considered a critical biomedical prevention strategy as part of combination prevention. At the same time, it is important to understand that PrEP is not a replacement for other prevention strategies. Instead, PrEP is an additional prevention choice for people who are at substantial risk of HIV acquisition. PrEP should be given as part of combination prevention (condoms and lube, STI screening and management, HIV testing and counselling, risk and harm reduction) and with comprehensive support (Adherence counselling, legal and social support, mental health and emotional support, sexual and reproductive support).

Prevalence among key population groups has been decreasing compared to the general population and other sub-population groups. According to the two Integrated Biological and Behavioural Surveys (IBBS) conducted in 2008 and 2014 prevalence among men who have sex with men (MSM) decreased from 19.4% in 2008 to 5.5% in 2014. Female sex worker (FSW) prevalence decreased from 16.6% in 2008 to 5.1 in 2014. Likewise, HIV prevalence among miners decreased from 3.9% in 2008 to 1.0% in 2014.

Estimated HIV prevalence among pregnant women, which is used as a proxy for the general population, increased from 0.9% in 2011 to 1.9 in 2019 based on ante-natal clinic (ANC) surveillance report (2019). This infers that prevalence among KPs is more than double that of the general population as shown by the ANC data. However, there is concern that new infections in young women are on the increase and targeted prevention measures would need to be prioritized for the future. This is supported by the high teenage pregnancy rate (15.8%, MICS, 2014), indicating the limited use of condoms.

Based on the afore-mentioned observations, the next 100 new infections may have come from KPs and other vulnerable groups.

RATIONALE FOR PREP AND NPEP GUIDELINES

The rationales for the introduction of these guidelines are:

1. To offer standardised and high-quality management of PrEP and nPEPfor persons at high risk and exposed to HIV infection in the Caribbean.
2. To ensure that PrEP and nPEP protocols in the Guyana reflect evidence-based international standards of practice.
3. To present simplified algorithms for establishing risk, assessment, diagnosis, treatment, clinical and laboratory monitoring, and follow-up of adults for PrEP and nPEP.
4. To provide streamlined information on the benefits of PrEP and nPEP to facilitate a public health approach in reducing HIV transmission in the Guyana.
5. To ensure cost-effectiveness of PrEP and nPEP delivery through the use of fixed-dose combination and other cost-effective approaches.
6. To reduce medical errors in the delivery of PrEP and nPEP.
7. To ensure that research evidence is converted promptly into practice, by educating practitioners and patients through regular updates and training.

TARGET AUDIENCE

The guidelines are primarily intended for use by clinical practitioners who deliver PrEP and PEP services in the Guyana. These include but not limited to physicians, nurse practitioners, social workers, pharmacist and others. Additional audiences of interest include:

- ✓ Programme Managers_ HIV, STI, TB, PMTCT and others
- ✓ HIV clinical teams- physicians, nurses, social workers, HIV counsellors, pharmacists and others.
- ✓ Primary Health Care practitioners,
- ✓ Hospital staff and departments, especially Emergency Rooms, Labor and Delivery and Infectious Disease wards.
- ✓ National Laboratory managers,
- ✓ Persons from the key populations in the Caribbean- Men who have sex with men, sex workers and transgender persons
- ✓ Community-Based Organisations who deliver educational and preventative services to KPs.

Guiding principles

The following principles have informed the development of the guidelines and should guide the implementation of the recommendations herein:

- ✓ These guidelines should contribute to the Guyana, achieving its commitments to 95-

95-95by 2025 and ending AIDS by 2030.

- ✓ These guidelines should contribute to the reduction of HIV prevalence in KPs- MSM, FSW and TGs.
- ✓ These guidelines promote a client-centred, individualised approach to PrEP and PEP delivery.
- ✓ These guidelines realise the rights and responsibilities of persons accessing PrEP and PEP in their care, specifically in relation to adherence to ARVs and safe sex practices.
- ✓ These guidelines will be implemented with respect for and protection of human rights of all persons who access PrEP and PEP services, including the promotion of gender equity and ensuring informed consent where necessary.
- ✓ These guidelines emphasise the importance of leveraging PrEP and PEP services to provide more comprehensive and holistic care, including screening, diagnosing and treating other sexually transmitted infections such as Hepatitis B virus (HBV).
- ✓ These guidelines present technical recommendations that are driven by global scientific evidence but informed by the local context including HIV epidemiology in Guyana, the increased risk of HIV acquisition and transmission among KPs in the country, availability of resources and anticipated cost-effectiveness.
- ✓ These guidelines are user-friendly with a focus on what to do rather than why to do it. It provides the user with the ability to quickly peruse, understand and make decisions on PrEP and PEP management in a methodological way. It provides a practical, person-centred approach to addressing PrEP and PEP through scenarios, trigger questions and developing of individualised care.
- ✓ These guidelines present key information as tables and figures that can be further synthesised to produce knowledge products such as standard operating procedures and other clinical aides. These can be made widely available and readily accessible for use by PrEP and PEP practitioners.

PRE-EXPOSURE PROPHYLAXIS (PREP)

Introduction to PrEP

WHO defines oral Pre-Exposure Prophylaxis (PrEP) as, "the use of antiretroviral (ARV) drugs before HIV exposure by people who are not infected with HIV in order to block the acquisition" (World Health Organisation 2016). In 2012, WHO issued a conditional recommendation for PrEP use among sero-discordant couples and among men and transgender women who have sex with men (World Health Organisation 2012). WHO revised this guidance (World Health Organisation 2015) and made a strong recommendation for governments to consider adding PrEP as part of combination prevention strategies for MSM in countries with a high prevalence of HIV. The WHO provided further updates in 2016 recommending that oral PrEP containing Tenofovir (TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches(World Health Organisation 2016). Linked to this recommendation, substantial risk of HIV infection was provisionally defined as HIV incidence around 3 per 100 person-years or higher in the absence of PrEP. HIV incidence higher than 3 cases per 100 person-years has been identified among some groups of MSM, TG women in many settings, and sero-discordant couples. Individual risk varies within groups at substantial risk, depending on individual behaviour and the characteristics of sexual partners.

In 2017, WHO published a PrEP implementation tool which comprised of twelve modules to assist countries to develop PrEP programmes (World Health Organisation 2017). In 2019, PAHO offered an online training course on how to implement PrEP. These on-going efforts are intended to raise awareness of PrEP and support countries to implement PrEP as part of their combination prevention strategies. Guyana through its National strategic Plan 2025, is committed to the delivery of differentiated prevention services with the inclusion of PrEP and nPEP, hence optimizing combined HIV/STI Prevention services for Key Populations and general population.Guyana pilotedPrEP in 2019 through a Private-Public partnership initiative targeting discordant couples. This now gives Guyana an opportunity todevelop strategiesand a comprehensive approachto introduce PrEP and nPEP to all public facilities offering Care and Treatment services.

Evidence for PrEP

Highly active antiretroviral treatment is significant to reduce disease progression, morbidity and mortality from HIV. The successes of Treatment as Prevention (TasP), led to the consideration using ARV to prevent the acquisition of HIV in HIV negative persons. To amass

the evidence on the efficacy of PrEP, nine trials were scheduled between 2004 and 2005. (Caceres 2015). Of these, five were completed. These, considered first-generation trials yielded mixed results and generated various controversies among stakeholders. In 2005, UNAIDS and the Global Advocacy for HIV Prevention (AVAC) led a process to develop acceptable standards for the ethical conduct of future trials. The development of these standards ushered in an era of PrEPrandomized controlled trials (RCTs) starting in 2010.

These guidelines were developed on the basis WHO's systematic review and meta-analysis of evidence on oral PrEP for all populations, which included nine studies of TDF-FTC and four studies on Tenofovir only for PrEP.

Evidence was gathered primarily from four randomized clinical trials that provided the best evidence in the use of Tenofovir/Emtricitabine (TDF-FTC) for PrEP in Guyana. These trials are:

1. The iPrEx study (Grant RM 2010) was a phase 3, double-blind RCT evaluating once-daily (TDF-FTC) or placebo in 2499 **HIV-negative men or transgender women who have sex with men** with evidence of high-risk behaviour for HIV infection in Peru, Ecuador, Brazil, the US, Thailand and South Africa. All subjects received standardised, safe sex counselling, access to condoms, and STI testing and treatment. The overall efficacy was 44% when compared to placebo.
2. The Partners PrEP study(Baeten 2012)(Baeten JM 2014)(Baeten et al. 2012 and Baeten et al. 2014) was a double-blind RCT evaluating once-daily single-agent tenofovirdisoproxil or Truvada or placebo in 4747 **HIV negative individuals in aheterosexual partnership with a person already infected** with HIV (a sero-discordant heterosexual couples) in Kenya and Uganda. It found that once-daily Truvada reduced the relative risk of acquiring HIV infection by 75% compared to placebo.
3. The PROUD study (McCormack 2016) was an open-label trial of once-daily Truvada in 544 **HIV-negative men or transgender women who have sex with men** in England. Participants were randomised to start PrEP with Truvada immediately on study entry or after a deferral period. The study found that once-daily Truvada reduced the relative risk of acquiring HIV infection by 86% compared with no prophylaxis.
4. The IPERGAY study (Molina 2015) was a double-blind RCT evaluating Truvada or placebo taken 'on-demand' before and after sexual activity in 414 **high-risk men who have sex with men** in France and Canada. The participants took a median of 15 tablets per month. On-demand Truvada reduced the relative risk of acquiring HIV infection by 86% compared with placebo.

The results of these clinical trials have increased the understanding of who can use PrEP, what antiretroviral are effective ARVs, their dosing regimens and side effects. The results indicate that PrEP is effective in preventing HIV transmission, and hence,PrEP is considered a critical biomedical prevention strategy as part of combination prevention. At the same time, it is important to understand that PrEP is not a replacement for other prevention

strategies. Instead, PrEP is an additional prevention choice for people who are at substantial risk of HIV acquisition. PrEP should be given as part of combination prevention (condoms and lube, STI screening and management, HIV testing and counselling, risk and harm reduction) and with comprehensive support (Adherence counselling, legal and social support, mental health and emotional support, sexual and reproductive support).

Oral Pre-exposure Prophylaxis (PrEP)

Oral PrEP is the use of antiretroviral (ARV) drugs by HIV negative people to prevent the acquisition of HIV. In 2015, the WHO recommended that **"Oral PrEP (containing TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches.**"This was a strong recommendation based on the high quality of evidence from several clinical trials. PrEP is an additional prevention choice for people who are at substantial risk of HIV acquisition.

