Pre- and Post-Exposure Prophylaxis of HIV

Standard of Public Health Intervention Management

(Protocol)

2022

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The protocol was prepared by the LEPL L. Sakvarelidze National Center for Disease Control and Public Health.

The document was developed with the technical support of the United Nations Population Fund (UNFPA) and the Doctors of the World (France) representation in Georgia (MDM).

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1.1. Protocol Title

Pre- and Post-Exposure Prophylaxis of HIV

1.2. Protocol Development Methodology

The protocol was developed by the LEPL L. Sakvarelidze National Center for Disease Control and Public Health with technical support from the United Nations Population Fund (UNFPA).

The protocol was developed according to the Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV/AIDS.

The protocol is also based on the guidelines and recommendations of the US Centers for Disease Control and the World Health Organization.

Key sources:

1. Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV/AIDS, 2021

2. Preexposure Prophylaxis for the Prevention of HIV Infection in The United States – A Clinical Practice Guideline - USA; Centers for Disease Control and Prevention;

3. Preexposure Prophylaxis for the Prevention of HIV Infection in The United States - Clinical Providers' Supplement - USA; Centers for Disease Control and Prevention;

4. Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV - Recommendations for use in the context of demonstration projects - July 2012; - World Health Organization (WHO);

5. Guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV- USA; Centers for Disease Control and Prevention;

6. UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021;

7. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection - Recommendations for a public health approach - Second edition - June 2016; - World Health Organization (WHO);

8. World Health Organization. (2019). Technical brief: what's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP. (WHO)

During the development of the protocol, international recommendations were translated, coordinated and adapted. As a result, on the one hand, the protocol meets the international requirements, and on the other hand, takes into account the local context of Georgia.

1.3. Purpose of the Protocol

The purpose of the protocol is to define standard approaches for providing pre- and post-exposure prophylaxis services to high-risk populations in Georgia.

The goal of these interventions is the prevention of HIV infection in populations with particularly high-risk behaviors in Georgia.

1.4. Target Group

Pre-exposure prophylaxis (PrEP)

PrEP is recommended for any HIV-negative person who meets the substantial risk criteria, namely:

- Men who have sex with men (MSM) and transgender individuals who report anal intercourse (insertive or receptive) without a condom in the past 12 months, and any one additional factor:

A) Sexual intercourse with 2 or more partners;

B) Sexual intercourse with an HIV-positive partner who is not on ARV treatment (at least 1 case of detectable viral load in the past 12 months)

C) Diagnosis of a sexually transmitted infection;

D) Use of post-exposure prophylaxis;

E) Sexual activity under the influence of psychoactive substances (chemsex)

F) Use of post-exposure prophylaxis.

- Heterosexual men and women who report intercourse (vaginal or anal) without a condom with a person of the opposite sex in the past 12 months, and any one additional factor:

A) Sexual intercourse with 2 or more partners;

B) Sexual intercourse with an HIV-positive partner who is not on ARV treatment (at least 1 case of detectable viral load in the past 12 months)

C) Diagnosis of a sexually transmitted infection;

D) Use of post-exposure prophylaxis;

E) Sexual activity under the influence of psychoactive substances

- Injecting drug users who report sharing injecting equipment in the past 12 months, and/or are at sunstantial risk of HIV infection according to the criteria listed above.

Post-exposure prophylaxis (PEP)

Post-exposure prophylaxis (PEP) for HIV should be initiated for all exposed individuals who are at risk of contracting HIV.

1.5. Intended Audience of the Protocol

This protocol is intended for the following specialists, according to their professional competence:

- Doctor-infectionists/ HIV infection specialists;
- Epidemiologists;
- Social workers;
- Community and outreach workers;
- Nurses;
- Laboratory workers;
- Researchers;
- Public heath specialists;
- Decision and policy makers.

1.6. Terms of Applying the Protocol in Institutions

Recommendations of this protocol include the provision of pre- and post-exposure prophylaxis services, organized in a medical facility and/or community/non-governmental organization.

The protocol covers clinical/medical and social/support services.

The protocol is applied when the beneficiary contacts a preventive or medical facility, whether it is a non-governmental organization, a community organization or a state facility, which specializes in the prevention and treatment of HIV infection.

In the case of PrEP, the protocol is applied until it is required to do so for the beneficiary's needs, or until the beneficiary continues to engage in high-risk behaviour and agrees to receive the services.

In the case of PEP, the protocol continues to be applied after the completion of the 28-day course determined by the international recommendations and this protocol, and based on the assessment of beneficiary's individual needs, he or she is offered other HIV prevention services.

Chapter II. Description of the Interventions

2.1. Description of the Intervention – PrEP

Pre-exposure prophylaxis (PREP) is a method of HIV prevention in people at particularly high risk of HIV infection, using HIV/AIDS medications.

PrEP is prescribed to adults who are at high risk of contracting HIV infection, and regularly engage in high-risk sexual activity and other high-risk behaviour.

In particular, pre-exposure prophylaxis (PrEP) should be offered to individuals at substantial risk of HIV infection as an additional preventive measure within combination HIV prevention strategy.

Pre-exposure prophylaxis involves the use of tenofovir/emtricitabine (TDF/FTC. 300/200 mg) in one of two possible regimens:

1) **Daily** regimen - TDF/FTC 300/200 mg - one pill per day is recommended for all relevant populations, irrespective of gender, orientation, or risk behavior (strong recommendation, high-quality evidence)

2) **On-demand (event-driven)** regimen is recommended for men who have sex with men, using 2+1+1 dosing which means taking a total of 4 TDF/FTC 300/200 mg pills before and after the high-risk sexual intercourse (TDF/FTC 300/200mg - 2 pills 2-24 hours before the intercourse, 1 pill 24 hours after the initial dose, 1 pill 24 hours after the second dose, see Diagram 2) (strong recommendation, high-quality evidence).

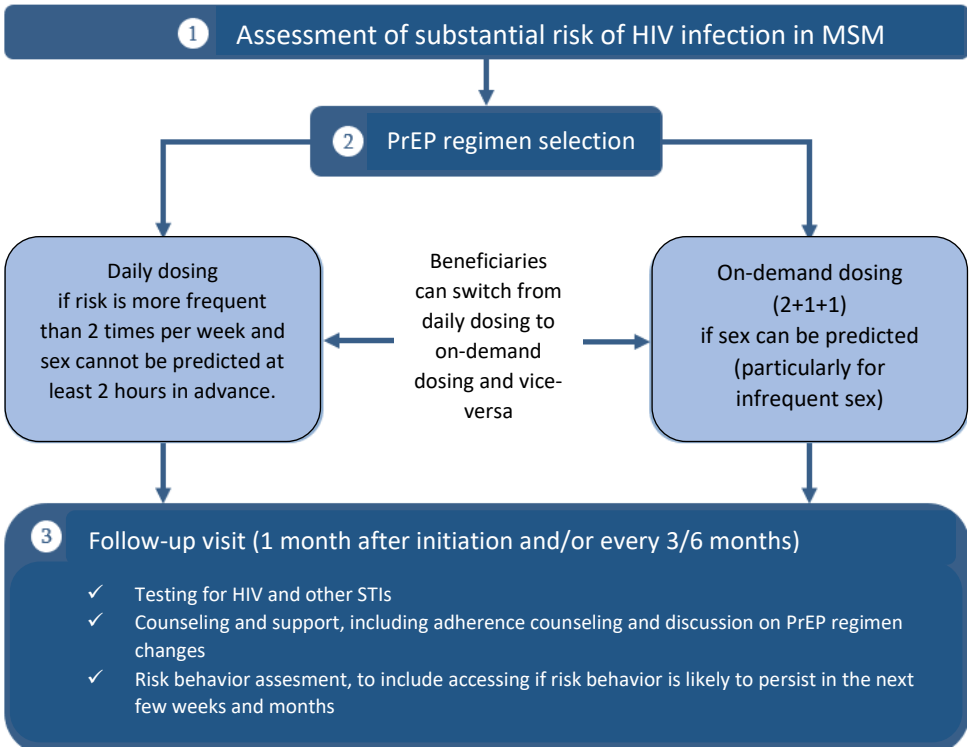
PrEP is prescribed to adults who are at substantial risk of HIV infection and do not use condoms regularly. HBV status must be known prior to PrEP initiation. In case of chronic HBV infection, on-demand PrEP regimen is contraindicated. Although chronic HBV infection is not a contraindication to daily PrEP regimen, prior to prescribing PrEP, consideration should be given to the need for continuous tenofovir treatment in case of PrEP termination. Before starting PrEP, it is advisable for a person with a chronic HBV infection to have a consultation with an appropriate specialist.

Evidence for the effectiveness of on-demand PrEP regimen is available only for men who have sex with men. Evidence is insufficient for other populations, particularly for transgender people, heterosexuals who engage in high-risk activities, and injecting drug users. Therefore, the above-mentioned regimen is recommended only for men who have sex with men; in all other populations daily PrEP regimen should be used.

In men who have sex with men, daily PrEP should be used by taking one TDF/FTC pill per day when sexual intercourse is frequent or cannot be planned in advance. PrEP can be discontinued in periods when the person does not engage in sexual activity. The frequency of intercourse depends on many factors, including sexual practice, lifestyle, relationship status, age, etc. The risk of contracting HIV depends largely on the prevalence of HIV in the community.

For MSM, PrEP regimen (daily or on-demand) should be selected on a case by case basis, based on the patient's lifestyle, sexual practice and frequency of sexual activity. If the frequency of sexual activity does not exceed two per week and it is possible to predict, on-demand PrEP can be prescribed. Daily regimen is appropriate for beneficiaries who cannot predict the timing of sex or whose potential exposures to HIV are more frequent than 2 times per week (Diagram 1).

