Ministry of Health and Social Protection of the Population of the Republic of Tajikistan

Guidelines for the introduction and conduct of pre-exposure prophylaxis of HIV infection in the Republic of Tajikistan

Dushanbe 2020

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Members of the technical working group:

1. Kamolzoda M.G. – Deputy Minister of Health and Social Protection of the Population of the Republic of Tajikistan. Chief Sanitary Doctor – Team Leader ;
2. Vohidov S.D. – Head of the Department of Sanitary and Epidemiological Safety, Emergency Situations and Emergency Medical Care of the Ministry of Health and Social Protection of the Population of the Republic of Tajikistan;
3. Nurov R.M. – Director of the State Institution "Republican Center for prevention and control of AIDS"
4. Nurlyaminova Z.N. – Deputy Directorfor Treatment of the State Institution "Republican Center for prevention and control of AIDS"
5. Talbov U.S. - Head of the Dispensary Department of the State Institution "Republican Center for prevention and control of AIDS"
6. Kholnazarov R.D. - VrAh Infectious Disease Specialist of the State Institution "Republican Center for prevention and control of AIDS"
7. Davlatov B.A. - Infectious Disease Doctor of the State Institution "Republican Center for prevention and control of AIDS"

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Minister of Health and Social
Protection of the Population of
the Republic of Tajikistan
Abdullozoda J.A.

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Content

ABBREVIATION

ART	Antiretroviral therapy
ARWP	Antiretroviral drugs
CART	World Health Organization
HIV	Human immunodeficiency virus
HBV	Viral hepatitis B
EXT	Viral load
ALT	Alanine aminotransferase
PrEP	Pre-exposure prophylaxis
DAN	Sentinel epidemiological surveillance
SDCP	Situational oral pre-contact prophylaxis
AIDS	Acquired immune deficiency syndrome
PHC	Primary health care
SCS	Post-exposure prophylaxis
REAG	Key populations
UGN	Vulnerable groups
LUIN	People who inject drugs
MSM	Men who have sex with men
MHO	International organization
OH	Public (non-profit) organization
RS	Sex workers
UNAIDS	Joint United Nations Programme on HIV/AIDS
TDF	Tenofovir disoproxil fumarate
TAF	Tenofovir alafenamide

Preface

In the Republic of Tajikistan, a steady trend of increasing HIV infections has been formed. Tajikistan is one of the few countries where HIV prevalence has increased by more than 25% over the past 10 years.

Tajikistan is inthe concentrated stage of the epidemic among key populations. HIV prevalence among people who use drugs (PWID) is about 12.9%, among female sex workers (MS) - 3.5% and among men who have sex with men (MSM) - about 2.7% (DEN data 2014, 2015).

In recent years, there have been changes in trends in HIV transmission, and the sexual route of transmission accounts for about 65% of all new cases, which poses a threat of widespread HIV infection among the population. Sexualpartners of key populations (REAG) and people living with HIV (partners of PWID, MSM, living in discordant couples, clients of sex workers) are the most vulnerable in this situation. etc.). In this context, it is particularly important to note the vulnerability of an uninfected partner in discordant couples where one of them is HIV-positive. According to the Electronic HIV Case Tracking System, more than a thousand discordant couples live in Tajikistan.

Tajikistan isstrongly committed to the goals of the Joint United Nations Programme on AIDS (UNAIDS) Rapid Response Strategy for the period 2016-2021, including ending the AIDS epidemic by 2030 and achieving the 90-90-90 targets by 2020.

Particular importance in the eliminationof epi dementia is currently attached to innovative approaches to the prevention of HIV infection, in particular, the introduction of pre-exposure prophylaxis.

These guidelines are intended for medical workers providing coordinated services in the field of HIV infection, with the aim of introducing pre-exposure prevention of HIV infection into the activities of providers of preventive and medical-socialservices in the Republic of Tajikistan (Centers for the Prevention and Control of AIDS, PHC institutions, narcological services, Centers for the Protection of the Population against Tuberculosis, Reproductive Health Centers, Public Organizations, etc.).

The guidelines willbe periodically updated on the basis of new who and UNAIDS recommendations.