There are two types of PrEP. There are:

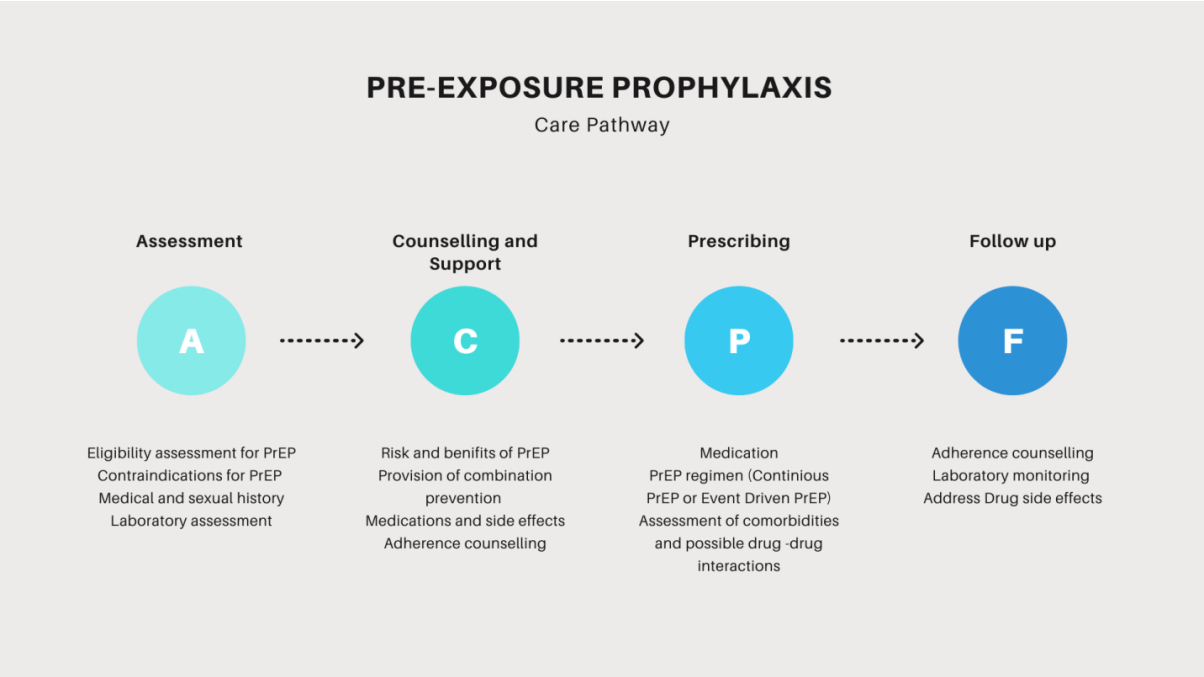
1. Daily Oral PrEP: This is the use of daily antiretroviral medication (1 tab once a day) to prevent HIV acquisition.
2. Event-Driven PrEP: This is the use of double dose (2 pills which serve as a loading dose) of TDF-FTC (or TDF-3TC) between 2-24 hours in advance of sex, then a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills. Event-Driven PrEP is indicated for **ONLY** MSM. There is limited data for the use of Event-Driven PrEP in other population groups. (World Health Organisation 2019)

PrEP should be given as part of combination prevention that should include use of condoms and lubricants, STI screening and management, HIV testing and counselling, HIV and STI risk reduction management and harm reduction for intravenous drug users.

Care pathway for people using PrEP

The pathway of care for persons using PrEP can be divided into assessment, counselling and support, prescription and follow up. See Figure 2 below:

Figure 2: Pathway of care for persons using PrEP.



ASSESSMENT FOR PrEP

Eligibility for PrEP

Aligned to WHO recommendations, eligibility of PrEP should be assessed using the following criteria:

1. The person must be HIV negative
2. The person must not have any suspicion of acute HIV infection
3. The person must be at substantial risk of HIV infection
4. The person must not have any contraindications to PrEP medicines.
5. The person must be willing to use PrEP as prescribed.

The WHO minimum age for PrEP is 15 years. It states that PrEP is recommended for "sexually mature adolescents and young adults – typically, people age 15 – 24 years." (World Health Organisation 2018). In Guyana, the Maternal and Child health policy allows

for persons from the ages of 13 access health care and contraceptive services, as of such Guyana will be guided by this same principal and target persons from age 13 and above.

Contraindications to PrEP

It is contraindicated to prescribe PrEP under the following circumstances:

1. The person is HIV positive or did not do an HIV test to rule out infection.
2. The person has signs and symptoms of acute HIV infection.
3. The person has an estimated creatinine clearance of less than 60 ml/min.
4. The person is seeking occupational or non-occupational PEP.
5. The person who is unable or unwilling to strictly adhere to the treatment protocol as prescribed.
6. The person who has an allergy or contraindications to any medicine in the PrEP regimen.

The initial assessment should consist of two components:

1. Take a comprehensive medical history (including sexual and drug histories).
2. Conduct appropriate laboratory testing.

Medical and Sexual History

One of the main reasons for a comprehensive medical and sexual history is to determine whether the person/s are eligible or ineligible based on the criteria above.

Screening to determine -"substantial risk."

1. At the individual level – An individual is at substantial risk for HIV acquisition who has any of these risk factors within the last six months(World Health Organisation 2017)
    - Vaginal or anal sex without condoms with more than one partner, or
    - A sexual partner who is HIV positive is either not on antiretroviral therapy or has not achieved viral suppression, or
    - A history of sexually transmitted infections (STI) by laboratory testing or self-report or syndromic STI treatment, or
    - Use of post-exposure prophylaxis (PEP) or
    - Requesting PrEP.
    -

Screening questions to determine "substantial risks" of sexually active individuals.

To aid in the medical and sexual history taking the clinical provider can, WHO recommends a list of screening questions- see Box 1. Any question that elicits a "yes" response in a high prevalence setting should serve to initiate a discussion on the risks and benefits of PrEP.

Box 1: General screening questions to determine substantial risk (WHO July 2017)

Questions for all persons	**Questions for discordant couples (person whose sex partner if HIV positive)**	**Questions to screen for increased vulnerability.**
Have you had sex with more than one person?	Is your partner taking ART for HIV?	Have you received money, housing, food or gifts in exchange for sex?
Have you had sex without a condom?	Has your partner been on ART for more than six months?	Have you been forced to have sex against your will?
Have you had sex with anyone whose HIV status you do not know?	At least once a month, do you discuss whether your partner is taking HIV medication daily?	Have you been physically assaulted, including assault by a sexual partner?
Have you injected drugs and shared injecting equipment?	If you know, when was your partner's last HIV viral load test? What was the result?	Have you injected drugs or hormones using shared equipment?
Are any of your partners at risk of HIV, through sexual or drug-using behaviour?	Do you desire pregnancy with your partner?	Have you used recreational or psychoactive drugs?
Do you have sex with a person who has HIV?	Do you use condoms every time you have sex?	Have you been forced to leave your home (especially if due to sexual orientation or violence)?
Have you received a new diagnosis of a sexually transmitted infection?		Moved to a new place (possibly having a higher prevalence of HIV exposure)?
Have you used or wanted to use PrEP or PEP for sexual or drug-using exposure to HIV?		Have you lost a source of income (such that you may need to exchange sex for shelter, food or income)?
		Have you left school earlier than you planned?

Determination of acute HIV infection

Acute HIV infection occurs after primary HIV infection. It is defined as the time from HIV infection to seroconversion, which can take up to six weeks. The presentation ranges from asymptomatic to symptoms of fever, sore throat, aches and pains and lymphadenopathy, mouth sores, headaches and rash. While these signs and symptoms are not specific to HIV but can be seen in most acute viral syndromes, HIV infection can be suspected if a person presenting with an acute viral syndrome had condomless sex in the past 14 days. If this occurs, then defer PrEP and repeat antibody testing after four weeks. If there is seroconversion, the HIV test should be positive.

The rationale for ruling out acute HIV infection is to prevent the development of HIV drug resistance to ARVs used for PrEP.PrEP treatment is adequate to prevent HIV acquisition, but it is not suitable for the treatment of an HIV positive person. PrEP is usually a two-drug combination, while HIV treatment currently entails a combination of three or more antiretrovirals of different classes to attain viral suppression. It is for this reason; persons must be carefully screened to ensure that they are HIV negative before starting PrEP.

Determination of contraindications to PrEP medicines

The current PrEP medicines are tenofovirdisoproxil and emtricitabine (TDF-FTC). TDF, primarily, can affect the kidneys, bone and affect HBV infection. In taking the medical history, the appropriate questions should be asked to rule out renal and hepatic pathologies. It is also important to ask the patient about the use of other medicines to determine whether those medications will interact with the PrEP medications. A list of drugs that can interact with PrEP Medication is provided in Annex 2.

> HIV infection can be suspected if a person presenting with an acute viral syndrome had condom-less sex in the past 14 days.

Determination of willingness to use PrEP

Practitioners should explain to the patient, how to take PrEP, the possible side effects of the medication, the need for adherence, the need to reduce their risk and the need for monitoring and follow up. During this process, the practitioner should access whether there is a willingness to use daily PrEP or Event-Driven PrEP in MSM. Poor adherence will result in inadequate amounts of TDF-FTC in the body to protect against HIV infection; this would put the person at increased risk of acquiring HIV infection. A corollary risk is that if the concentration of the drug is at a suboptimal level in the body, there is a risk that HIV can

develop resistance to these medicines in HIV infection occurs. For more information on counselling, please check the counselling and support section.

LABORATORY TESTS

The following laboratory testing is recommended:

- *Determination of HIV status*

All persons should have an HIV test done before starting PrEP. All persons should be tested according to National Testing Protocol. The HIV test serves to establish the HIV status of the individual. An HIV negative result is one of the eligibility criteria, and PrEP should be considered for patients with no signs of HIV seroconversion.

Conversely, an HIV positive test is a contraindication for PrEP.WHO recommends using serial testing strategies within a validated testing algorithm and using WHO prequalified assays, WHO defined serial testing algorithms for high (>5%) and low (<5%) prevalence settings. See attached algorithms as Annex 3.

Other Laboratory testing.

Renal Function Test: PrEP medications are excreted by the kidneys. It is important before starting PrEP to access kidney functions using creatinine clearance. If someone has creatinine clearance <60ml/min, then PrEP should not be offered. If creatinine clearance is <60ml/min in anyone receiving TDF-FTC for PrEP, renal function should be reevaluated within a week, and if it remains depressed then consideration should be given to stopping PrEP.

- **Creatinine Clearance** must be done every six months. More frequent testing is recommended in persons with a history of diseases that affect the kidney such as diabetes. Less frequent testing is recommended for persons younger than 45 years of age, persons with a baseline estimated creatinine clearance greater than 90ml/min and body weight more than 55 kg.
- **Hepatitis B test:** It is important to know if the patient has HBV. If a person tests positive for chronic HBV infection, TDF-FTC can be used as both PrEP and as a treatment for HBV. However, if TDF-FTC is discontinued prematurely; then this can result in rebound viraemia and fulminate liver damage. For this reason, Event-Driven PrEP is **NOT** recommended in patients with chronic HBV infection.
- **Hepatitis C test:** This should be done in MSM and other high-risk groups such as people who inject drugs and repeated every 12 months.
- **Tests for Other Sexually Transmitted Infections** such as for Syphilis, Neisseria Gonorrhoea and Chlamydia Trachomatis): All persons should be screened for other sexually transmitted

infections and treated for any positive results. Repeat testing should be done regularly- see Table 1 for the testing schedule.