Diagram 1. Algorithm for PrEP Regimen Selection in MSM

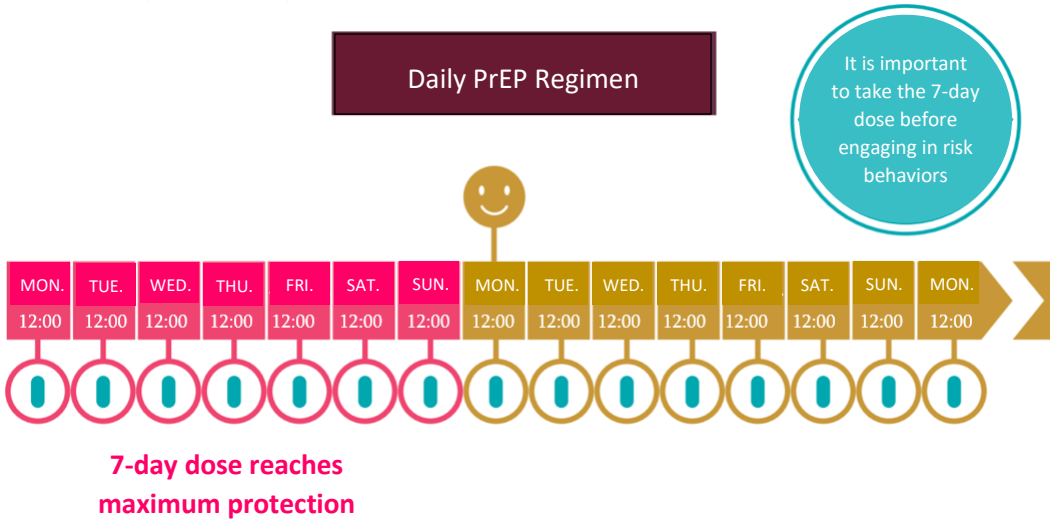


PrEP is a medical intervention that offers a high level of protection against HIV, but does not provide protection against other sexually transmitted diseases. Therefore, PrEP is used in combination with other preventive measures. PrEP treatment should be supervised by a doctor expirienced in the use of HIV medications. Sexual health specialist could also be involved.

2.1.1. Characteristics of Daily PrEP Regimen

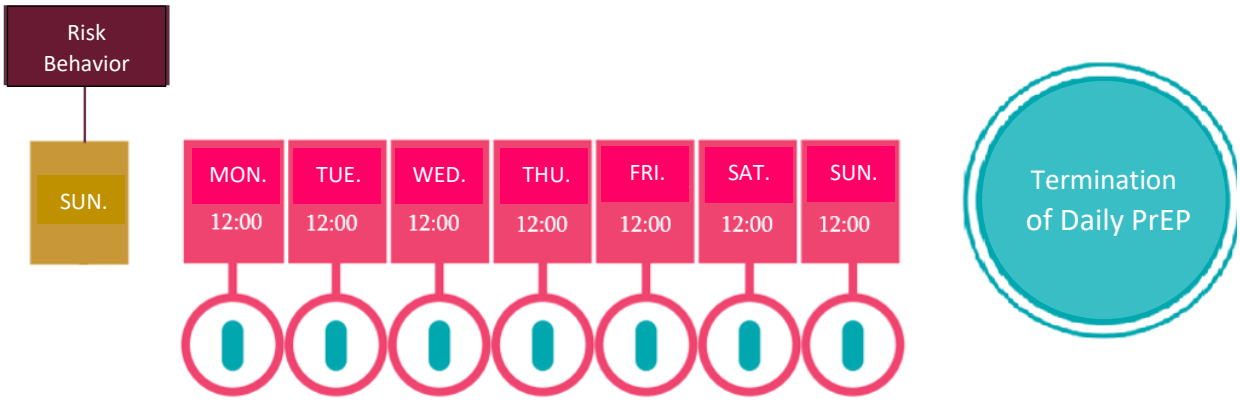
According to the World Health Organization (WHO) recommendations, optimal effect and maximum protection of PrEP is achieved after taking the appropriate dose of medication for seven days.

Diagram 2. Daily PrEP Regimen



If the daily PrEP regimen is terminated, it is important for the beneficiary to continue taking one pill per day for seven days, starting from the last risk behavior event.

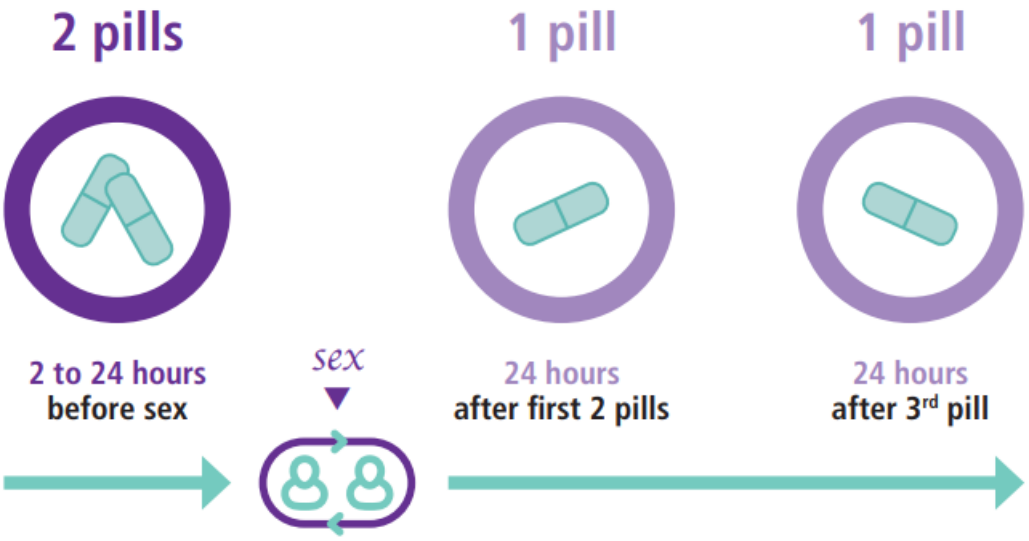
Diagram 3. Termination of Daily PrEP Regimen



2.1.2. Characteristics of On-demand PrEP Regimen

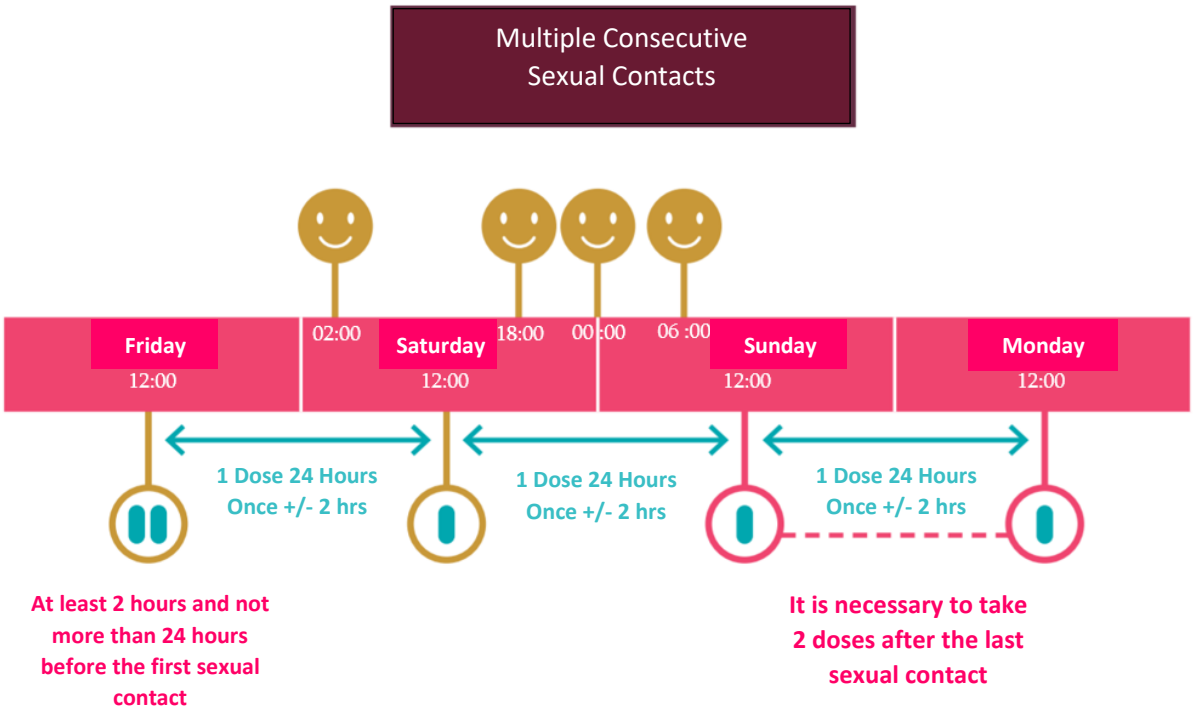
On-demand PrEP regimen entails taking a total of 3 doses and 4 pills (TDF/FTC 300/200mg with 2+1+1 dosing). With on-demand PrEP, the medication must be used at least 2 hours before the risk behavior.

