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**NATIONAL CLINICAL PROTOCOL
ON PRE-CONTACT AND HIV PREVENTION**

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Pre-exposure prophylaxis of HIV (PrEP).

Pre-exposure prophylaxis of HIV (PrEP) means not only the use of antiretroviral (ARV) drugs by uninfected people, but also a set of preventive measures aimed at preventing HIV infection of a person at risk of infection.

Who is prescribed PrEP?

1. Serodiscordant couples are couples who maintain long-term sexual/sexual relationships in which only one of the partners has HIV.

PrEP should be offered to an uninfected partner in a serodiscordant pair, if the infected partner does not receive ARVs or ARVs are ineffective (detectable viral load), in the case of an undetectable viral load, the infected partner does not need to be present in PrEP.

PrEP can be considered as one of several options to protect an uninfected partner in serodiscordant couples **at the time of conception**.

PrEP is necessary on the basis of local epidemiological factors and individual assessment.

PrEP is a medical intervention that represents a high level of protection against HIV infection, but does not protect against other STIs, and should be used in combination with other prevention methods, including personal protective equipment.

The indication for pre-exposure prophylaxis of HIV infection is the high risk of HIV infection and the patient's willingness to carefully follow the doctor's prescriptions for PrEP, including the regimen of medication and periodic HIV testing.

The PrEP is appointed by commission, a surveillance card is opened for persons who are assigned to the PrEP, personal data, anamnesis, and the reason for the appointment of the PrEP are recorded in the observation card.

The use of PrEP should be monitored by an infectious disease physician/gynecologist experienced in reproductive/sexual health and ART use, if possible as part of the joint monitoring of the patient.

Eligibility criteria for use of PrEP

- No contraindications to TDF or 3TC (FTC)
- HIV-negative status
- Willingness and ability to adhere to PrEP

WHO recommends PrEP if the prevalence of HIV in the high-risk group to which the patient belongs is 3% or more.

Criteria and inadmissibility of the use of PrEP, and special situations

- Pre-onset HIV, before PrEP;
- Creatinine clearance less than 60 ml / min;

- Adolescents <35 kg or <15 years of age, on the Tanner Scale a score of 3 (assessment of puberty) or more;
- Unwillingness/unable to adhere to daily PrEP;
- When prescribing PrEP, it is necessary to pay attention to the fact that TDF / 3TC is active against the hepatitis B virus. Taking TDF / FTC requires careful monitoring in persons infected with hepatitis B, due to the risk of ricochet of viremia in case of discontinuation
- Individuals with osteopenia/osteomalacia/osteoporosis are at risk of bone loss associated with taking TDF;
- Continued PrEP during pregnancy or breastfeeding is recommended for those at risk of HIV infection; Tenofovir is undesirable to use in conjunction with other nephrotoxic drugs (for example, aminoglycosides);
- DOTS drugs do not interact with PrEP drugs and there is no need for dose adjustment;
- Patients on multidrug-resistant TB (MDR-TB) therapy may have an increased risk of kidney side effects. PrEP should be postponed until treatment for MDR-TB ends;
- Standard hormonal contraception does not affect the effectiveness of PrEP, and vice versa, PrEP also does not affect the concentration of hormonal contraception in the blood.

Conducting PrEP

Before the start of PrEP, the patient is counseled, during which he should receive the following information:

- ✓ On the goals and principle of prEP, its effectiveness, role in the complex of measures aimed at HIV prevention;
- ✓ On the principle of voluntary participation in the pre-exposure prophylaxis program;
- ✓ The fact that the drug should be taken by the patient strictly in accordance with the recommendations given by the doctor;
- ✓ On methods of HIV prevention, including measures aimed at reducing the risk of contact with HIV. That the use of personal protective equipment increases the effectiveness of PrEP, further reducing the risk of HIV and STI infection;
- ✓ On the mode of administration of drugs used for PrEP;
- ✓ On the possible side effects of ARVs used for PrEP;
- ✓ On the need for regular medical supervision.

Examination before the start of PrEP

When examining before starting PrEP, it is necessary to make sure that the participant is not infected with HIV to assess whether there are any contraindications or restrictions to the prescription of drugs intended for PrEP.

A confirmed negative fourth-generation HIV test result prior to PrEP allows the administration of TDF/3TC ARVs.

1 month after the start of PrEP, and thereafter every 3 months, HIV testing is necessary.

If a positive HIV test result is detected, PrEP should be stopped and the participant referred for HIV tests.

TDF / 3TC suppresses the reproduction of not only HIV, but also the hepatitis B virus. Therefore, before starting PrEP, it is necessary to determine the serological status of HBV and, in the presence

of this infection, be careful when canceling TDF / 3TC, as this can cause an exacerbation of the course of hepatitis B. The presence of chronic hepatitis B is not a contraindication to the appointment of PrEP, but when it is carried out or the decision to cancel it in these patients, the fact of hepatitis should be present with hepatitis B. The presence of chronic hepatitis B Taken into account.