Table 1: Laboratory testing schedule at baseline and follow up

Pathogen/Analyte	Initial test	Follow up test
HIV (HIV antibodies (anti-HIV)	Before starting PrEP	Retest every three months.
Creatinine	Before starting PrEP	Retest every six months.
HBV (Hepatitis B surface antigen (HBsAg))	Before starting PrEP. If the HBsAg test is reactive, then use WHO HBV treatment guidelines. If HBsAg is not detected, consider vaccination.	
HCV (HCV antibodies (anti-HCV))	Before starting PrEP. Consider testing for HCV in MSM or People who inject drugs.	Annually.
Syphilis (treponemal antibodies)	Before starting PrEP.	Consider retesting every three to six months.
Syphilis (rapid plasma reagintiter)	Before starting PrEP. (Especially pregnant women).	
Neisseria gonorrhoeae (GC)	Before starting PrEP, use of nucleic acid testing (NAT) technologies is preferred if unavailable syndromic treatment can be used.	Retest every three to six months.
Chlamydia trachomatis (CT)	Before starting PrEP, use of nucleic acid testing (NAT) technologies is preferred if unavailable syndromic treatment can be used.	Retest every three to six months.

Counselling and Support

PrEP must be given with comprehensive support that should include adherence counselling at initial and all follow-up visits, legal and social support, mental health and emotional support and sexual and reproductive support. The goals of counselling depend on whether the person is contemplating PrEP, has chosen PrEP or is being followed up while on PrEP. The areas of focus are detailed in Box 2. In Keeping with WHO guidance, counselling should be client-centered, that is where the counsellor works with the client to determine what is best for that person.

Box 2: Areas of focus for counselling

Contemplating PrEP focuses on

- Raising awareness of PrEP
- To assist persons in determining whether PrEP is right for them.

Starting PrEP focuses on

- Dosing requirements for greatest protection.
- What to do if a dose is missed
- Common adherence strategies
- The importance of ongoing monitoring while on PrEP
- Side-effects and side-effects management
- How to safely discontinue and restart PrEP
- Sexual health protection strategies beyond PrEP
- Harm reduction for people who use drugs
- Comprehensive HIV prevention planning

Follow up on PrEP focuses on

- Current sexual health and/or drug use behaviours
- Intention to remain on PrEP
- Facilitators and barriers to PrEP use.
- Addressing adherence problems
- Challenges of disclosure to partner(s).

PRESCRIBING PREP

PrEP medicines

The following ARV combination regimens are recommended:

- **The Preferred Option**

This is a combination ARV regimen of ***Tenofovir disoproxilfumarate (TDF) 300 mg/ Emtricitabine (FTC) 200 mg PO daily.*** The evidence shows that TDF-FTC is safe and effective for MSM, trans women, trans men and heterosexual men and women.(WHO July 2017).

- **The Alternative Option**

This is a combination ARV regimen of **Tenofovir disoproxilfumarate (TDF) 300 mg/ Lamivudine (3TC) 300 mg PO daily**. The evidence shows that this is also safe and effective for MSM, trans women, trans men and heterosexual men and women.

- **Other Options**

As Guided by a WHO meta-analysis and the Partners PrEP trial found that single-agent Tenofovir disoproxilfumarate (TDF) 300mg PO daily was safe and effective for heterosexual men and women, and in people who inject drugs.(WHO July 2017)

PrEP can be prescribed as**Daily Oral PrEP and Event-Driven PrEP(ED-PrEP)**

- **Daily oral PrEP** is one pill of TDF 300mg /FTC 200mg combination every day, withfood, ideally at the same time of the day- see figure 3.

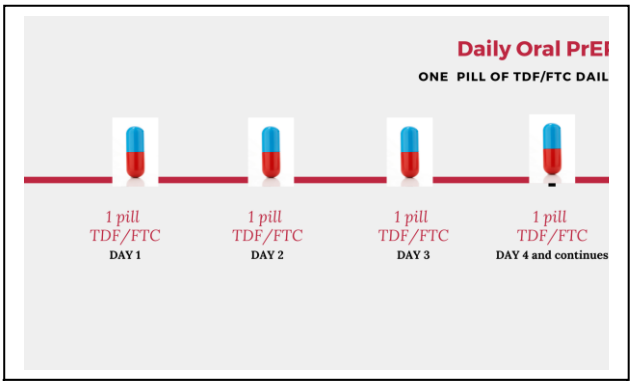


Figure 3: Daily Oral PrEP

Ifa patient does not take the pill on time, then it should be taken within the next 18 hours. Aligned with WHO recommendation providers should dispense at least 90 day supply of medicationthat when starting continuous PrEP or re-starting PrEP. This is to ensure that the person has adequate medication until the next visit. Most clinics would prescribe 90 days' supply and request the client to return for an earlier follow up to review adherence and tolerability of medication and laboratory testing for HIV.

- **Event-Driven PrEP** is indicated **ONLY** for men who have sex with men. ED-PrEP is highly effective in reducing the risk of HIV acquisition in this community. It also provides choice and convenience for MSM at high risk for HIV acquisition for a brief period or has sex less than two times per week. ED-PrEP is a good option for MSM who can anticipate, plan, or delay their sexual events. Pill burden is significantly lower in ED-PrEP that is cost-saving and better for adherence. ED-PrEP is recommended for MSM who find this approach effective, acceptable, and convenient and plans accordingly- see *Table 2.*

Table 2: Indications and contraindication of Event-Driven PrEP

ED-PrEP is recommended for	ED-PrEP NOT recommended for
Men who have sex with men (MSM): -Whom would find ED-PrEP more effective and convenient -Who has infrequent sex (example: less than two times per week on average). -Who can plan for sex at least two hours before in advance or who can delay sex for at least two hours?	-Cisgender women or transgender women -Transgender men having vaginal/ frontal sex -Men having vaginal or anal sex with women -People with chronic HBV infection

ED-PrEP is given as two pills of TDF/FTC as a loading doses 2 to 24 hours before unprotected sex, followed by a third (single) pill 24 hours after the loading dose and a fourth (single) pill 48 hours after the loading doses (2 + 1 + 1)- see figure 4.

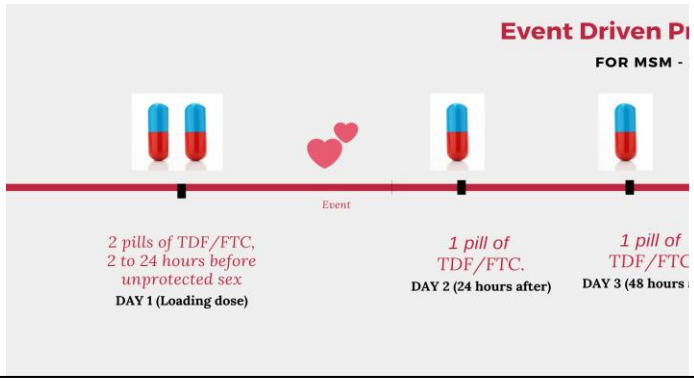
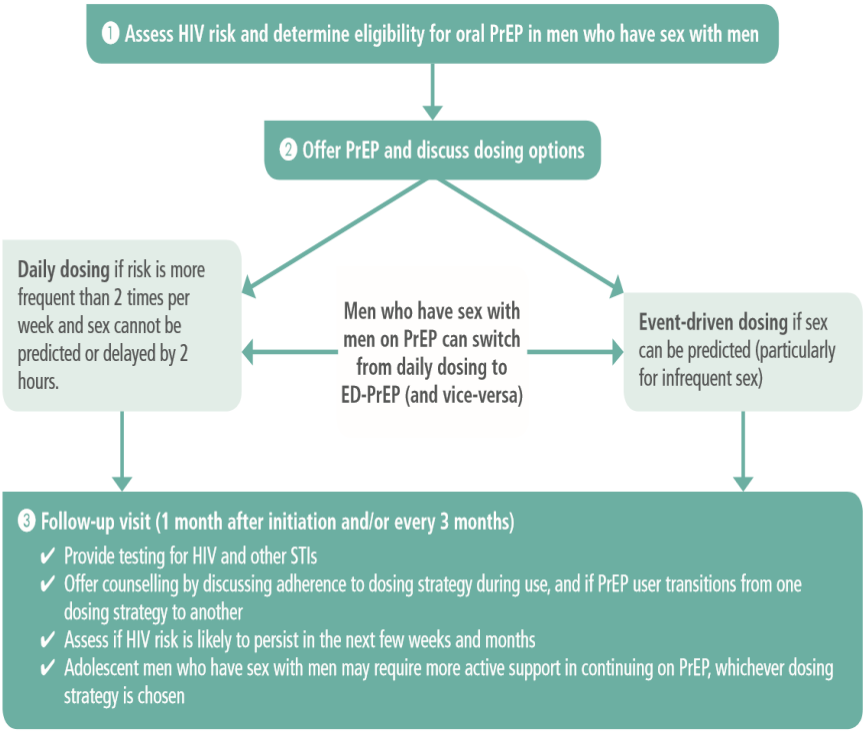


Figure 4: Event Driven PrEP

ED-PrEP should be adapted based on sexual exposures. In cases where ED-PrEP was initiated, and sexual exposure continued beyond the event, then one pill should be taken daily, followed by one pill per day for two days after the last sexual exposure. In cases where a new period of pill intake begins less than six days after the previous pill intake, the scheme is one pill before the event (lower loading dose) followed by one pill per day for the two following days. In cases where the last pill intake happened more than seven days ago, the regimen is repeated at 2+1+1. Depending on the circumstances, MSM can switch between ED-PrEP and Daily PrEP. See Figure 5.

Figure 5: Switching from Event-Driven PrEP to Oral Daily PrEP and vice versa for MSM. (World Health Organisation 2019)



The differences in the management between Daily Oral PrEP (heterosexual, MSM, Trans-women, Trans-men and Drug users) and Event-Driven PrEP (only for MSM) are presented in *Table 3.*

Table 3: Comparison of Daily Oral PrEP and Event-Driven PrEP (World Health Organisation 2019)

	Daily Oral PrEP	Event-Driven PrEP
For whom	Heterosexual, MSM, Tran women, Transmen and Drug users.	**Only** Men who have sex with men (MSM).
Efficacy	86%	86%
Medication	TDF-FTC	TDF-FTC
Prescribing method	Continuous	As needed
Initial Dose	One tablet per day	Two tablets on the first day

Time to effectiveness	Seven days	From 2 to 24 hours
Maintenance dose	One tablet per day	Post sex (one tablet at 24 hours) and the (second tablet at 48 hours).
Stopping PrEP	Continue taking one tablet for 28 days after last sexual exposure.	Continue taking one tablet for two days after last sexual exposure

SAFETY IN THE USE OF PREP MEDICATION

Renal function: The kidneys excrete Tenofovirdisoproxil and emtricitabine. The summary of product characteristics (SPC) recommends that creatinine clearance is calculated in all people before initiating therapy using TDF-FTC for HIV. It also recommends that renal function (creatinine clearance and serum phosphate) is monitored, after 2 to 4 weeks, after three months and every 3 to 6 months of tenofovir use in people without renal risk factors. The following is recommended:

- If someone has creatinine clearance <60ml/min, then PrEP should not be offered.
- If serum phosphate is <0.48 mmol/litre or creatinine clearance is decreased to <60ml/min in anyone receiving TDF-FTC for PrEP, renal function should be re-evaluated within a week, consideration should be given to stopping treatment.
- Concurrent or recent use of nephrotoxic medicines should be avoided, such as NSAID.