Diagram 4. On-demand PrEP Regimen



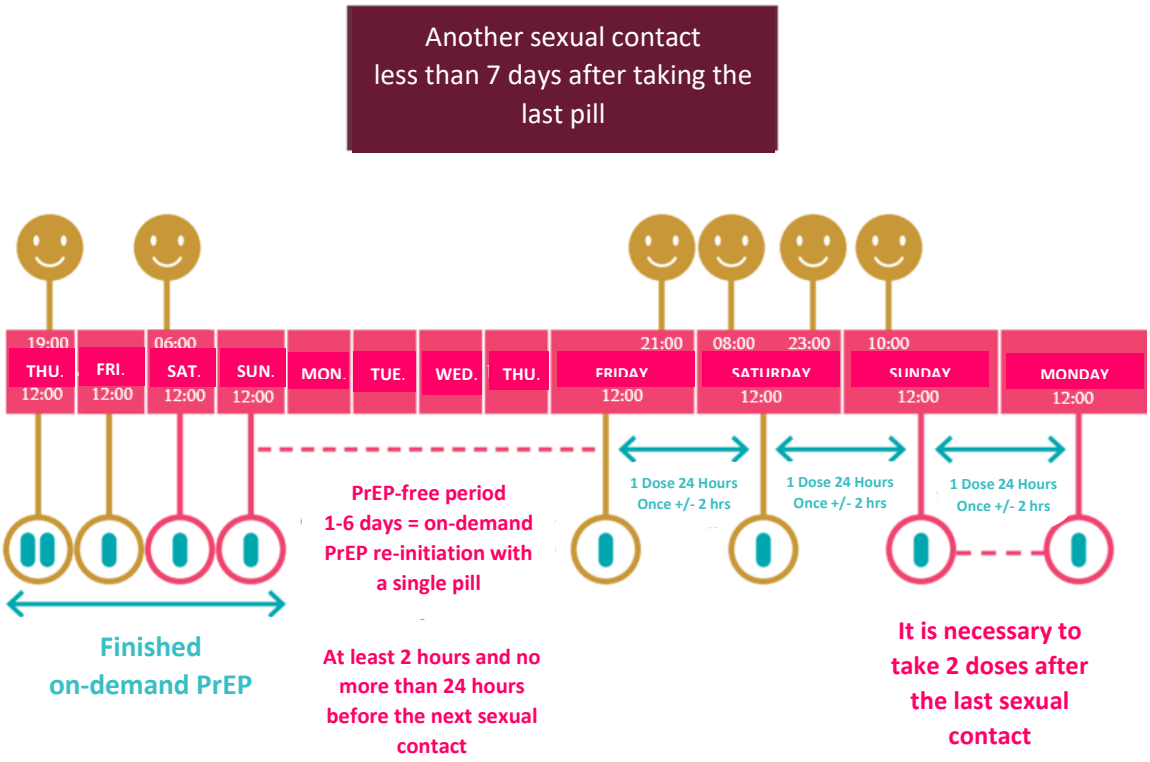
If the person has more sexual contact 24 hours after taking the initial dose, they should continue taking one pill per day (preferably at the same time, no more than 2 hours earlier or later). In addition, if the person decides to discontinue on-demand PrEP, they should take two doses of PrEP after the last sexual contact, with a 24-hour interval.

Diagram 5. On-demand PrEP for Multiple Consecutive Sexual Contacts



If a person has taken on-demand PrEP in the last seven days, there is no need to use two pills as an initial dose, one pill is sufficient is such cases. However, it is important to take the pill at least 2 hours before the risk behavior.

Diagram 6. On-demand PrEP Regimen Less Than 7 Days After the Last Intake



If 7 days or more have passed since taking the last dose, on-demand PrEP is re-initiated with a standard regimen, and 2 pills are used as an initial dose.

2.1.3. Considerations for Prescribing PrEP

- Before starting PrEP, it must be made certain that the person is HIV-negative. Symptoms of acute HIV infection must not be present, and the 4th generation HIV antibody test results must be negative. While using PrEP, the aforementioned test should be repeated after a month, and then every three months thereafter. PrEP must be stopped immediately if symptoms of acute HIV/AIDS or HIV seroconversion occur, and the patient should be referred to an HIV/AIDS treatment facility;

- HBV serological status must be determined before PrEP initiation. If the result is negative, the test should be repeated every 6 months. If HBV seromarkers are not detected, beneficiary should be offered hepatitis B vaccination;

- Hepatitis C antibody screening is necessary both before and during the PrEP treatment. If the result is negative, the test should be repeated every 6 months. If the result is positive, beneficiary should be reffered to an appropriate specialist from the state program of hepatitis C elimination, for confirmatory testing, and further treatment;

- Screening for sexually transmitted infections is necessary before and during PrEP. This includes a serologic test for syphilis, and nucleic acid-based molecular tests for gonorrhea and chlamydia. Patients should be informed that PrEP does not provide protection against sexually transmitted infections;

- Before PrEP initiation, the patient should be informed that the medication affects kidney and bone health. Renal function should be assessed before starting PrEP.

- Adherence counseling is necessary before PrEP initiation. The medication is effective only if the prescribed regimen is fully adhered to;

- Beneficiaries should be informed that although the medication is prescribed for a long period of time, they will only receive a one-month supply on the first appoitment, and a maximum of three months' supply thereafter.

PrEP is an intervention that offers a high level of protection against HIV, but does not provide protection against other sexually transmitted diseases. Therefore, PrEP is used in combination with other preventive measures. PrEP treatment should be supervised by a doctor expirienced in the use of HIV medications. PrEP should be provided with the involvement and supervision of community members from key populations to ensure beneficiary-centered service provision and comprehensive support for beneficiaries throughout the continuum of care.

Table 1. Outline of the PrEP Service Provision Principles

Identifying substantial risks of contracting HIV	HIV-positive sexual partner who is not on ARV treatment (at least 1 case of detectable viral load in the past 12 months); History of sexually transmitted diseases; Number of sexual partners; Systematic non-use of a condom; Commercial sex work; Injection drug use; Sexual intercourse under the influence of drugs or alcohol.
Meeting clinical criteria before PrEP initiation	Documented HIV-negative status; Absence of symptoms of acute HIV infection; Normal kidney function; Documented negative hepatitis B status and vaccination;
Medications	TDF 300 mg / FTC 200 mg
Strategies for PrEP prescription	A) Daily dose B) 2+1+1 before and after high-risk sexual activity
On-demand PrEP	On-demand PrEP is recommended only for men who have sex with men. On-demand PrEP is contraindicated in people with chronic hepatitis B infection.
Other services	Follow-up visits at least every 3 months, for the following purposes: HIV testing; STI symptom assessment; hepatitis B and C testing; syphilis testing; side effect management; adherence counseling; risk reduction counseling; Also, renal function assessment and STI testing once in every 6 months.

2.2. Description of the intervention – PEP

Post-exposure prophylaxis is the use of ARV medication, which should be initiated as soon as possible in the first 72 hours after the possible exposure to HIV. PEP eligibility assessment includes consideration of the HIV status of the possible source, HIV-related risk factors, as well as

epidemiological patterns and HIV prevalance in both the general population and key communities.

Chapter III. Standard of Service Provision

3.1. Standard of PrEP Service Provision

3.1.1. Purpose of Pre-exposure Prophylaxis

Pre-exosure prophylaxis aims to reduce HIV incidence, and thereby reduce HIV-related morbidity, mortality, and resulting expenses for individuals, communities and countries.

Therefore, pre-exposure prophylaxis providers should consider the following:

- The program should include the use of only those medications with evidence-based proof of safety and efficacy.
- The program is intended for people with HIV-negative status who meet the criteria based on their risk behaviors;
- Patients should be continuously informed about the prescribed medication and its safe use.
- Patients should receive ongoing treatment adherence support services to ensure that each beneficiary takes the appropriate amount of medication for protection against HIV.
- Patients should receive ongoing counseling and risk-reduction services, as well as other preventive services and referrals, to minimize the risk of contracting HIV;
- Patients should be continuously monitored for HIV infection, STIs, drug toxicity, and risk levels in order to provide services tailored to each patient's individual needs.

3.1.2. Recommended Medications

Currently, the combination of TDF and FTC is the only safe and effective medication for HIV-negative individuals at high risk of contracting HIV.

Therefore, TDF/FTC is the recommended combination medication for pre-exposure prophylaxis.

Although evidence suggests that TDF alone is effective in certain populations (injecting drug users and heterosexual men), it should not be used separetely in men who have sex with men.

Therefore, the approved pre-exposure prophylaxis medication for MSM and transgender women is the combination drug tenofovir/emtricitabine (TDF/FTC 300/200 mg), using one pill once a day.

The duration of pre-exposure prophylaxis depends on the specific needs and behaviors of the patient, and should be determined on an individual basis.

Additionally, On-demand (event-driven) PrEP is recommended only for men who have sex with men, using the 2+1+1 regimen, which means taking a total of 4 TDF/FTC 300/200 mg pills before and after the high-risk sexual intercourse (TDF/FTC 300/200mg - 2 pills 2-24 hours before the intercourse, 1

pill 24 hours after the initial dose, 1 pill 24 hours after the second dose, see Diagram 2) (strong recommendation, high-quality evidence).