In addition, TDF can have a nephrotoxic effect and affect mineral metabolism, in particular, bone calcification, which is especially important for older women.

It is necessary to check the renal function (creatinine clearance by the calculation method) and bone mineral density before starting PrEP and every 3 -6 months while taking TDF.

It is also recommended to conduct a study for the presence of diseases that often occur in patients who have a high risk of HIV infection (hepatitis C and STIs). The patient should be provided with information that taking drugs for PrEP may not give an immediate preventive effect, since within seven days after the start of taking PrEP, the concentration of ARVs in the tissues increases to a level that provides the maximum preventive effect.

PrEP can be given for a long time, but each subsequent use of PrEP should be prescribed for a maximum period of 3 months (90 tablets) to guarantee subsequent monitoring.

If a participant is no longer at risk of HIV infection, discontinuation of PrEP is recommended. However, it is recommended that PrEP be discontinued no earlier than 28 days after the last risky contact that may have led to the risk of HIV infection, this will preserve the protective effect of PrEP.

To participate in the pre-exposure prophylaxis program, it is necessary to obtain the voluntary informed consent of the participant.

Recommended clinical and laboratory tests before PrEP:

	Note
Consultation with an infectious disease doctor	Proposal for consultation on adherence to PrEP. In addition to counseling the participant, when collecting anamnesis and physical examination, attention should be paid to the presence of signs of acute HIV and symptoms of STIs. If necessary, it is necessary to consult other specialists.
Test for antibodies to HIV in the blood	Preferably fourth generation test systems. The statute of limitations for testing when prescribing ARVs should not exceed 4 weeks. It is necessary to repeat the test 4 weeks after the start of PrEP to exclude seronegative ocne. The use for this purpose of determining antibodies in saliva is not recommended due to low sensitivity.
Kidney function study	It is necessary to conduct a laboratory analysis of urine, as well as the determination of creatinine in the blood and to calculate the clearance of creatinine (see section ART for renal pathology). With creatinine clearance of less than 60 ml / min,

	PrEP is contraindicated.
Hepatitis B testing	A study on HBsAg is necessary. If a positive result is detected, further actions are carried out, determined by the algorithm for diagnosing hepatitis B. Deciding whether to vaccinate against Hepatitis B in the absence of antibodies to HBsAg
STI test	ELISA antibodies to HCV, serological examination for syphilis.
Pregnancy test for women of fertile age	

ARVs for PrEP

TDF/ 3TC (300/300 mg) 1 tablet daily alternative to TDF/FTC

Individuals starting PrEP may notice side effects of treatment (nausea, spastic abdominal pain, or headache) during the first few weeks, they are usually mild, self-reported, and do not require discontinuation of PrEP. Individuals starting PrEP who have received information about this starting syndrome may show greater adherence to treatment.

Observation during PrEP

The goal is to advise the patient on HIV prevention, find out the patient's HIV status, form and evaluate adherence, identify and correct side effects, identify possible concomitant diseases, including viral hepatitis and STIs.

Recommended examinations during prEP

	Note
Consultation with an infectious disease doctor	1 and 3 months after the start of PrEP. Then every 3 months. Pay special attention to the signs that make it possible to suspect the presence of acute HIV infection and STIs. If necessary, the appointment of consultations of other specialists. At the end of 12 months of PrEP, it is recommended that you discuss with the patient whether it should be continued. If PrEP is terminated for any reason and at any time, it is recommended that the patient be tested for HIV. HIV prevention counselling is

	also provided.
HIV Antibody Test	1 and 3 months after the start of PrEP, then every 3 months
Pregnancy test for women of fertile age	Every 3 months
Creatinine test and creatinine clearance calculation	The frequency of the study after 3 and 6 months, then every 6 months. In diseases accompanied by impaired renal function (for example, diabetes mellitus, hypertension), this study should be carried out more often. With creatinine clearance less than 60 ml / min, PrEP should be discontinued. If creatinine clearance is reduced, but has not reached this level, consultation with a nephrologist is recommended, and the decision to continue PrEP is made individually.
Serological studies for hepatitis B and C, syphilis	Every 6 months
DEXA scans	Despite the fact that TDF negatively affects bone mineralization, special studies of mineral metabolism, in particular DEXA scans, are not recommended during PrEP. However, the question of their appropriateness may arise with prolonged (more than a year) prEP or in patients with an increased risk of osteoporosis.

Adherence

PrEP is only appropriate during periods of risk, not throughout life. PrEP is only effective when ARVs are taken in a timely manner. The best way to maintain adherence to medication is to offer PrEP as a freely chosen method of HIV prevention. Measures to increase adherence to preventive therapy should include informing clients that, when taken correctly, PrEP is a highly effective method of preventing HIV infection and that it is necessary to do so. so that taking these drugs becomes one of the important elements of the daily routine.