Hepatitis: The SPC for TDF-FTC states that people infected with HIV with chronic HBV or HVCtreated with antiretroviral therapy are at an increased risk for severe and potentially fatal hepatic adverse reactions. Emtricitabine and tenofovir individually and in combination have shown activity against HBV in pharmacodynamic studies, and discontinuation of TDF-FTC in people infected with the HBV may be associated with severe acute exacerbations of hepatitis. The SPC states that people with HBV who stop treatment with TDF-FTC should be closely monitored for several months. In people with advanced liver disease or cirrhosis, stopping treatment is not recommended because an exacerbation of hepatitis may lead to hepatic decompensation.

General tolerability: The SPC states that the most frequently reported adverse reactions considered possibly or probably related to treatment with emtricitabine or Tenofovir disoproxilfumarate are nausea (12%) and diarrhoea (7%). It also states that no new adverse

reactions were identified from the iPrEx and Partners PrEP studies, and the most frequent adverse reaction reported in the TDF-FTC group in the iPrEx study was headache (1%). In iPrEx and IPERGAY, there were increased rates of gastrointestinal events with TDF-FTC compared with placebo. In the Partners PrEP study, there were increased reports of gastrointestinal side effects and fatigue in the TDF-FTC group, mainly during the first month. In PROUD, 21/275 (8%) people in the immediate TDF-FTC group interrupted or missed doses because of adverse events (most commonly nausea, headache and arthralgia), but study drug was restarted in 20 of these people.

CLINICAL FOLLOW-UP AND MONITORING

The goal of clinical follow-up and monitoring is to:

- Determine whether to continue prescribing PrEP.
- Confirm HIV –negative status using a fourth-generation HIV antibody test or as recommended by the National Testing protocol.
- Assess risk behaviours and provision of risk reduction counselling and condoms.
- Assess STI symptoms and if, present, testing and treatment for STIs.
- Conduct follow up testing as per protocol- creatinine clearance should be checked at three months after initiation, and every six months.
- Conduct pregnancy test in women of reproductive age and trans-men at every visit, and if pregnant, there should be a discussion on the continued use of PrEP.
- Assess adherence and adverse events.
- Evaluate for medication adherence. If there is poor or non-adherence, establish the reasons and counsel and management accordingly.
- Monitor for side effects of TDF-FTC, depending on the type of side effects these should be managed accordingly.
- Consider bone mineral density (BMD) testing if the patient is expected to remain on TDF-FTC for more than a year and has predisposing factors for bone disease.

The schedule for follow up is summarised in Table 4.

Table 4: Follow-up interventions after PrEP initiation.

Intervention	Follow-up after PrEP initiation
HIV testing	Three monthly(consider a more frequent visit if adherence issues are anticipated).
Assessment for symptoms of AHI	Three monthly
STI screen	Three monthly
Hepatitis C (MSM, Trans women and those at risk for HCV)	Every 12 months
Serum Creatinine	Every six months (Use a shorter duration if the person has an underlying kidney pathology)
Urine Pregnancy test	If indicated
Address side effects	Three monthly
Provide adherence counselling	Three monthly

STOPPING PREP

Persons may choose to stop PrEP. To do so if the person is on continuous daily PrEP, then they should continue using a daily dose TDF-FTC for 28 days after last sexual exposure. For MSM who are on Event-Driven PrEP then used one tablet (TDF-FTC) at 24 hours after last sexual exposure, then another tablet (TDF-FTC) at 48 hours after last exposure.

The rationale for stopping PrEP includes:

1. Patient's request
2. Safety concerns
3. Medication non- adherence
4. Non-adherence to clinic follow-up
5. Concern for drug diversion (patient giving away the drug)
6. The patient becomes HIV positive. In this case, the patient should be immediately linked to care
7. The patient is no longer considered to be at high risk.

CONCLUSION (PREP)

Based on the National strategic plan of Guyana, HIVision 2025, it is the aim new HIV infections be reduced by 95%, and HIV/AIDS be eliminated by 2030. Hencethe choice of oral pre-exposure prophylaxis (PrEP) containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches.

During the expansion of this service, PrEP will therefore be available at all public facilities offering Care and Treatment services and its availability continues at the identified private Care and Treatment facilities, hence increasing theaccessibility of HIV prevention services.

NON OCCUPATIONAL POST EXPOSURE PROPHYLAXIS (NPEP)

Introduction

Since the early 1990s ARVs have been prescribed to persons occupationally exposed to HIV infection. Over the years, the provision of Post Exposure Prophylaxis (PEP) has been extended from only occupational exposure to non-occupational exposures, including sexual assault, unprotected sexual exposure, and injecting drug use. In 2007, the World Health Organisation (WHO) and International LabourOrganisation (ILO) issued PEP guidelines for occupational exposure and sexual assault based on expert opinion(World Health Organisation/ International Labour Organisation 2007). In 2013 new guidelines (World Health Organisation 2013) were published, which recommended changes in antiretrovirals (ARVs) regimens, and the harmonisation of prescribing practices. There have been subsequent updates in 2014 through a supplement (World Health Organisation 2014) and 2016 with the publication of new consolidated guidelines (World Health Organisation 2016).

Guyana's precautions guidelines and practices are actively promoted in all healthcare facilities. Infection control designees are identified to monitor and oversee universal precautions, PEP drug availability, and utilization. Evaluate the HIV status of the source patient, if possible, the source patient should have a rapid test done. If source cannot be tested or refuses testing, manage exposed person as if source was HIV-positive. The ARV regimen for PEP should be available 24 hours a day including nights and weekends at all healthcare facilities. In Guyana PEP kits are available at all private and public sector hospital emergency departments.The average risk of HIV transmission due to percutaneous Occupational Exposure (needle stick) injury is 0.3%, while the risk due to a mucocutaneous exposure is estimated at 0.09%.

Potentially infectious body fluids include blood, spinal fluid, pleural fluid, pus, and amniotic fluid. Urine, sweat, and faeces are not considered infectious unless visibly bloody. The risk of HIV transmission in a single sexual assault is comparable to the risk associated with occupational exposure. However, the risk may be higher if the assault caused physical trauma (a rape) or if the source or the exposed individual had genital ulcerative lesions at the time of the incident.Reporting of all suspected cases of sexual assault to the police is legallymandated.Offer post-coital contraception, STI prophylaxis and psychologicalcounselling.

In the Caribbean, very few countries have explicit PEP policies. Countries with policies have retained a traditional focus on occupational exposure and sexual assault. While occupational exposure does occur, it is often very rare. In keeping with the WHO 2013 guidance, there is a need to prioritized increased access to PEP for non-occupational exposure, such as unprotected sexual exposure and injecting drug use. These guidelines will focus on prophylaxis for non-occupational exposure.

Scope and purpose

These guidelines aim to provide evidence-based recommendations for the appropriate use of HIV post-exposure prophylaxis for non-occupational exposure (nPEP) to blood, genital secretions, or other potentially infectious body fluids that might contain human immunodeficiency virus (HIV). These guidelines aim to prevent HIV transmission by increasing the understanding of the risk of transmission, the timing of initiation of nPEP, appropriate ARV regimen use, drug interactions, and nPEP follow up.

These guidelines are in keeping with WHO evidence-based recommendations. Clinicians are the primary audiences and will use these guidelines to prescribe nPEP. Other clinical practitioners such as nurses, social workers and counsellors will use these guidelines to support the initiation and follow up nPEP through counselling for adherence to ARVs, monitoring and reporting of adverse effects and timely and adequate follow up while on nPEP. Other non-clinical stakeholders such as civil society community implementers will use these guidelines to conduct educational sessions for persons at high risk for HIV acquisition. These guidelines cover the management of adolescents and adults on nPEP and do not apply to the management of exposed children requiring HIV post-exposure prophylaxis.

Summary recommendations

The following summarizes key recommendations in the assessment for, initiation and followup of persons exposed to HIV. The nPEP is recommended as follows:

1. All individuals with the exposure that has the potential for HIV acquisition should be started on nPEP as soon as possible within 72 hours. ***nPEP is not recommended beyond 72 hours of exposure.***
2. Assessment for nPEP eligibility should be based on the HIV status of the source whenever possible and may include consideration of background prevalence and local epidemiological patterns.
3. Parenteral or mucous membrane exposures (sexual exposure, oral cavity) to bodily fluids including blood, blood-stained saliva, breast-milk, genital secretions and cerebrospinal, amniotic, rectal, peritoneal, synovial, pericardial or pleural fluids. May pose a risk of HIV infection and warrant post-exposure prophylaxis.

4. Before the initiation of nPEP, it is important to establish the HIV status of the exposed person using national HIV testing algorithms.
    - ***If the exposed person is tested HIV negative, then offer nPEP.*** A repeat HIV test should be done at 8-12 weeks after initiation of nPEP.
    - ***If the exposed person is tested, HIV positive, then nPEP is not recommended***. The exposed persons should be referred to an HIV treatment site for management.

5. Three ARV drugs are recommended from at least two classes for nPEP. The first recommended regimen is a combination of two NRTIs and one INSTI. TLD is a fixed-dose combination of **TDF 300 mg, 3TC 300 mg, and DTG 50 mg**
6. The second regimen comprises of two nucleoside reverse transcriptase inhibitors (NRTI) backbone, which is made up of **Efavirenz/Emtricitabine/Tenofovirdisoproxilfumarate 200mg/300mg/600mg**
7. nPEP should be given for 28 days. If a dose is missed beyond 48 hours, then nPEP should be discontinued.
8. Accurate medication history should be taken, including the use of over-the-counter medications before nPEP is prescribed.
9. The use of Tenofovir can result in nephrotoxicity and therefore, creatinine clearance should be checked at baseline and monitored during follow up to ensure that it is < 60ml/min. Tenofovir is contraindicated in patients with compromised renal function.
10. All exposed persons starting nPEP should be counselled on adherence to ARVs and HIV risk reduction strategies.
11. All exposed person should be tested for HBV and HCV using national testing algorithms.
    - For persons testing positive, Tenofovir can be used to treat HBV however stopping tenofovir can result in hepatic flares that will require adequate management
    - For persons testing negative, Hepatitis B vaccine should be offered to those at substantial risk.
12. All exposed persons should be screened for sexually transmitted infections such as Chlamydia, Gonorrhoea and Syphilis. It any of these are positive; then the patient should be treated accordingly.

DEFINITION OF PEP

The WHO defines post-exposure prophylaxis as"the medical response given to prevent the transmission of blood-borne pathogens following potential exposure to HIV."(World Health Organisation/ International Labour Organisation 2007).
There are two types of PEP, these are:

- **Occupational post-exposure prophylaxis (oPEP**) which refers to PEP given to healthcare workers for percutaneous or mucous membrane exposures sustained in the practice of their professions.(John G Bartlett 2019)
- **Non-occupational post-exposure prophylaxis (nPEP)** refers to PEP given to persons exposed through sexual encounters (consensual and non-consensual) and shared needles. (John G Bartlett 2019)These guidelines will focus on nPEP.