Table 2. Recommended Medications

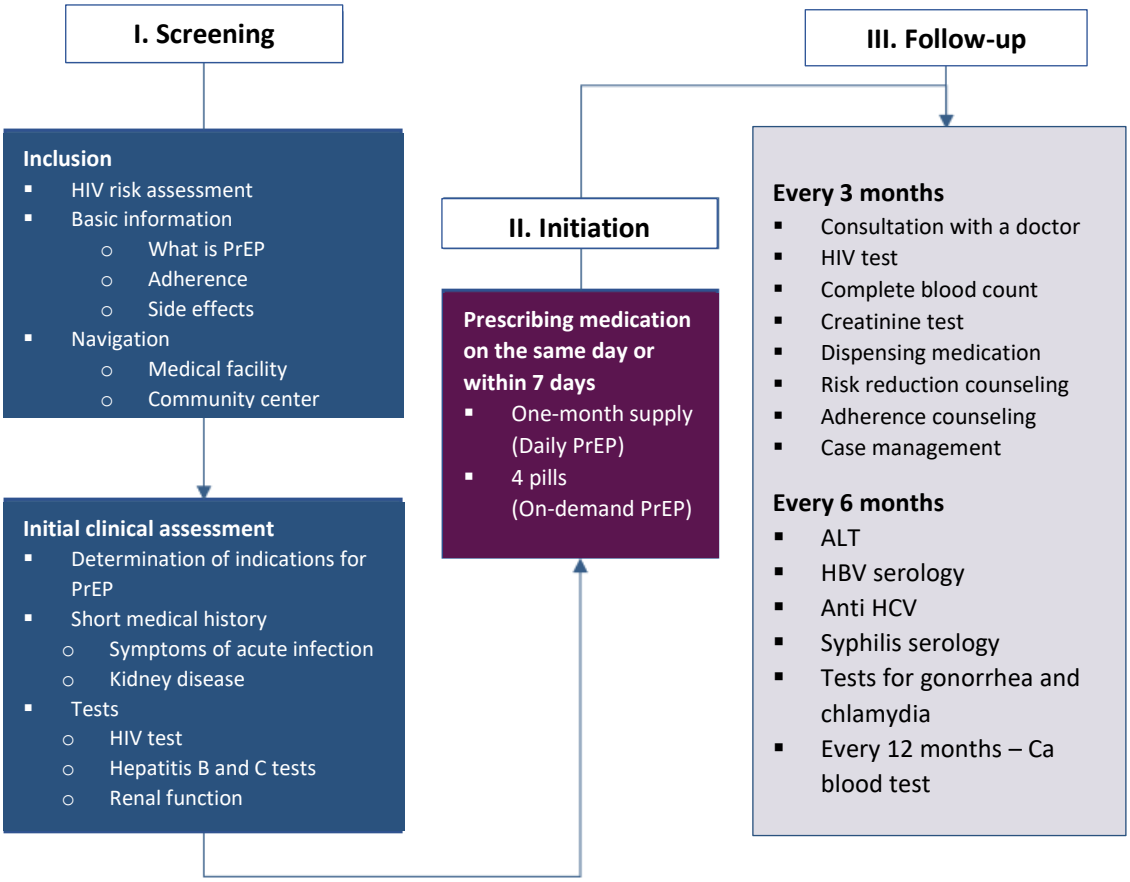
Daily PrEP			
Name	Dose	Frequency	Side Effects
Tenofovir Disoproxil Fumarate (TDF)	300 mg	Once a day	Nausea, Flatulence
Emtricitabine* (FTC)	200 mg	Once a day	Skin rash, Headache
TDF + FTC	300mg / 200 mg	Once a day	
On-demand PrEP			
Name	Dose	Frequency	
TDF + FTC	300 mg / 200 mg	A total of 4 pills used before and after the high-risk sexual intercourse (TDF/FTC 300/200mg 2 pills 2-24 hours before the intercourse, 1 pill 24 hours after the initial dose, 1 pill 24 hours after the second dose).	

Table 3. Drug Interactions between TDF/FTC and Other Medications

	TDF	FTC
Buprenorphine	No significant effect; Dose adjustment is not required;	No data
Methadone	No significant effect; Dose adjustment is not required;	No data
Acyclovir; Valacyclovir; Cidofovir; Ganciclovir; Valganciclovir; Aminoglycosides; Multiple or high doses of non-steroidal anti-inflammatory drugs, or other medications that reduce kidney function or interfere with renal secretion	No significant effect; Dose adjustment is not required;	No data

3.1.3. Stages of Service Provision

Table 4. Stages of PrEP Service Provision



I. Screening

Screening is the first stage of PrEP services, and involves the phases of inclusion, navigation, and initial clinical assessment. Screening is usually the most intensive stage in PrEP service provision.

- Inclusion involves an HIV risk assessment, which identifies the person's needs and inclusion criteria. This stage also includes selecting an appropriate PrEP strategy - daily or on-demand - based on the individual's risk behavior patterns. During the inclusion stage, beneficiaries also receive basic education and information on PrEP and how it works, as well as on treatment adherence, and medication side effects.

- During the navigation phase, individuals eligible for PrEP are reffered to clinical services. This phase may also include providing proactive support, including case management, based on the specific needs of the individual.

- The final service included in the screening stage is the initial clinical assessment, conducted by a health care provider/physician. Clinical assessment must be conducted before PrEP initiation, and it includes an evaluation of signs and symptoms of acute HIV infection and/or sexually transmitted infections (STIs), history of kidney disease, and other clinical signs. Another essential component of this stage is HIV testing, as well as laboratory assessment of renal function, hepatitis B and C and STI testing, and a pregnancy test for women.

II. PrEP Initiation

- Once the clinical assessment is conducted, and laboratory tests confirm that the beneficiary has no contraindications to PrEP, medication is prescribed.
- If laboratory test results, including those for HIV and renal function, are available on the first appointment, PrEP should be prescribed and initiated on the same day. If laboratory test results are not available on the first appointment, PrEP should be prescribed and initiated within the next 7 days, in order to minimize the risk of contracting HIV in-between testing and PrEP initiation.

During the PrEP initiation stage, beneficiaries recieve medication according to the selected strategy (daily or on-demand). In case of daily PrEP, beneficiaries receive a month's supply of medication. While in the case of on-demand PrEP, they recieve four pills, as per the regimen described above.

III. Follow-up

In accordance with the consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV/AIDS, as well as community and social services set by this protocol:

Every three months:

- HIV antibody testing
- Consultation with a doctor
- Complete blood count
- Creatinine test
- Dispensing medication
- HIV risk behavior assessment and risk reduction counseling
- Adherence counseling
- Case management and social support services (a needed)

Every six months:

- Alanine aminotransferase (ALT)
- HBV serology (HBsAg, anti-HBc, anti-HBs)
- Hepatitis C virus test (anti HCV)
- Serological test for syphilis
- Nucleic acid-based molecular testing on urine samples to detect gonorrhea and chlamydia

Every twelve months:

- Calcium (Ca) blood test

Table 5. PrEP Service Standard and Monitoring Plan/Schedule

	Initial Phase	1 Month	3 Months	6 Months	9 Months	12 Months
Consultation with a doctor	X	X	X	X	X	X
Dispensing medication	X	X	X	X	X	X
HIV antibody test	X	X	X	X	X	X
Complete blood count	X	X	X	X	X	X
HIV risk behavior assessment and risk reduction counseling	X	X	X	X	X	X
Adherence counseling	X	X	X	X	X	X
Case management and social support services (as needed)	X	X	X	X	X	X
Creatinine test	X	X	X	X	X	X
Alanine aminotransferase(ALT)	X			X		X
Calcium (Ca) blood test						X
HBV serology (HBsAg, anti-HBc, anti-HBs)	X			(X)		(X)
Anti-HCV	X			(X)		(X)
Serological test for syphilis	X			X		X
Nucleic acid-based molecular test for gonorrhea and chlamydia	X			X		X

3.1.4. Risk Behavior Assessment and Eligibility Criteria

To be eligible for the PrEP program, a person must meet the program's criteria in terms of their risk behaviors. In particular, the program is intended for HIV-negative adult men and transgender women who have sex with men, and have regularly engaged in one or sereval risk behaviors over a 6-month period prior to inclusion in the program. Risk behaviors include:

- A regular sexual partner who is HIV-positive and is not on ARV treatment (at least 1 case of detectable viral load in the past 12 months);
- Involvement in commercial sex work;
- Injection drug use;
- High-risk sexual behavior under the influence of drugs and/or alcohol;
- History of sexually transmitted diseases;
- 2 or more sexual partners;
- Non-use of a condom during insertive or receptive sexual intercourse;
- Use of post-exposure prophylaxis (PEP) for prevention.

Table 6. PrEP Eligibility Criteria

Age	>18;	Legal Adult Under the Law of Georgia
HIV Status	HIV-negative according to the tests performed prior to inclusion in the program	
Meets any of the following criteria within the last six-month period		
Has a regular sexual partner who is HIV-positive		
Is involved in commercial sex work		
Uses injective drugs		
Has or has had any sexually transmitted diseases (syphilis; gonorrhea; chlamydia)		
Has 5 or more sexual partners		
Did not use a condom during insertive or receptive sexual intercourse		
Has used post-exposure prophylaxis for HIV prevention		
Uses alcohol and drugs for sexual stimulation		

Risk behavior must be assessed at the outset in order to identify the specific sexual or other behavior that puts the beneficiary at risk of contracting HIV, and to plan an appropriate management approach and strategy. Risk behavior should be routinely monitored by both a physician and a social or community worker.