Eligibility of nPEP

nPEP is recommended for anyone at substantial risk for HIV acquisition. Substantial risk, based on the following:

- Exposure of:vagina, rectum, eye, mouth or other mucous membranes, non-intact skin, or percutaneous needle stick injuries
- Exposure with: bodily fluids such as blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid visibly contaminated with blood
- From: source likely to be HIV infected
- Time from exposure: should be less than 72 hours.

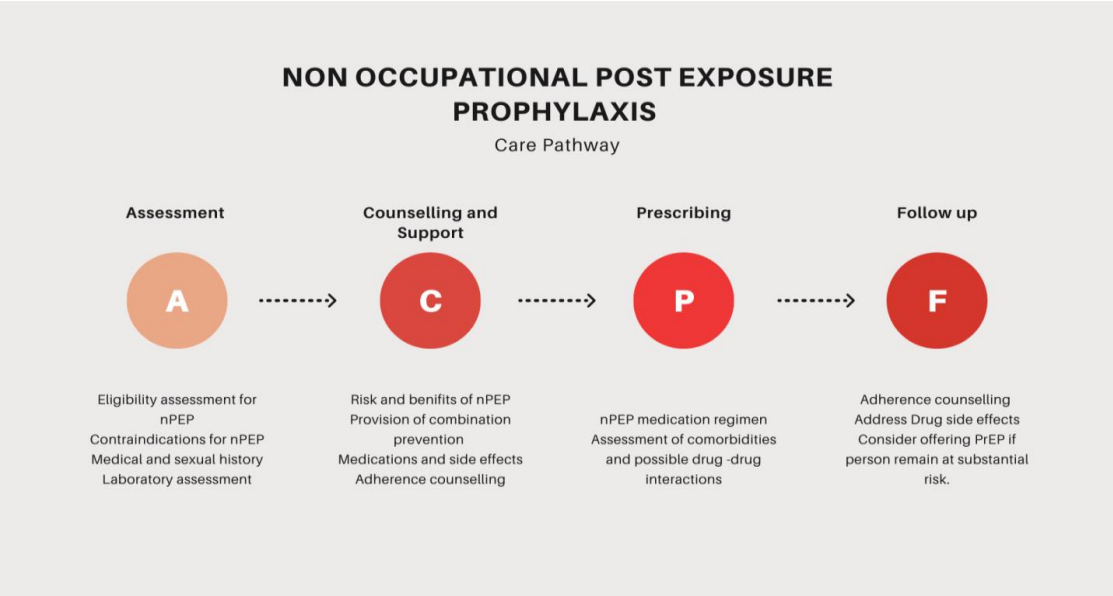
nPEP is NOT recommended in the following situations:

- The exposed individual is HIV positive. In these cases, the persons should be referred to HIV treatment services
- The source is established to be HIV negative and without any clinical signs of seroconversion
- Time from exposure is greater than 72 hours
- Exposure to bodily fluids that do not pose a significant risk: tears, non-blood-stained saliva, nasal secretions, urine and sweat.

CARE PATHWAY FOR PERSONS USING NPEP

The pathway of care for persons using nPEP can be divided into assessment, counselling and support, prescription and follow up. See Figure 6 below:

Figure 6: Care pathway for persons on nPEP



1. Assessment of nPEP

The baseline assessment should be conducted as early as possible for any person who has been exposed and at risk for HIV acquisition to determined eligibility for nPEP. A systematic approach outlined in figure 7 is recommended, and the initial assessment should address the following areas:

1. The HIV status of the exposed person.
2. The HIV status of the source person.
3. Determination of risk-related exposure.
4. Time of Exposure

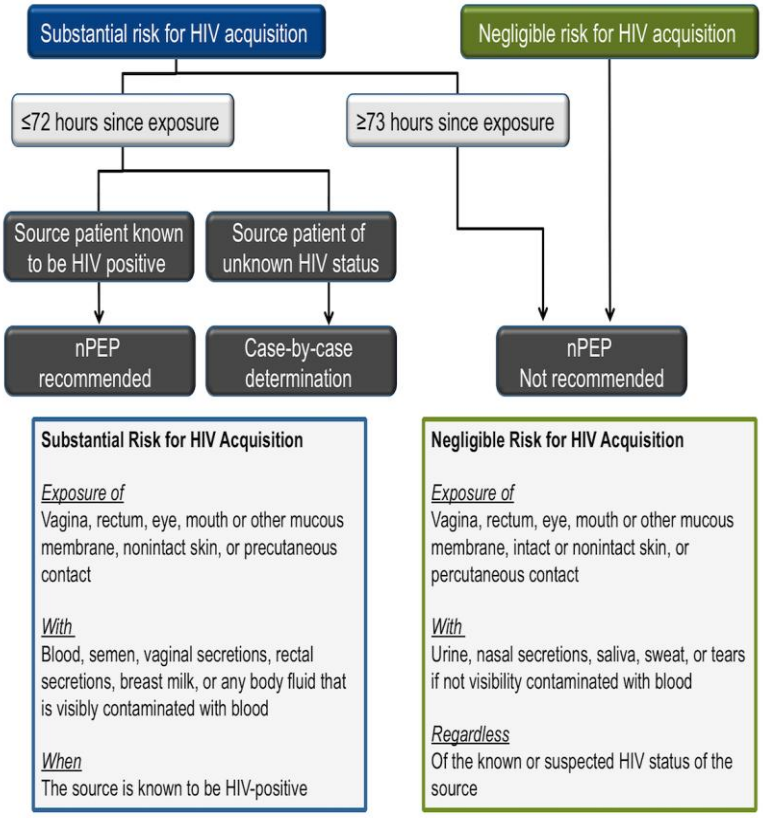


Figure 6: Algorithm to determine eligibility for nPEP (Taken from CDC)

The HIV status of the exposed person

The first step in evaluating eligibility is to determine the HIV status of the person seeking medical care. The person should be assessed using the national HIV testing protocol. Usually, an HIV Ag/Ab test is used. If this is not available, then use a rapid HIV Ab test. If no rapid test is available, do not delay initiation of PEP while waiting for baseline HIV test results. If the person is at "substantial risk", then nPEP is recommended.

If the exposed person is tested positive for HIV at baseline, then nPEP is not recommended. Instead, the person should be linked to HIV care, and baseline HIV related laboratory tests obtained according to the National Treatment Guidelines.

The HIV status of the source person

It is important to determine the HIV status of the source. This determines the need for nPEP. In this regard, the following is recommended:

1. Test the source person for HIV national HIV testing algorithms.
    a) ***If the source person is tested positive for HIV or is known to be HIV positive*** attempts should be made to check their CD4 count, Viral Load, ART regimen and adherence to guiding the assessment of transmission risk. In relation to the assessment of transmission risk, the following should be considered:
        - If the source person has a documented suppressed VL and 100% adherence to medication regimen, then they should be considered to be non-infectious. In keeping with Treatment as Prevention (TasP) data of undetectable = untransmittable, then PEP should not be given to the exposed person.
        - If the source person is on ARV medication but not virally suppressed, then nPEP is recommended.

    b) ***If the source person is tested negative for HIV,*** and there is no clinical reason to suspect acute HIV, then nPEP should not be offered to the exposed person. If the exposed person is already on PEP, this should be discontinued.
2. If the source person is unavailable, then an assumption on the HIV status can be made using local prevalence, and a case by case determination is made whether to offer nPEP.
3. Test the source person for other infection including tests for HBV(HBV surface Ab, HBV core Ab, HBV surface Ag) and HCV (HCVAb) and refer for treatment if any of these are tested positive.

Risk of Transmission is calculated as follows:

1. Risk of HIV transmission = risk that the source is HIV positive x risk per exposure.
2. If the transmission risk is greater than 1 in 1000 – then PEP is indicated.
3. If the transmission risk is between 1 in 1000 and 1 in 10,000 – PEP may be considered.
4. If the transmission risk is less than 1 in 10,000 is not recommended. (BASHH 2015).

Determination of Risk-Related Exposure

It is important to determine whether the exposure confers an actual risk for HIV transmission. The probability of transmission of HIV or risk of an acquisition depends on the exposure characteristics, the infectivity of the source and the host susceptibility.

Risk of HIV acquisition is categorized as substantial risk and negligible risk of HIV acquisition. A substantial risk of HIV acquisition is defined as contact involving an area of the body associated with HIV acquisition (vagina, rectum, eye, mouth or other mucous membranes, non-intact skin, or percutaneous needle stick injuries) with an infectious body fluid (e.g. blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid visibly contaminated with blood). The risk of transmission also depends on the type of sexual

exposure whether protected or unprotected (anal insertive/receptive, vaginal or oral sex) and whether there is mucosal disruption in either the source person or the exposed person (as might occur in traumatic sex including sexual assault, or the presence of ulcerative genital disease) increases risk of sexual HIV transmission). Using these criteria, table 5 summaries the difference between substantial and negligible risk and table 6 establishes the risk of HIV transmission with a single exposure from an HIV infected source. (John G Bartlett 2019).

Table 5: Substantial vsNegligible Risk

Criteria	Substantial Risk	Negligible Risk
Exposure of	Vagina, rectum, eye, mouth, mucous membrane, non-intact skin or percutaneous contact	Vagina, rectum, eye, mouth, mucous membrane, intact or non-intact skin or percutaneous contact
Exposure with	Blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated by blood.	Urine, nasal secretions, sweat or tears if not visibly contaminated with blood
The HIV status of the source	HIV positive	Regardless of the known or suspected HIV status of the source

Table 6: Risk of HIV transmission from a single exposure from an HIV infected source

Exposure	Risk			
	Without male condom or ART use	With make condom	With ART use	With a male condom and ART use
Blood transfusion	90%	-	-	-
Receptive anal intercourse	1.38%	0.28%	0.06%	0.011%
Needle sharing IDU	0.63%	-	-	-
Needle stick injury	0.23%	-	-	-
Insertive anal intercourse	0.11%	0.0	0.0	0.0

		2%	04%	009%
Receptive vaginal intercourse	0.08%	0.016%	0.032%	0.006%
Insertive vaginal intercourse	0.04%	0.008%	0.016%	0.003%
Receptive oral intercourse	Low	-	-	-
Insertive oral intercourse	Low	-	-	-
Mucous membrane exposure	0.09%	-	-	-
Intact skin	Negligible	-	-	-
Biting, spitting, throwing body fluids, sharing sex toys	Negligible	-	-	-

Time of the exposure

It is crucial to determine when the exposure occurred in persons seeking care. nPEP should be considered if the exposure occurred within the last 72 hours. If exposure occurred, more than 72 hours, nPEP is not effective and not recommended.

Laboratory Investigations

In addition to the initial assessments, the following baseline laboratory tests are recommended for the exposed individual. See Table 7 for further details.