Table 7. Risk Behavior Assessment Questionnaire

#	Risk Assessment		Score
1	How old are you?	<18	0
		18 - 28	8
		29-40	5
		41-48	2
		49 and more	0
2	How many male sexual partners have you had in the last 6 months?	0-2 Partners	0
		2-5 Partners	4
		5 > Partners	7
3	In the last 6 months, how many times have you had unprotected receptive anal sex?	1 or more	8
		0	0
4	In the last 6 months, how many times have you had unprotected insertive anal sex?	1 or more	5
		0	0
5	In the last 6 months, how many of your sexual partners were HIV-positive?	>1	8
		1	4
		I don't know	2
		None	0
6	In the last 6 months, have you used any injection drugs?	Yes	4
		No	0
7	In the last 6 months, have you used post-exposure prophylaxis?	Yes	8
		No	0
8	Are you or have you been involved in commercial sex work over the last 6	Yes	8
		No	0
9	In the last 6 months, have you used alcohol or drugs for sexual stimulation?	Yes	4
		No	0
			Total score

3.1.4.1. By Whom and in What Setting Should the Risk Behavior Assessment Be Conducted?

Risk behavior assessment involves examining a person's sexual history, and drug use practices. Community members are often reluctant to talk about their behaviors and related details, especially given the negative attitudes, criminalization, stigma, and dicrimination they face in the country.

To overcome this barrier, it is crucial for the risk behavior assessment and the interview about a person's sex life, drug use, and other risk behaviors, to take place in a community-oriented, friendly environment that allows the person to speak as openly as possible.

It is important that this process is conducted using the peer-driven intervention model, and that the initial communication with a beneficiary is carried out by a community member, social worker, outreach worker, case manager, or other appropriate specialist.

If a beneficiary directly contacts a medical facility, and it becomes necessary for the medical staff to conduct risk behavior assessment, it is recommended that the personnel providing the service offer the beneficiary to contact a community organization to receive additional services.

3.1.4.2. Risk Behavior

When identifying the eligibility criteria for inclusion in the PrEP program and conducting a risk behavior assessment, it is important to communicate and discuss related issues with the beneficiary.

It is important to have beneficiary-oriented dialogue in order to gather comprehensive information about the person's risk behaviors.

In order to assess risk behaviors, it is important to gather information about the beneficiary's sexual practices, sexual partners, HIV and STI, and drug use practices.

In order to obtain detailed information, the following issues should be addressed during the conversation with the beneficiary:

Table 8: Key Issues in Assessing High-Risk Behavior

Sex Partners	Gender Identity
	Number of sexual partners
	Characteristics of sexual partners ▪ Sex ▪ Gendel identity ▪ HIV status ▪ Sexual behavior and other
Sexual Practices	Types of sexual practice (vaginal, anal, oral)
	Fetishes (BDSM, fisting, rimming and others)
	Condom use practice
	Anal douching
	Sex work
	Transactional sex
	Hormone use
Drug Use Practices	Frequency of drug use and types of drugs

	Specifics of drug use (where, when, in what environment)
	Forms of drug use (injecting, non-injecting, recreational, etc.)
	Use of sterile injection and non-injection equipment
	Substance use in a sexual context, including chemsex
HIV Infection and Sexually Transmitted Infections	HIV testing, the last test and the result
	Testing for other infections (viral hepatitis, gonorrhea, chlamydia, syphilis, trichomoniasis, etc.)
	The practice of serosorting (selecting a sexual partner based on their HIV status)
	Referral to post-exposure prophylaxis
Characteristics of High-Risk Behavior	Frequency of high-risk behavior (normal or non-risky behavior)
	The possibility of high-risk behavior identification (is it possible to plan and determine risky behavior in advance, or is it spontaneous, unplanned)
	How far in advance can a high-risk behavior be planned?

Based on the assessment of high-risk behavior and the individual characteristics highlighted within the mentioned, if it is determined that the inclusion of what is indicated for the person in the PrEP, the service provider (medical staff and/or social/community worker), together with the beneficiary, determines the optimal scheme of PrEP for a specific individual (daily or situational).

3.1.5. Adherence to Treatment

Published data from studies on PrEP emphasize that treatment adherence is critical to maximize the benefits of prevention, as well as to minimize the risk of developing drug resistance in HIV-infected individuals with low adherence. A pharmacokinetic study among MSM (the STRAND study) showed a 99% reduction in risk of HIV infection with 7 doses per week, 96% with 4 doses per week, and 76% with 2 doses per week.

Nevertheless, the conclusions/results of this study emphasize the need for a high level of adherence in order to achieve a high preventive effect.

Recent analyzes of HIV antiretroviral treatment adherence studies, as well as results from PrEP studies, suggest different approaches and tools to effectively support patients to maximize adherence to medication.

These approaches include continuous patient education; managing side effects; determining the specifics of taking medications based on individual needs, including work and social factors; using reminder systems and tools; taking into account financial, substance abuse, mental health, or other medical and social factors; ongoing social support.

The issue of adherence to ARV prophylaxis regimens is closely related to the patient's full understanding of the drug information. It is vital that patients taking preventive medications know in detail how to take the medication (how many pills to take at a time, when to take the medication, etc.) and what to do if they encounter difficulties (what to do if they miss the medication, etc.). One of the main causes of treatment non-adherence is side effects, which is why a side effect management plan should be developed for each patient. It is important that the plan also incorporates ways to manage side effects that the patient finds intractable/problematic. The plan should consider additional medications that may alleviate the symptoms, as well as the need for continued condom use if the patient stops taking the PrEP.

The need for HIV testing every three months should be discussed with the patient. Patients may be disturbed by this frequency of testing, and it is important to explain the need for frequent testing and the need to avoid developing drug resistance if infected.

Table 9: Key Components of Treatment Adherence Counseling

Build trust and two-way communication with the beneficiary, provide simple and straightforward information and education

- The dosage of the drug and the regimen for taking it;
- Side effect management;
- Influence of adherence on effectiveness of PrEP;
- Symptoms of acute HIV infection and recommended actions.

Adherence support

- Adjust the medication intake to the beneficiary's daily routine;
- Identify medication reminder tools to avoid missed doses;
- Identify and overcome barriers to adherence.

Monitor adherence in a friendly and host environment

- Normalize missed prescribed doses, do not berate the beneficiary for missed doses, explain the need for daily medication to achieve optimal protection;
- Identify barriers to adherence and plan ways to solve them with the beneficiary;
- Evaluate side effects and develop a management plan.

Be prepared to answer other questions, such as: "What if people see the medication and think I am HIV positive?"; "Do I need to tell my partner about taking the medication?"; "Do I need to take the medication regularly even if I am not having sex?"; "Will taking extra doses protect me additionally?"; "How long should I take the medication?";

3.1.5.1. Adherence Plan

An adherence plan should be developed as soon as the patient is prescribed the medication. The development of the adherence plan and its follow-up should be handled by community workers, although medical staff should be directly involved in the process. The adherence plan is individualized and adjusted to the patient's individual needs.

An adherence plan should include the following:

1) Adjustind medication times in PrEP with the patient's regularly scheduled activities to ensure that medication intake is integrated into the patient's daily routine;

2) The use of reminders;

3) Using organizational approaches and tools (e.g., calendars, weekend strategies) to adjust medication administration to non-standard schedules;

4) Evaluation of medication disclosure possibilities to identify individuals who can support the patient in taking and adhering to the treatment regimen;

Table 10. Development of An Adherence Plan

3. Organizational skills

- How to take the medication in a non-daily regimen, such as if you go out on the weekend or if you don't spend the night at home;

- Create a simple strategy that is universal to all environments and situations;

4. Social support and disclosure

- Determine who can help the patient to develop adherence

  - Assess the patient's surroundings
  - Who knows about taking the medication?
  - About the reasons for taking the medication? Are they supportive?

- Together with the patient, make a plan to inform these individuals about taking medications and, if necessary, invite them to a consultation

Depending on the individual patient's needs, additional problems and factors such as substance abuse, depression, housing problems, as well as social problems and other factors that negatively affect adherence to treatment may also be identified. It is important to consider these issues as much as possible and support the patient by providing additional services or referring them to these services.

3.1.5.2. Monitoring Patients Participating in PrEP: Assessment of Adherence

Regular assessment of treatment adherence and HIV testing is necessary.

Self-assessment of adherence (taking medications) is an overestimate of true/actual adherence because patients fear negative attitudes from clinical/medical staff after providing actual information about taking medications.

Therefore, it is vital that treatment adherence monitoring and evaluation take place in a friendly, non-judgmental environment that allows patients to honestly share information about treatment adherence and obstacles. Accurate information about adherence helps to correctly identify problems and tailor individual approaches.

Table 11. Questions for Assessing Adherence

- How many times did the patient miss the medication?

- How many times the medication was missed during a particular period. It is better to assess long periods (30 days, 7 days) than short periods (3 days) due to the fact that short-term assessment enables changes in the schedule of taking (weekends, holidays), as well as increasing the dosage of the medication by patients before the visit is a common occurrence.

- How regular and typical is medication skipping?

- Specific factors that cause medications to be omitted?

Based on this information, develop a plan with the patient to improve adherence that answers the following questions

- What could have been done differently in the medication schedule or format?

- In addition, what will contribute to the regular intake of medication?

It is also important to assess the side effects of the medication, as side effects are a major barrier to adherence. Undesirable effects must be managed by medical personnel, and community workers must also be involved in this process.

3.1.6. Risk Reduction Counseling

Developing and maintaining safe sexual and other practices is critical to both the prevention of HIV infection and the clinical and social management of patients with PrEP.

Risk-reduction counseling should be provided to PrEP patients on a regular basis, depending on individual needs, at least every 3 months, although there may be patients who need monthly or more frequent counseling.

Assessment of a patient's high-risk behavior using a standardized questionnaire should be done routinely prior to risk assessment counseling.

To determine each patient's current risk behavior and to compare changes in behavior before and after prescribing a PrEP.

Risk reduction counseling should be conducted by community workers on a peer-to-peer principle.

Table 12. Key Issues in Risk Reduction Counseling

Risk reduction counseling includes providing integrated information about HIV/AIDS and other STIs, as well as high-risk sexual and other practices. Risk reduction counseling includes the following:

- General information on HIV
- About routes of transmission and prevention;
- Reducing the harms caused by high-risk sexual behavior and drug use.
- The client's personal/specific risks associated with HIV transmission;
- Future actions to mitigate these risks;
- General information related to STIs, as well as specific/personal risks of the patient;
- Safe sex practices and the importance of condom use; - safe injection practices;
- Referring and accompanying the patient as needed.

3.1.6.1. Reducing the Harm Caused by High-Risk Behavior

Providing condoms and lubricants

Data from clinical trials of PrEP strongly emphasize that PrEP is effective only in combination with regular condom use.

Therefore, a regular provision of condoms to PrEP patients is of vital importance.

Condom-compatible lubricants must be supplied along with condoms.

Condoms and lubricants should be provided by community workers on a regular basis, taking into account the individual needs of each patient and the nature of the high-risk behavior.

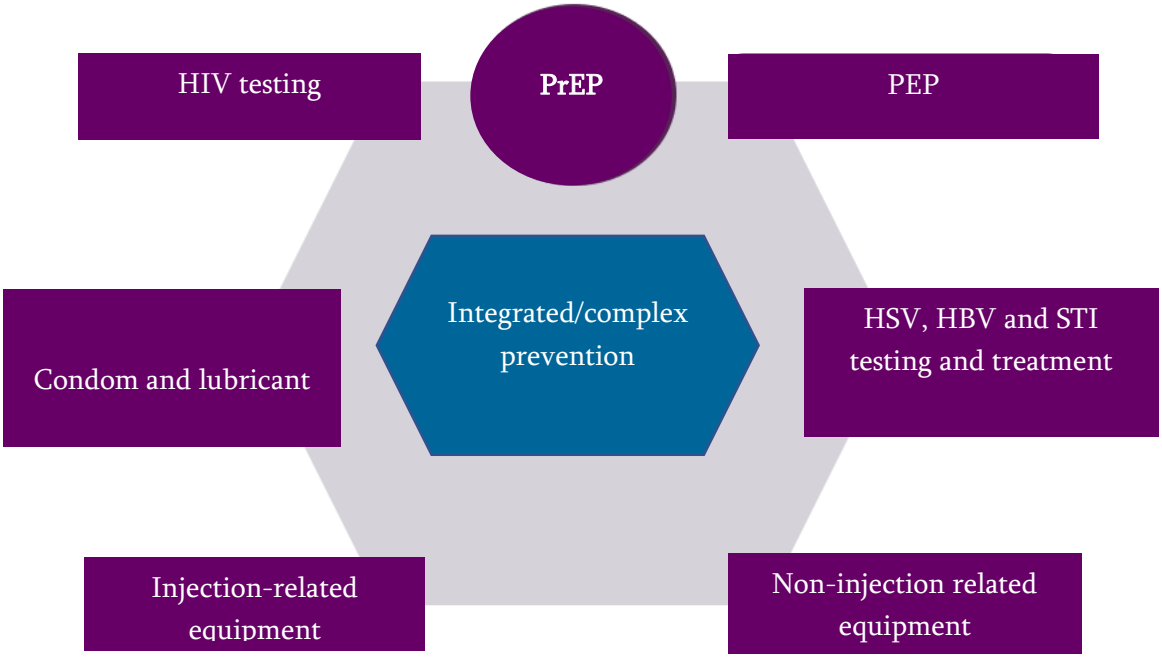
Supply of equipment necessary for the safe use of drugs

Depending on the individual high-risk behaviors of PrEP beneficiaries, it is important to provide them with comprehensive harm reduction services.

In cases of high-risk behaviors related to drug use, it is important to provide the person with appropriate services to reduce the risks and harms associated with both injecting and non-injecting drug use. In particular, it is important to provide individual with both injection equipment (needles,

syringes, “butterflies” (winged needle/scalp vein set), injection water, etc.) and equipment necessary for non-injection use (smoking, suction-inhalation tubing, etc.).

Diagram 7. Comprehensive Package of HIV Prevention and Harm Reduction for Beneficiaries Involved in PrEP



3.1.7. Laboratory Tests

All patients identified as needing PrEP as a result of a high-risk behavioral assessment must undergo medical/laboratory tests, including testing for HIV, hepatitis B and C, syphilis, and blood creatinine levels.

The purpose of these laboratory tests is to identify those patients in whom PrEP (tenofovir/emtricitabine containing drug) may cause complications or harm; and/or who may require advanced clinical monitoring.

3.1.7.1 HIV Testing

HIV testing and documentation of results are necessary to confirm that the patient is HIV free at the time of enrollment in PrEP program.

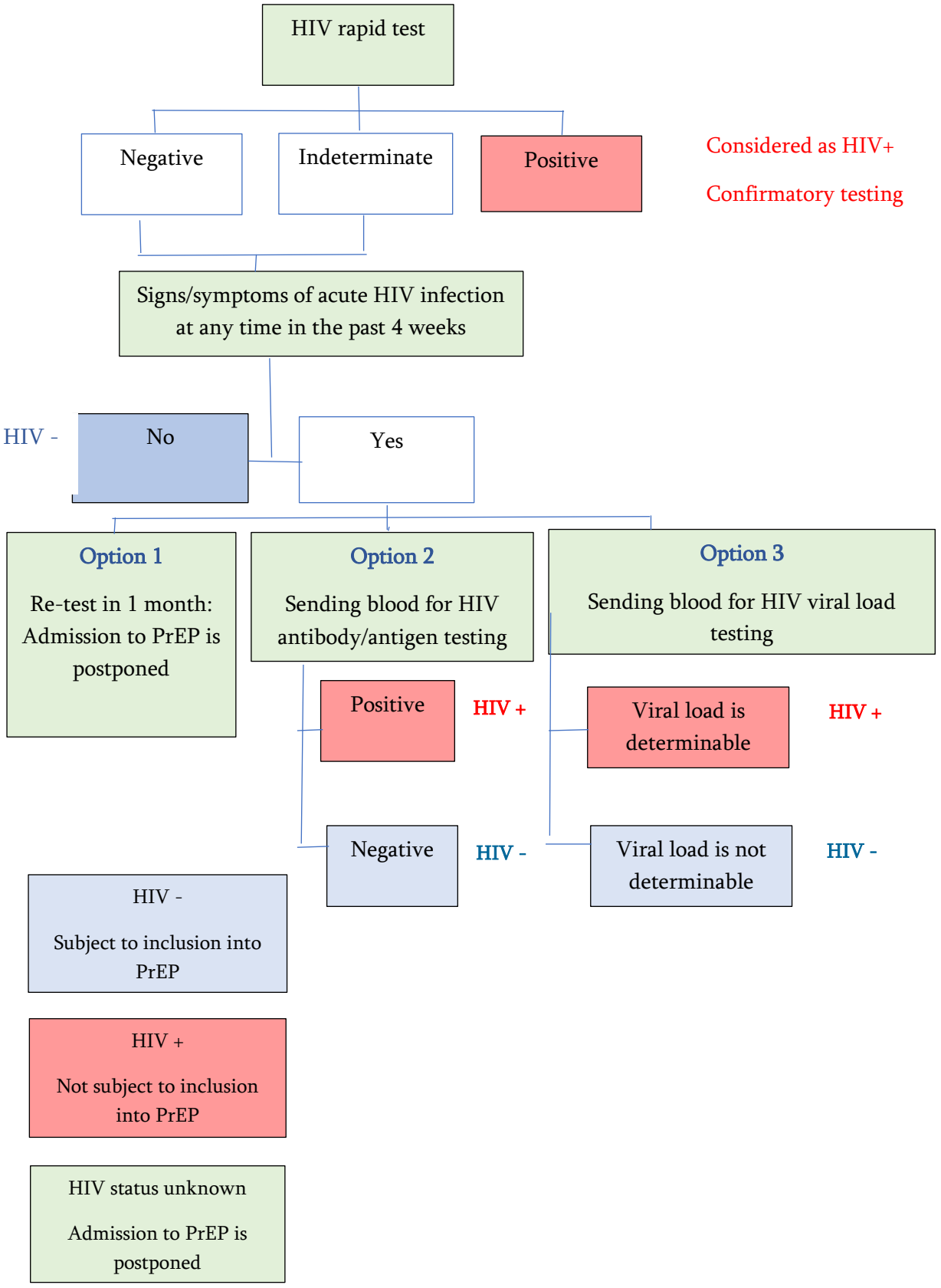
Before you prescribe PrEP, you must make sure that the person is not infected with HIV. Must not have symptoms of acute retroviral disease and must be negative for HIV antibodies with the fourth-generation test.

HIV testing should be repeated at least every 3 months to ensure patient safety.

Physicians must document HIV-negative status at least 1 week before a patient is enrolled in PrEP.

The physician should not discuss a patient's reported test results and/or HIV status; or test results from another facility (other than those involved in PrEP).

Table 13. Identification of HIV Status



3.1.7.2. Acute HIV Infection

PrEP is for people whose sexual, injecting, or other practices/behaviors put them at particularly high risk for HIV infection.

Therefore, regardless of a documented negative HIV test result, the symptoms of acute HIV infection should be evaluated;

3.1.7.3. Assessment of Renal Function

Before starting a PrEP program, in addition to certainty of a person's HIV-negative status, a renal function test is also necessary, as elevated creatinine is a contraindication for TDF/FTC in PrEP. TDF is widely used in combination antiretroviral therapy regimens. Reduced renal function and isolated cases of acute renal failure have been reported in patients receiving regimens containing TDF.