Table 7: Baseline investigation for nPEP

Baseline Investigations	Rationale
Laboratory tests for all persons considering nPEP	
HIV Ag/Ab test	To determine the HIV status of the exposed person and where possible the source person. Tests preferably should be HIV Ag/Ab, if not available, then use HIV Ab test. Testing should follow national testing protocol. See annex 3.
Hepatitis B surface +core Ab, and surface Ag).	If negative consider vaccination, if positive, be cautious in the use of tenofovir (TDF) as can result in "hepatic flares" if discontinued suddenly.
Hepatitis C antibody.	If positive, consider treatment.

Additional tests for persons exposed sexually	
Screening for Treponemapallidum (rapid plasma regain)	If syphilis is diagnosed and treat and retest six months after treatment.
Screen for chlamydia trachomatis and Neisseria gonorrhoea	If positive, treat and retest in three months.
Additional tests for persons starting nPEP	
Serum creatinine	This is used to identify pre-existing renal diseases. The PEP backbone TDF/FTC is contraindicated if creatinine clearance is less than 60ml/min.
Hepatic aminotransferase levels	If abnormal, then choose an optimal ARV? Regimen that does not compromise liver functions.
Pregnancy status (women of reproductive age)	All women of childbearing age should be offered pregnancy testing. Repeat test at 4 to 6 weeks. Emergency contraception should be offered as soon as possible and within five days following sexual exposure.

Counselling Patient taking nPEP

All exposed persons seeking nPEP should be counselled before and at the initiation.

Counselling before nPEP initiation should address the following:

- Risk of transmission based on specific exposure sustained
- Basics of nPEP including its efficacy in preventing HIV infection
- The importance of a baseline and follow up HIV test at 8-12 weeks
- Importance of the follow up clinical visits including a repeat HIV test at 8-12 weeks
- The symptoms of the acute retroviral syndrome and how to prevent transmission, if HIV seroconversion occurs
- Risk reduction strategies and the use of combination prevention

Counselling while on nPEP should be conducted at follow up visits and address the following:

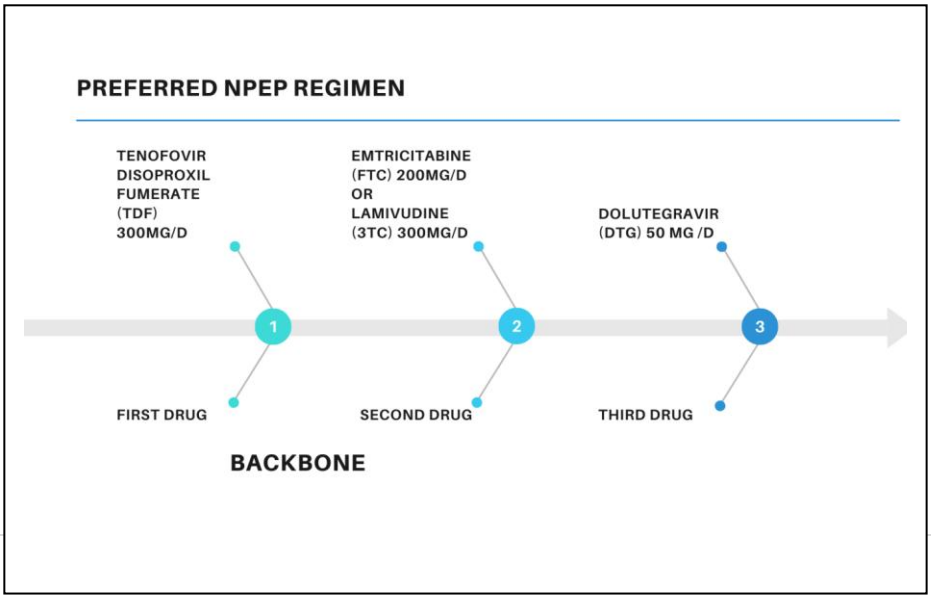
- The importance of adhering to the full 28 days course of treatment
- Common side effects and when to seek emergency care
- Possible drug interactions
- Importance of follow up evaluations while taking nPEP.

PRESCRIBING NPEP

What medication to use and how to use it

If a patient decides to take nPEP, their medical history, current medication and creatinine clearance, HBV status and pregnancy status should be taken into account when selecting the ARV regimen. Pill burden, tolerability, drug to drug interactions should be considered when selecting ARVs for nPEP. As indicted by the WHO conditional recommendation with low certainty evidence "an HIV post-exposure prophylaxis regimen with two drugs is effective, but three drugs are preferred. (World Health Organisation 2015) Also, in keeping with the WHO recommendation with low certainty evidence for adults and adolescents that TDF+3TC (or FTC) is recommended as the preferred backbone regimen for HIV post-exposure prophylaxis(WHO 2018). And with low certainty evidence that Dolutegravir (DTG) is recommended as the third preferred drug for HIV post-exposure prophylaxis(WHO 2018) See ***Figure 7*** below.

Figure 7: Recommended preferred nPEP regimen



Further conditional recommendations with low certainty evidence were guided by WHO that when available Atazanavir/ritonavir (ATV/r) – 300mg +100mg once daily or Darunavir/ritonavir (DRV/r) – 800mg +100mg daily or 600mg +100mg twice daily, or Lopinavir/ ritonavir 400mg/100mg twice daily or 800mg/200mg once daily or Raltegravir (RAL) – 400mg twice daily (WHO 2018)These are outlined in table 8.

Table 8: Alternate regimens for nPEP

First Drug	Second Drug	Third Drug
Preferred regimens for the second drug, either Lamivudine or Emtricitabine.		
TenofovirDisoproxilFumarate (TDF) 300mg once daily	Lamivudine (3TC) 300mg once daily	Dolutegravir (DTG) 50mg/daily
	Emtricitabine (FTC)200mgs once daily	
Alternative regimens (Dolutegravir (DTG)50mg is substituted for one of the ARVs listed below)		
		Atazanavir/ Ritonvir (ATV/r)300mgs/100mgs once daily
		Darunavir/Ritonavir (DRV/r)800mgs/100mgs once daily or 600mgs/100mgs twice daily
		Lopinavir/ Ritonavir (LPV/r) 800mgs/ 200mgs once daily or 400mgs/100mgs twice daily
		Raltegravir (RAL) 400mgs twice daily

Duration of medication

After potential exposure, nPEPis prescribed as a course for 28 days.

Discontinuation or missed doses nPEP

Persons must take their medication. Missed doses can lower the concentration of the drug and make it ineffective against HIV. Depending on the regimen being used, the drugs might have a different half-life. Discussion to continue or stop nPEP will rely on the biological and

pharmacological rationale. Table 10 below guides how to approach missed doses of ARVs based on the time elapsed since the last dose.

Table 10: Discontinuation of nPEP

Scenarios	Recommendation	Comments
Scenario1:<24 hours elapsed since the last dose.	Take missed doses immediately, and subsequent doses at the usual time.	Reinforce the importance of adherence and reevaluate motivation to continue nPEP.
Scenario 2: 24-48 hours have elapsed since the last dose.	Continue nPEP	Reinforce the importance of adherence and reevaluate motivation to continue nPEP.
Scenario 3:>48 hours since the last dose	Recommend stopping nPEP.	

Side effects of ARVS used form PEP

Antiretroviral medication used fornPEP may have various side effects, but many can be mild that will require symptomatic management. Some ARVs can have significant can will adequate management, including substituting with another ARV. It is important, for side effects and drug toxicity, particularly in cases of severe or life-threatening toxicity or hypersensitivity. Table 11 outlines the common toxicities and suggested management. It is also important, as part of the counselling, to educate patients on the possible side effects and the need to return to the clinic if necessary for urgent follow up.

Table 11: ARV Toxicities and suggested management

ARV Drug	Major types of toxicity	Suggested management
AZT	Severe anaemia, neutropenia	Substitute with TDF or another appropriate ARV

DTG	Hepatotoxicity Hypersensitivity reactions	Substitute with another therapeutic class (EFV or boosted PIs)
ARV/r	Hepatotoxicity	Substitute with ATV/r or LPV/r.
	Severe skin and hypersensitivity reactions	Substitute with another therapeutic class
EFV	Persistent central nervous system toxicity (such as dizziness, insomnia, abnormal dreams) or mental symptoms (anxiety, depression, mental confusion) Hepatotoxicity	Substitute with another class such as integrase inhibitor (DTG).
LPV/r	Electrocardiographic abnormalities (PR and QRS interval prolongation, torsades de pointes)	Use with caution in people with pre-existing conduction disease or those on concomitant drugs that may prolong the PR or QRS intervals
	Diarrhoea	Substitute with ATV/r, DRV/r or integrase inhibitors.
RAL	Rhabdomyolysis, myopathy, myalgia Hepatitis and hepatic failure Severe skin rash and hypersensitivity reaction	Substitute with another therapeutic class (etravirine, boosted PIs).
TDF	Acute kidney injury and Fanconi syndrome	Substitute with AZT. Do not initiate TDF at creatinine clearance <60 mL/min, uncontrolled hypertension, untreated diabetes, or presence of renal failure.

FOLLOW-UP AND MONITORING

The following laboratory testing, outlined in table 12, is recommended before starting nPEP. This is to ensure that there are no contraindications for starting nPEP.

Table 12: Laboratory testing for nPEP

Tests	Baseline	Repeat	Rationale
HIV	Yes	At three months post-exposure	Yes. Testing beyond three months are only recommended: -if the person has ongoing risk behaviour -can identify a specific incidence of HIV exposure in the past three months -are pregnant and residing in a generalised HIV epidemic setting. -have an indeterminate HIV status. -if a person is confirmed as positive, then they should be linked to care.
Hepatitis B (if no history of vaccination)	Yes	No	Yes (only if not immune)
STI testing (Chlamydia, gonorrhea and syphilis).	Yes	At 14 days	
Creatinine	Yes	Only if abnormalities at baseline.	
Alanine Transaminase (ALT)	Yes	Only if abnormalities at baseline. Hepatitis B/C coinfected or on Kaletra.	

PREVENTION STRATEGY

Persons who present for nPEP following sexual or injection drug use exposure may be excellent candidates for PrEP. It is recommended that persons receiving a 28 days course of nPEP should be evaluated for transitioning to PrEP in the following scenarios

- They have repeatedly sought nPEP.
- They engage in behaviours that result in frequent, recurrent to HIV exposures that require frequent use of nPEP.

Persons meeting one or both of the above criteria can transition to PrEP after completing the 28-day course of nPEP. Before transitioning from nPEP to PrEP, it is essential to ensure that the person remains HIV negative- See section 1 of these guidelines in PrEP.

SPECIAL CONSIDERATIONS

Pregnancy

Pregnancy is not a contraindication for nPEP. The recommended regimen for nPEP is usually safe in pregnancy. See table 11 above on side effects of ARVs.

Dolutegravir – has been associated with potential neural tube birth defects in infants born to mothers who received dolutegravir during pregnancy. PEP providers should, therefore, avoid the use of dolutegravir in pregnant women, especially in the first trimester as the risk of developing neural a tube defect from dolutegravir use occurs during the first 28 days of pregnancy.

Efavirenz- is classified as a Category D drug by the FDA.A is category D when there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant the use of the drug in pregnant women despite potential risks. Efavirenz, due to its risk of potential teratogenicity, should be avoided during the first trimester of pregnancy or in women with childbearing potential.