Renal function should be assessed using the COCKCROFT-GAULT formulas, determining creatinine clearance (eCrCl).

The criterion for inclusion in clinical trials of pre-exposure prophylaxis for HIV-negative individuals was an eCrCl level ≥60 mL/min. To date, there is no data on the safety of prescribing TDF/FTC to people with impaired renal function. Therefore, all people should be tested for serum creatinine and estimated creatinine clearance (eCrCl) using the COCKCROFT-GAULT formulas before starting PrEP. People with eCrCl levels <60 should not be given PrEP using TDF/FTC.

Table 14. COCKCROFT - GAULT formulas

General formula
eCrClcg = [[(140-age) x IBW x 0,85 for females] ÷ (creatinine in serum x 72) **IBW = ideal body weight** Males: IBW = 50 kg + 2.3 kg for each inch over 5 feet. Females: IBW = 45.5 kg + 2.3 kg for each inch over 5 feet. Age in years, weight in kg-s, creatinine in mg/100 ml. **Low actual weight adjustment for eCrCl calculation** if the ABW (actual body weight) is less than the IBW use the actual body weight for calculating the eCRCL. **High actual weight adjustment for eCrCl calculation** It is used only if actual body weight is 30% or more above the IBW. Otherwise, use IBW. eCrClcg = [[(140-age) x AjBW] ÷ (creatinine in serum x 72)] (0,85 for females) AjBW = IBW + 0.3 (ABW - IBW) AjBW = adjusted body weight ABW – actual body weight **eCrCl calculation in terms of Body Surface Area (BSA)** May be used if body weight exceeds or is less than IBW eCrClBSAadj = 1.73m^2 x eCrCl (ml/min) ÷BSA (m^2) BSA (Dubois and Dubois formula) – (height (m)^{0,725} x weight (kg) ^{0,425}) ÷ 139.2

3.1.7.4. Serological Tests for Viral Hepatitis

Sexually active adults, especially men who have sex with men, are at increased risk for hepatitis B and C infection. Therefore, it is recommended that they receive hepatitis B vaccination. Therefore, both HBV and HCV status should be documented before prescribing TDF/FTC. People who are especially vulnerable to HBV infection should be vaccinated.

In addition, TDFs are active anti-HBV drugs. This is important to consider because if a patient with an active HBV infection stops taking these drugs, liver function should be monitored carefully, since reactivation of the HBV infection can cause irreversible liver damage.

Table 15. Hepatitis B Screening Serology

HBsAg	Total Anti-HBc	IgM Anti-HBc	Anti-HBs	Interpretation	Intervention
Negative	Negative	---	Negative	Suspect case	Vaccination
Negative	Positive	---	Positive	Immune (had infection in the past)	Documenting
Negative	Positive	---	Positive	Immune (as a result of vaccination)	Documenting
Positive	Positive	Positive	Negative	Chronic Hep B	Evaluate for treatment
Positive	Positive	Positive	Negative	Acute Hep B	Monitor and evaluate for treatment
Negative	Positive	---	Negative	Indeterminate – Could be: • Eliminated infection (the most common); • False-positive anti -HBc there is a suspicion; • "Low grade/quality" chronic infection; • Eliminated acute infection;	Evaluation of each case

After immunovaccination, only anti-HBs are positive, anti-HBc is negative.

3.1.7.5. Complete Blood Count (CBC)

As part of the pre-exposure prophylaxis program, beneficiaries must get a CBC test at their first clinic visit, as well as a creatinine test and a hepatitis B virus surface antigen (HBsAg) test. CBC count disorders (anemia (normo-, hyper-, or hypochromic), leukopenia, thrombocytopenia, severe leukocytosis, left shift in the leukocyte formula, so-called "leukemic failure", marked thrombocytosis, etc.) are relative contraindications for tenofovir/emtricitabine administration and require assistance from specialists in the relevant field.

3.1.8. Termination of PrEP

There may be several reasons for the termination of PrEP services:

- The patient's own decision;
- Altered high-risk behavior;
- Intolerance to drug-induced toxicity;
- Chronically low adherence to treatment, which could not be improved by additional interventions and efforts;
- HIV infection;

If you terminate the PrEP for any of the reasons listed, you must document the following:

- HIV status at the time of termination of the PrEP;
- The reason for termination of PrEP;
- The level of adherence to treatment;
- Risk behavior is as documented in the last evaluation;

If a patient who has terminated PrEP wants to participate in the program again, he or she must go through all the procedures and tests again.

In the case of situational PrEP, PrEP is considered discontinued after taking a 3-dose (4-tablet) regimen (it is also important to test the patient for HIV after 3 months). If the patient needs to be re-enrolled in PrEP, the procedures are carried out according to the scheme described in Chapter 2, subsection 2.1.2 of this protocol.

When both daily and situational PrEPs are terminated, patient data are stored in the service database and do not need to be re-registered.

3.2. Standard of PEP Service Provision

3.2.1. Recommended Medications

Post-exposure prophylaxis with two drugs is effective, but three drugs are preferred (conditional recommendation, low quality evidence).

Preferred modes for use under the PEP:

- Tenofovir (TDF) + lamivudine (3TC) (or emtricitabine, FTC) is the preferred initial combination for post-exposure prophylaxis in adults and adolescents (strong recommendation, low quality evidence);

- For post-exposure prophylaxis in adults and adolescents, dolutegravir (DTG) is preferred as a third-line drug (strong recommendation, low quality evidence). Alternatives to dolutegravir include raltegravir (RAL), atazanavir/ritonavir (ATV/r), darunavir/ritonavir (DRV/r), or lopinavir/ritonavir (LPV/r) (conditional recommendation, low quality evidence).

3.2.2. Matters Related to the Prescription of Medications:

- ARVs should be administered for a full 28 days (strong recommendation, very poor quality evidence);

- Reinforced adherence counseling is recommended for all individuals beginning post-exposure prophylaxis (conditional recommendation, medium quality evidence).

3.2.3. Basis for Prescribing PEP

PEP should be initiated in all HIV exposed persons at risk for HIV infection. In addition, risk assessment and determination of the need for prescribing should be made in accordance with the table below.

Table 16. Recommendations for Prescribing PEP

	Source: HIV-positive		Source: HIV status unknown	
	Viral load unknown or detectable (>50 copy/ml)	Viral load undetectable (<50 copy/ml)	High prevalence country/group	Low prevalence country/group
Types of sexual exposure				
Receptive anal intercourse (passive role)	Recommended	Not Recommended B	Recommended	Not Recommended
Insertive anal intercourse (active role)	Recommended	Not Recommended B	Negotiable C,D	Not Recommended
Receptive vaginal intercourse	Recommended	Not Recommended B	In general, not recommended C,D	Not Recommended
Insertive vaginal intercourse	Negotiable C	Not Recommended B	Not Recommended C,D	Not Recommended
Oral sex with ejaculation	Not Recommended	Not Recommended	Not Recommended	Not Recommended

		B		
Oral sex without ejaculation	Not Recommended	Not Recommended B	Not Recommended	Not Recommended
Sperm splash into the eye	Not Recommended	Not Recommended B	Not Recommended	Not Recommended
Cunnilingus	Not Recommended	Not Recommended B	Not Recommended	Not Recommended
Occupational and other exposures				
Co-use of injectable drugs	Recommended	Not Recommended B	Negotiable E	Not Recommended
Injuries by sharp objects	Recommended	Not Recommended B	Negotiable C,E,F	Not Recommended
Blood splash into mucous membranes	Recommended	Not Recommended B	Negotiable	Not Recommended
Human bite	Mostly not recommended G	Not Recommended	Not Recommended	Not Recommended
Injection with a needle dumped in public places	Not Recommended	Not Recommended	Not Recommended	Not Recommended

Recommended: PEP should be given immediately if there are no contraindications
Negotiable: The probability of HIV transmission is low. The risk must be assessed individually. (With footnotes c, d below)
In general, not recommended: The risk of HIV transmission is very low. The possible side effects and toxicity of PEP drugs outweigh the benefits unless there is an obvious specific factor that increases the risk. (See footnotes c, d, e, f). The administration of PEP in such cases should be done rarely.
Not recommended: The risk of infection is negligible/zero. In such cases, the PEP should not be administered.

A When assessing the source of HIV infection, one of the decisive factors is whether the source belongs to a high-prevalence or high-risk country. The likelihood that a source from a high-prevalence country or high-risk group is HIV-positive is high. Georgia is a low-prevalence country, but HIV prevalence is high among **MSM** (men who have sex with men), **IDU**s (injecting drug users), and **CSW**s (commercial sex workers). HIV prevalence by country can be found at the following link: https://aidsinfo.unaids.org

B Source is HIV-positive, on antiretroviral therapy, with good adherence and an undetectable viral load for at least 6 months. If there is any uncertainty or doubt about viral load or adherence to ARV therapy, PEP should be administered immediately.
According to "PARTNER 1 and 2" and "HPTN052" studies, <200 copies/ml is considered the threshold for an undetectable viral load.

C Factors influencing decision making for all exposures: better knowledge of local HIV prevalence in a population with an index case (a)

D Factors influencing the decision: 1. Mucosal integrity disorders, such as genital ulcers and anal or vaginal trauma after sexual abuse or first intercourse; 2. Multiple episodes of exposure over a short period of time (e.g., group sex); 3. Sexually transmitted infections in both partners; 4. Persons at high risk of HIV infection (MSM, trans*)
E HIV prevalence among IDUs varies greatly depending on the local epidemic and country of origin. HIV prevalence among IDUs is particularly high in Eastern Europe and Central Asia. Regional rates can be found in the UNAIDS Gap report: http://www.unaids.org/sites/default/files/media_asset/05_Peoplewhoinjectdrugs.pdf.
F Factors that can affect decision-making include occupational exposures: deep trauma or bolus blood injection.
G PEP should only be considered if all three of the following criteria are met: 1) the person who has bitten - saliva with visible blood contamination; 2) the viral load of the individual (who has bitten) is known or suspicious >3.0 log copies/mL; 3) the bite caused severe and/or profound tissue damage.

3.2.4. Laboratory Examinations

Before enrolling in the PEP, the beneficiary must be tested for HIV infection, and a complete blood count and a blood creatinine level must be determined at the time of enrollment. In addition, it is recommended that the beneficiary be tested for viral hepatitis B and C and STIs. According to the table below.

Laboratory tests are necessary to (1) determine the HIV status of the person for whom PEP is being considered, (2) identify and clinically treat other conditions arising from sexual contact or injecting exposure, (3) determine any other conditions that may affect the PEP regimen.

Table 17. Laboratory Examinations

	Basis	After 4-6 weeks	After 3 months	After 6 months
HIV Ag/Ab testing A (or antibody testing if Ag/Ab and antibody testing is not available)	X	X	X	X B
Complete blood count	X	-	-	-
Blood creatinine determination C	X	-	-	-
HBV Serology (HBsAg, anti-HBc, anti-HBs)	X	-	-	X D
anti-HCV	X	-	-	X E
	For beneficiaries with sexual exposure			
Serological test for syphilis F	X	X	-	X
Gonorrhea G	X	X H	-	-
Chlamydia G	X	X H	-	-
A In case of a positive or indeterminate HIV antibody test, confirmatory status testing should be performed. **B** Only if infection with hepatitis C occurred during initial exposure; Delayed HIV seroconversion occurs in people co-infected with HIV and hepatitis C.				

C Creatinine clearance should be determined using the Cockfort-Gault formula described in 3.1.7.3 of this protocol.
D If the beneficiary is susceptible to hepatitis B at baseline testing.
E If the beneficiary is susceptible to hepatitis C at baseline testing.
F If a person is found to be infected and has been treated for syphilis, a serological test for syphilis should be performed 6 months after the end of treatment.
G Testing for chlamydia and gonorrhea should be done with nucleic acid amplification tests. Patients with confirmed chlamydia or gonorrhea should be retested 3 months after treatment.
H In case of absence of treatment at baseline or presence of symptoms at a follow-up visit.

3.2.5. Medical Card

The PEP provider and treating physician must maintain the patient's medical record in accordance with the following table:

Table 18. Medical Card

Patient's name	Physician's name, surname:
Patient's surname	
Sex assigned at birth ❍ Male ❍ Female	Patient's gender identity❍ Male ❍ Female ❍ Non-Binary

Rape ❍ Yes ❍ No	Is the identity of the offender known? ❍ Yes ❍ No

Testing and medical history					
Previous testing			**Baseline testing**		
name	result	date	result	date	other results
❍ HIV	❍ + ❍ -		❍ + ❍ -		❍ Biochemistry/functional liver tests (ALT)
❍ Hepatitis C	❍ + ❍ -		❍ + ❍ -		❍ Pregnancy ❍ + ❍ -
❍ Syphilis	❍ + ❍ -		❍ + ❍ -		Details of past and present anamnesis:
❍ Other STDs	❍ + ❍ -		❍ + ❍ -		
❍ HBsAg	❍ + ❍ -		❍ + ❍ -		Medications and allergies
❍ Anti-HBs	❍ + ❍ -		❍ + ❍ -		
❍ Anti-HBc	❍ + ❍ -		❍ + ❍ -		Psychiatric history
❍ Hepatitis A IgG	❍ + ❍ -				Drug and alcohol use

Exposure details	
Exposure date / /	**Exposure time (hour)** **Place:**
Sexual contact	Exposure through medical manipulation or shared needles
❍ Receptive anal intercourse ❍ Ejaculation	❍Occupational ❍ Non-Occupational
❍Insertive anal intercourse ❍ Circumcised ❍ Uncircumcised	❍Shared needle ❍ Medical manipulation
❍ Receptive vaginal intercourse	❍Hollow needle ❍Massive needle ❍Scarifier
❍ Insertive vaginal intercourse ❍ Circumcised ❍ Uncircumcised	Other exposures
❍Receptive oral sex ❍Insertive oral sex	❍Mucous membrane: ❍ Occupational ❍Non-occupational

Other risks	❍ Visible blood splashing:
Did you use a condom? ❍ Yes ❍ No	❍ Superficially ❍ On intact skin ❍ On mucous membrane
Condom condition: ❍ Broke ❍ Came off	Consequences of alcohol or drug intoxication ❍ Yes ❍ No

Assessment of the source of HIV infection							
Sex ❍ Male ❍ Female ❍ Non-Binary							
HIV Positive	ARV Therapy	HIV Risk Group	Partnership type		+	-	Unknown
❍ Known	❍ Not in treatment	❍ MSM	❍ Regular	**HBV**	❍	❍	❍
❍ There are doubts	❍ Unknown	❍ IDU	❍ Random	**HCV**	❍	❍	❍
❍ Known	❍ Treated in the past	❍ Country with high prevalence	❍ Other	**STDS**	❍	❍	❍
Latest viral load: Copy/ml Date:	❍ Currently undergoing treatment			Other STDS. Which?			

Sorting and assignment of PEP		
Date/ /	Time	Location
Is PEP recommended? ❍ Yes ❍ No		Hepatitis B immunoglobulin / /
Regimen initiation ❍ Yes ❍ No		Hepatitis B vaccination / /
Use of PEP in the last 12 months? ❍ Yes ❍ No		
Does the patient agree to take PEP? ❍ Yes ❍ No		
PEP receipt date / /	Time:	

Date of the next visit / /	Was PrEP recommended? ❍ Yes ❍ No

Name of drug	Dosage	Frequency
Hand out contraception? ❍ Yes ❍ No		

I confirm that based on the patient's medical history, the patient had a high-risk exposure to HIV, for which reason a course of post-exposure prophylaxis of HIV infection is indicated.
Physician's name, surname
Signature
Date: / /
E-mail
Phone number

Place of service povision

3.2.6. PEP Applications and Reporting Forms

Application Form

№_____ **Date** _____

Name of the sending organization: _____

Contact_____

Phone Number: _____

E-Mail:_____

Project: Post-exposure prophylaxis of HIV/AIDS - PEP

Patient

15 digit code_____

Age _____

Complaint/Condition _____

Recommended service_____

in effect* (hr) _____

*The time count starts from the time from exposure to the consultation.

Signature

Report Form

№_____ Date _____

Name of the organization _____

Contact _____

Phone Number: _____

E-Mail _____

Project: Post-exposure prophylaxis of HIV/AIDS - PEP

Basis for service provision - application form № _____

15 digit code _____

Services provided:

- o Post-exposure prophylaxis
- o Pre-exposure prophylaxis
- o Risk assessment consultations
- o HIV/AIDS testing
- o Testing for other diseases **Specify:** _____

Additional Comments:

_____

_____

_____

_____

Signature

Chapter IV. Technical Characteristics of the Interventions

4.1. Expected results

Protocol-defined pre- and post-exposure prophylaxis services are provided to populations with high-risk behaviors:

Maintaining the prevalence of HIV infection at current levels;

- Prevention of new HIV cases;
- Reduction of morbidity and mortality from HIV infection;
- Prevention of new STI cases;
- Reducing sexual and other risk behaviors associated with HIV and other STIs;
- Timely detection of HIV infection cases;
- Timely detection of viral hepatitis and timely referral of infected individuals to diagnostic and treatment services;

In the long term, the intervention defined by the protocol will contribute to the comprehensive prevention of HIV infection in Georgia, both among existing risk groups and in the general population. In the long term, PrEP intervention will help reduce the costs associated with HIV infection.

4.2. Resources needed to implement the intervention

Pre- and post-exposure HIV prevention interventions include the provision of both medical and social services, so the following types of logistical resources are needed for the implementation and quality execution of the intervention:

Table 19. Material, Technical and Human Resources Required for Providing Clinical Services

Resources	Need
Material-technical resources	
Fourth generation test for HIV infection	Mandatory
HIV infection/AIDS confirmatory test	Mandatory
Blood and/or serum creatinine level test	Mandatory
Hepatitis B virus surface antigen blood test	Mandatory
Anti-HBs quantitative blood test	Mandatory
Anti-HCV blood test	Mandatory
Syphilis antibody titer blood test	Mandatory
Complete blood count (CBC)	Mandatory
Resources for stocking and storage of medicines	Mandatory
Patients' registration database	Mandatory
Human resources	
Infectious disease physician	Mandatory
Medical epidemiologist	Preferably
Nurse	Mandatory
Pharmacist/dispenser of medicines	Preferably
Database manager	Mandatory

Table 20. Material, Technical and Human Resources Required for Providing Community Services

Resources	Need
Material-technical resources	
HIV infection simple rapid test	Mandatory
Resources for stocking and storage of medicines	Preferably
Human resources	
Social worker	Mandatory
Field worker	Mandatory
Voluntary counseling and testing consultant	Mandatory
Adherence consultant	Mandatory
Risk reduction consultant	Mandatory
Case management specialist	Preferably
Infectious disease physician	Preferably

4.3. Protocol Revision Period

The protocol must be reviewed and revised 2 years after approval. If substantial evidence is accumulated before the above deadline, some components of the protocol may need to be updated early.