Darunavir plus Ritonavir – this combination causes significant drug interactions with oral contraceptives

Nevirapine (NVP) – is not recommended for nPEP due to hepatotoxicity if CD4 > 250 cells/mm^3 in women and >400 cells/mm^3 in men (which is expected in HIV negative people).

Flulike symptoms during or after PEP-Persons experiencing skin rash or flulike symptoms while or after taking nPEP should be advised to return to the clinic for an urgent review to exclude an HIV seroconversion.

CONCLUSION ON PREP AND NPEP

PrEP and PEP are highly effective biochemical methods for preventing HIV acquisition. The key differences are summarized in table 13. These methods must be used as part of combination prevention (condoms and lubes, STI screening and management, HIV testing and counselling, risk reduction and harm reduction) and in the context of comprehensive support.

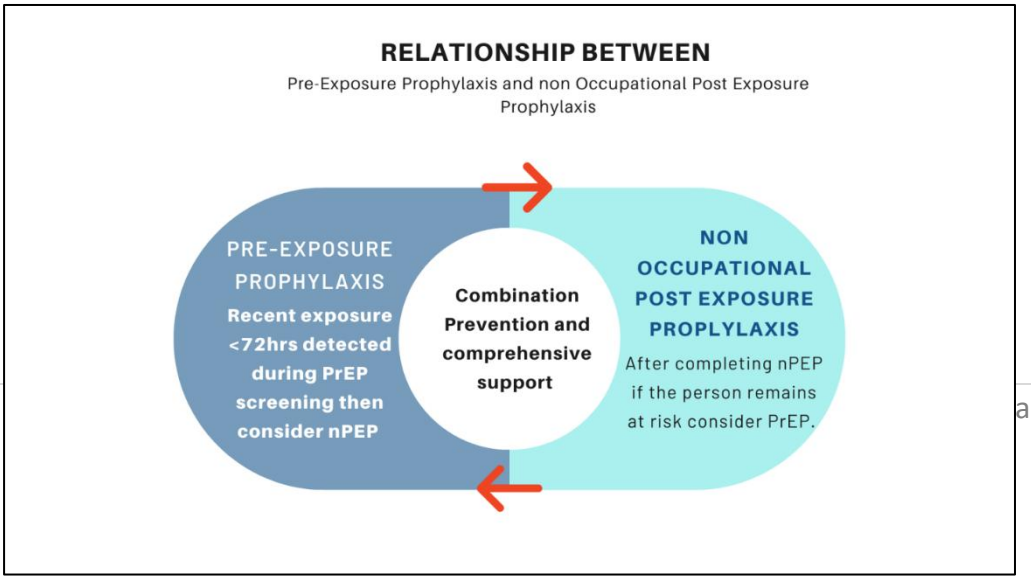
Table 13: Comparing PrEP and PEP

	PrEP	nPEP
Time to use	Before exposure to HIV. The person must be HIV negative.	After exposure to HIV. nPEP should be started as soon as possible after exposure and should not exceed 72 hours. If it exceeds 72 hours, then nPEP is not recommended.
Treatment	The once-daily pill of TDF-FTC or TDF+3TC.	The prefered regimen is TDF+FTC+ DTG or TDF+3TC+DTG once daily.
Duration of treatment	Continue as long as the person remains at substantial risk for HIV infection.	The course of treatment is for 28 days. Consider recommending PrEP if the person remains at substantial risk.

The relationship betweenPrEP and nPEP is illustrated in figure 8 and can be described as two-fold and bidirectional:

- If someone was recently exposed to HIV infection and is screened within 72 hours, then nPEP is required.
- If someone has been on nPEP within the past six months and continues to be at substantial risk for HIV infection, then PrEP should be considered.

Figure 8: Relationship between PrEP and nPEP



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Guyana Sexual and Reproductive Health Policy; Ministry of Health 2019.

Guyana Biological and Behavioural Surveillance Survey, 217

ANNEX 1: CHECK LIST FORCOUNSELLING OF CLIENTS

Let's talk about your sexual health for Sexual behavior

1. Counselling

What has been going on for you sexually in the past couple of months?

How much of the time did you use condoms?

Always ☐
Sometimes ☐
Never ☐

What has made it easier to use condoms during sex?

What has made it more difficult?

What concerns do you have about your sexual activities?

How might taking PrEP impact your sexual activity?

2. Drug use

Did you use any drug in the last 12 months? **Yes** ☐ ☐ **No**
If yes, which drug (alcohol as well as opioids, stimulants, cannabis, etc.)?
_____

And how did you use it (smoking, orally, injecting)? _____

When did you last use drugs (specify which substances)?_____

How often do you use drugs (once a year, month, week, day or more frequent)?

Has your drug use ever been a problem for you? **Yes** ☐ ☐ **No**

Note: referral to drug services may be appropriate if locally available

Do you think it may put you at risk of becoming infected or transmitting HIV? ☐ **Yes** ☐ **No**

3. Plan(s) for staying HIV- and STI-negative

You are reducing your risk for HIV by deciding to take PrEP. Let's talk about how PrEP fits into your risk reduction efforts. [Note should be made that PrEP will reduce the risk of acquiring HIV, but it will NOT reduce the risk of acquiring other STIs.

What other ideas/plans, if any, do you have for staying HIV/STI-negative?

Expected HIV testing and results? **Negative** ☐ **Positive** ☐

[After negative results are given:]

What are your thoughts and feelings about your negative test result?

How does this negative test result impact your plans or efforts to remain HIV-negative?

[After positive results are given, provide post-test counselling and linkage to treatment.

Do you have any experience with taking a daily medicine? **Yes** ☐ **No** ☐

What is your experience with taking daily medicine?

Are you currently taking daily medicines on a long-term basis? **Yes** ☐ **No** ☐

What helps you remember to take your pills? _____

What is your plan for taking PrEP daily? _____

What will you do about taking your pill if you are away from home for a night or two?

What will you do if you miss a dose of your PrEP pill?

What is your understanding of possible PrEP side-effects? How will you cope with side-effects if you have them?

4. Sexual health and what it has been like taking PrEP since your last visit

Pill-taking experience

How has it been for you to take PrEP?

_____

What side-effects have you had, if any?

_____

What challenges do you experience in taking the pills? When are you more likely to forget?

What have been your experiences with missing PrEP doses?

What helps or might help you to take your pills regularly? Helpful strategies may include:

☐ using a pillbox ☐ taking PrEP pills with other daily medicines

☐ using a phone alarm ☐ marking doses taken on a calendar

☐ having more support from your partner, a family member or a friend

☐ keeping the bottle in a visible location associated with daily activity such as brushing teeth or watching a daily TV programme

What keeps you motivated to take the PrEP pills?

_____

Have you discussed your PrEP use with others? ☐ **Yes** ☐ **No**

Why or why not? _____

With whom have you discussed it? _____

Since your last visit have you had any social experiences, positive or negative, that you think are related to taking PrEP? ☐ **Yes** ☐ **No**

5. Behaviour and activity

What has been going on for you sexually since your last visit?

How has PrEP changed your social and sexual goals?

What are your thoughts about condoms?

What about sexual partners: Are you having different kinds of conversations with sexual partners?

Have you increased or decreased the number of sexual acts and/or the number of partners?

Has taking PrEP changed what else you do to protect yourself from getting HIV and STIs

topping versus bottoming ☐ cond…use

discussing HIV and STI status and/or testing with partner… ☐

Has PrEP made you feel safer about sex? **Y…** ☐ ☐ **No**

Has PrEP made it easier for you to take charge of your health? ☐ **…** ☐

No

In addition to taking PrEP, what are your plans to stay HIV-negative?

[1] The PrEP forms were adapted for Guyana from those shared by the Ministry of Health and Wellness Barbados.

Annex 2: List of medications that interact with PrEP

This is a summary of key long-term use medications to be avoided or used with caution with **tenofovir-DF/emtricitabine (TDF/FTC)** when used as PrEP. Full details and interactions with additional comedications can be found at www.hiv-druginteractions.org .

	TDF/FTC	Comment
Analgesics		
Aspirin	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Celecoxib	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Diclofenac	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Ibuprofen	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Mefenamic acid	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Naproxen	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Nimesulide	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Piroxicam	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Antiarrhythmics		
Amiodarone	Caution	Increased TDF absorption. Monitor for TDF side effects.
Quinidine	Caution	Increased TDF absorption. Monitor for TDF side effects.
Anticonvulsants		
Topiramate	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Antidepressants		
Lithium	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Antidiabetic		
Empagliflozin	Avoid	Risk of bone toxicity.
Antifungals		
Amphotericin B	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Flucytosine	Caution	Monitor haematological parameters
Itraconazole	Caution	Increased TDF absorption. Monitor for TDF side effects.
Ketoconazole	Caution	Increased TDF absorption. Monitor for TDF side effects.
Antiprotozoals		
Eflornithine	Caution	Monitor renal function.
Meglumine antimoniate	Caution	Monitor renal function.
Pentamidine	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Pyrimethamine	Caution	Monitor renal function.
Antivirals		
Aciclovir	Caution	Monitor renal function.
Adefovir	Contraindicated	Risk of tubular necrosis. Contraindicated.
Cidofovir	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Famciclovir	Caution	Monitor renal function.
Foscarnet	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Ganciclovir	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Valaciclovir	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Calcium Channel Blockers		
Verapamil	Caution	Increased TDF absorption. Monitor for TDF side effects.

KEY: Contraindicated Avoid Caution

	TDF/FTC	Comment
Cytotoxics		
Capecitabine	Caution	Monitor side effects of cytotoxic agent.
Carboplatin	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Cisplatin	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Dacarbazine	Caution	Monitor renal function and haematological parameters.
Ifosfamide	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Methotrexate	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Oxaliplatin	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Hepatitis C DAAs		
Ledipasvir/Sofosbuvir	Caution	Increased TDF absorption. Monitor for TDF side effects.
Sofosbuvir/Velpatasvir	Caution	Increased TDF absorption. Monitor for TDF side effects.
Sofosbuvir/Velpatasvir/ Voxilaprevir	Caution	Increased TDF absorption. Monitor for TDF side effects.
Telaprevir	Caution	Increased TDF absorption. Monitor for TDF side effects.
Herbals/Supplements/Vitamins		
Cubeb pepper (Piper cubeba)	Caution	Increased TDF absorption. Monitor for TDF side effects.
Garlic	Avoid	Increased TDF absorption. Advise against use of supplements.
Liquorice (Glycyrrhiza glabra)	Caution	Increased TDF absorption. Monitor for TDF side effects.
Hypertension / Heart Failure Agents		
Furosemide	Caution	Monitor renal function.
Hydralazine	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Ranolazine	Caution	Increased TDF absorption. Monitor for TDF side effects.
Sacubitril	Caution	Monitor renal function.
Immune Modulators		
Hydroxyurea Hydroxycarbamide)	Avoid	Risk of pancreatitis and hepatitis.
Interferon alpha	Avoid	Risk of hepatic decompensation.
Interleukin 2 (Aldesleukin)	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Peginterferon alfa-2a	Avoid	Risk of hepatic decompensation.
Immunosuppressants		
Ciclosporin	Caution	Increased TDF absorption. Monitor for TDF side effects.
Mycophenolate	Caution	Monitor renal function.
Sirolimus	Caution	Monitor renal function.
Tacrolimus	Caution	Monitor renal function.
Lipid Lowering Agents		
Clofibrate	Caution	Monitor renal function.
Other		
Acetazolamide	Caution	Monitor renal function.
Penicillamine	Avoid	Risk of nephrotoxicity with TDF. Monitor renal function.
Probenecid	Caution	Monitor renal function.
Pyridostigmine	Caution	Monitor renal function.

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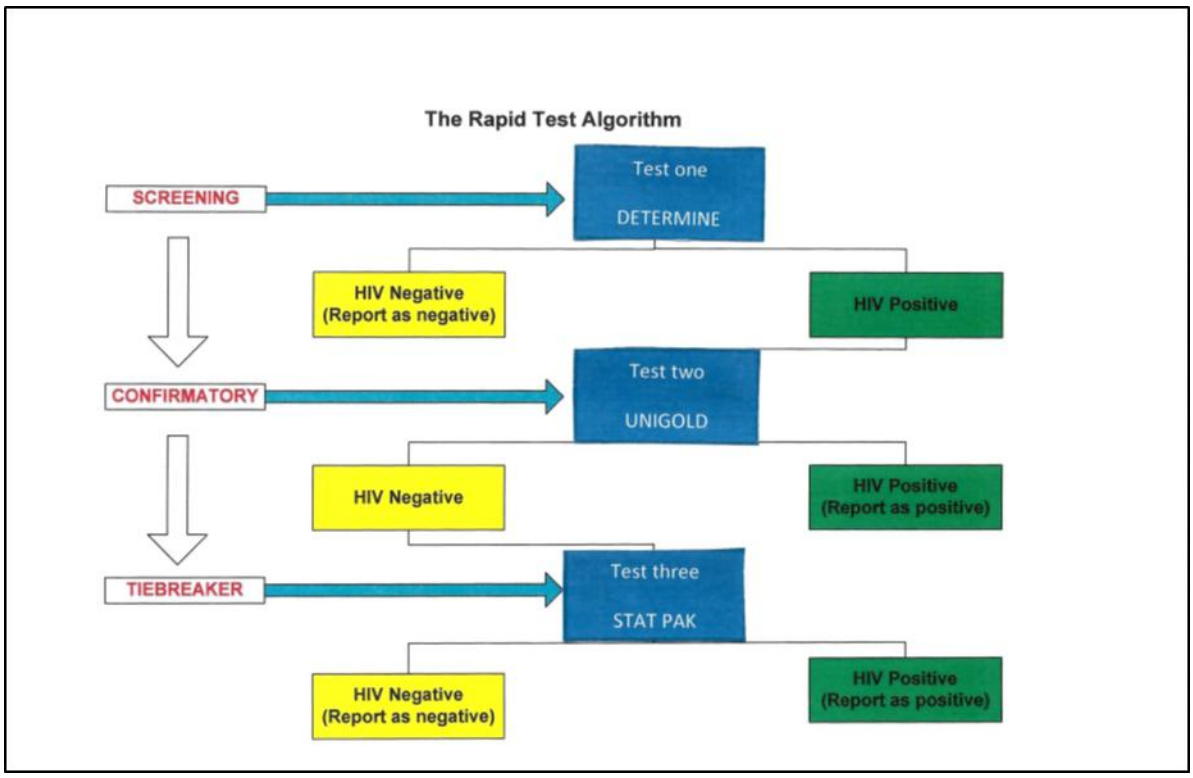
Annex 3: Guyana algorithm for HIV and syphilis test



This algorithm was adopted on August 28th,2015 by the Ministry of Health.

Annex 4: PrEP Clinic Follow-Up Form

Patient Name: _____ PrEP #: _____

Is this a scheduled/ follow-up visit? ☐ Yes☐No
If no, what is the reason for the unscheduled visit?
☐ Adverse Event ☐ Suspected Acute Viral Infection☐Seroconversion confirmation
☐ Prescription Refill ☐ STI

Clinical Review

STI symptoms	**Acute HIV infection**	**Side-effects of medication**
Blisters on vagina/penis	Fever	Nausea/vomiting
Blisters on anus	Lymphadenopathy	Bloating
Penile/vaginal discharge	Mouth sores/ulcers	Abdominal pain
Anal discharge	Myalgia	Dizziness
Rectal bleeding	Rash	Insomnia
Dysuria	Sore throat	Symptoms resolved

Other medication side-effects:
_____

Physical Exam: Overall appearance: Oriented in T/P/P:☐ Yes ☐ No
Appropriate mood/affect☐ Yes ☐ No

Drug and alcohol Use:

Sexual Practices						
In the past 3 months how many people did you have vaginal or anal sex with?						
☐0	☐1	☐ 2-4	☐5-9	☐10-20	☐>21	men
☐ 0	☐1	☐ 2-4	☐5-9	☐10-20	☐>21	women

Current number of partners: ……..

Condom use with regular partner: ☐ Always☐ Often ☐ Sometimes ☐ Rarely ☐ Never
Condom use with casual partner(s): ☐ Always ☐ Often ☐ Sometimes ☐ Rarely ☐ Never

Condom use changed since starting PrEP?

Medication Adherence

In the past 30 days, approximately how many tablets did you miss? ……..

Approximate number tablets missed prior to last 30 days? ……..

What was main reason for missing? ☐Forgot☐ Travel/away from home ☐Ran out of tablets ☐Adverse effects☐ Other

Follow-up investigations

	Tick if sample taken	Result		Tick if sample taken	Result
Rapid HIV			Syphilis		
Confirmatory HIV			Chlamydia		
U&Es/LFTs			Gonorrhea		
Hep B/C			HTLV 1+2		
Weight (kg)					
Estimated Creatinine Clearance (eCrCl) (Cockcroft-Gaultmethod):					

PLAN

Should or will the patient continue using PrEP?☐ Yes
☐ No, due to reactive HIV test ☐No, due to other abnormal test results ☐ No, due to poor adherence ☐ No, due to adverse events ☐ No, due to user decision
☐ Other:

Prescription & Follow-up:

Address side-effects and provide brief adherence counselling at **every visit.** Consider calculating eCrCl more frequently than q6 months if history of conditions affecting the kidney, ex. diabetes or hypertension; less frequently if age <45, baseline eCrCl> 90 ml/min, and weight more than 55 kg. Counsel on condom use, STI symptoms, mental health, intimate partner violence and substance use.

Additional Notes:

Healthcare provider: (Name) _____
(Signature) _____

Date: _____

[1] *The PrEP forms were adapted for Guyana from those shared by the Ministry of Health and Wellness Barbados.*

Annex 5: Record Form for PrEP Screening

Patient Name: _____ PrEP #: _____

PREP SCREENING			
What was your sex at birth?	Male	Female	Other
What is your current gender identity?	Male	Female	Other
What is your current age? years			
In the past 6 months:			
With how many people did you have vaginal or anal sex?	0 1 2* 3+* men 0 1 2* 3+* women		
Did you use a condom every time you had sex?	Yes	No*	Don't Know*
Did you have a sexually transmitted infection?	Yes*	No	Don't Know*
Do you have a sexual partner who has HIV?	Yes	No	Don't Know*
If "Yes," has he or she been on antiretroviral therapy for 6 or more months?	Yes	No*	Don't Know*
If "Yes," has the therapy suppressed viral load?	Yes	No*	Don't Know*
In the past 3 days:			
Have you had sex without a condom with someone with HIV who is not on treatment?	Yes**	No	Don't Know**
Have you had a "cold" or "flu" such as sore throat, fevers, sweats, swollen glands, mouth ulcers, headache or rash?	Yes***	No	Don't Know
Consider offering PrEP; **Consider offering PEP; ***Consider acute HIV.			

Healthcare provider: _____

Date: _____

[1] *The PrEP forms were adapted for Guyana from those shared by the Ministry of Health and Wellness Barbados.*

Annex 6: PROCEDURES WHEN INITIATING PREP (FIRST VISIT)

INVESTIGATION/ INTERVENTION	RATIONALE
HIV test	▪ To assess HIV infection status. ▪ If recent exposure (in the past 72 hours), consider PEP and re-test after 28 days. To complete a symptom checklist for possible acute HIV infection.
Serum creatinine	▪ To identify pre-existing renal disease (estimated creatinine clearance less than 60 ml/min).
Hepatitis B surface antigen	▪ If negative, consider vaccination against hepatitis B. If positive, suggest further testing and assessment for hepatitis B treatment.
Hepatitis C antibody	▪ Consider for MSM populations. If positive, refer for assessment and treatment.
Screening for Sexually Transmitted Infection (STIs)	▪ To diagnose and treat STIs (Syphilis, Chlamydia and Gonorrhea).
Pregnancy testing	▪ To guide antenatal care, contraceptive and safer conception counselling, and to assess risk of mother to child transmission. ▪ Pregnancy is not a contraindication for PrEP use.
Review vaccination history	▪ Depending on local guidelines, epidemiology and populations, consider vaccination for human papilloma virus.
Counselling	▪ To assess whether the client is at substantial risk of HIV. ▪ To discuss prevention needs and provide condoms and lubricants. ▪ To discuss desire for PrEP and willingness to take PrEP. ▪ To develop a plan for effective PrEP use, sexual and reproductive health. ▪ To assess fertility intentions and offer contraception or safer conception counselling. ▪ To assess intimate partner violence and gender-based violence. ▪ To assess substance use and mental health issues.

[1] *The PrEP forms were adapted for Guyana from those shared by the Ministry of Health and Wellness Barbados.*

Annex 7: PRE-EXPOSURE PROPHYLAXIS (PREP) CLIENT REGISTER

Adopted for MoH/NAPS based on WHO guidelines and recommendation

Facility PrEP Register
Year_____

	Date enrolled in HIV care (DD/MM/YY)				Fill when applicable									Laboratory Tests Results and date of test results (dd/mm/yyyy)						
	Day	Mo	Year	Clinic ID	First Name	Middle Name	Surname	Date of Birth (DD/MM/YY)	Age	Gender Identity	Population Status	Address	Contact Number(s)	Partner(s) Client Code	Initial HIV Test Result Stop date	Other STIs Screening Test Result Stop date	Other STIs Screening Test Result Stop date	Other STIs Screening Test Result Stop date	LFT Test Result Stop date	Creatinine Test Result Stop date	Other Labs (record type, resulst, date)
Key	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1																					
2																					
3																					
4																					

						Month 3					Month 6					Month 9					Month 12		
OPrEP Prescribed Start Date Regimen	OPrEP Stopped Reason Stop date	Patient Outcome	1	2	Regimen	HIV Result & Date	Side Effects	4	5	Regimen	HIV Result & Date	Side Effects	7	8	Regimen	HIV Result & Date	Side Effects	10	11	Regimen	HIV Result & Date	Side Effects
21	22	23	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44