I. INTRODUCTION

As defined by the World Health Organization (WHO), oral pre-exposure prophylaxis for HIV infection (PrEP)means the use of antiretroviral drugs (ARVs) by people who are HIV negative to prevent HIV infection before an event occurs that could lead to infection with the virus. WHO recommends that PrEP be offered to all people at increased risk of HIV infection. WHO recommends that PrEP be offered to all people at increased risk of HIV infection. But first of all, representatives of those population groups in which the incidence of HIV infection is at the level of 3 or more cases per 100 people per year.

It is important to remember that PrEP is part of a comprehensive package of prevention services, which should include HIV counselling and testing, the provision of male and female condoms and lubricants, ARV therapy for HIV-infected partners, voluntary medical male circumcision and harm reduction measures for people who inject drugs.

As part of a comprehensive strategy to prevent HIV infection, it is now recommended to offer as oral PrEP combinations containing tenofovir disoproxil fumarate (TDF) in combination with emtricitabine or lamivudine, or tenofovir alafenamide (TAF) in combination with emtricitabine, or a drug containing only TDF.

According to WHO, the effectiveness of oral PrEP among key populations(REAG) is confirmed by twelve trials conducted in Africa, Asia, Europe, South America and the United States. The results of these trials show that the use of ARVs, in particular TDF or combination preparations containing emtricitabine and tenofovir, provides effective pre-exposure prophylaxis of HIV. The degree of protection of people using PrEP did not depend on age, sex, ARV composition (tenofovir alone or a combination drug containing emtricitabine and tenofovir) or on the typeof contact sex (rectal or genital). The degree of protection is directly related to adherence to the Ostrelation Regime.

PrEP is an additional method of prevention that is used in conjunction with existing means , such as condoms. PrEP does not replaceor abolish the use of existing means of prevention. PrEP does not protect against syphilis, gonorrhea, chlamydia, or human papillomavirus (HPV). PrEP should be included in the package of services for

prevention, which includes screening for STIs and their treatment, risk reduction counseling, condoms and contraceptives.

Daily use of oral PrEP reduces the risk of HIV infection through sexual intercourse by more than 90%. The risk of contracting HIV through sexual intercourse can be further reduced by combining PrEP with condom use and other prevention methods.

Among people who inject drugs,DHP reduces the risk of HIV infection by more than 70%. It is important to note that this result was observed in those groups that excluded people with poor adherence and the absence of a detectable drug in their blood. Overall, PrEP reduced the risk of infection in this group of people by 49% *(Data from the Bangkok Study among PWID).*.

II. PURPOSE AND SCOPE OF APPLICATION OF THE METHODOLOGICAL RECOMMENDATIONS

The purpose of this document is to provide an overview of relevant information and issues to be taken into account in the implementation of PrEP for health and social service providers in the field of HIV prevention and treatment, including doctors, nurses, health care providers and NGO staff.

These recommendations were developed within the framework of a joint project of the State Supervision service of health and social protection of the population of the Republic of Tajikistan and the UNAIDS country office, as well as in partnership with ICAP at Columbia University, and are the result of a series of events to discuss the need to introducePREP in the Republic of Tajikistan (round tables and focus groups among REAG) in different regions of the country.

The information included in the guidelines is in line with WHO principles presented in the consolidated guidelines on the use of antiretroviraldrugs for the treatment and prevention of HIV infection (2016) and in the document on situational PrEP among MSM, in addition to the WHO recommendations on oral PrEP of July 2019.

2.1. Guiding Principles of PrEP

In implementing PREP for REAG and UGN, it is important to adopt a public health and rights-based approach.

PrEP does not replace or exclude other effective and standard approaches to HIV prevention, such as condom use and harm reduction programmes for people who inject drugs. Key populations can benefit most from the use of PrEP. At the same time, REAG representatives are the most likely to face stigma and discrimination in access to health services, which must be taken into account and ensure full respect for human rights when implementing PrEP, including the possibility of obtaining PrEP without a person disclosing his or her own services. belonging to a particular REAG. According to public health approaches, the final decision on the use of pre-exposure prophylaxis should belong directly to the person who will apply PrEP.

Like any way to prevent and treat HIV infection, a rights-based approach prioritizes universal health coverage, gender equality and the right to health, including access to and quality of PrEP services.

III. PRE-EXPOSURE PROPHYLAXIS (PREP)

PrEP is the use of ARVs by people with a negative HIV diagnosis to prevent HIV infection before an event occurs that could lead to infection with the virus.

There is a daily PrEP and a situational PrEP (PRSP).

According to WHO recommendations, ARVs, whichare used by people without HIV as PrEP, are a highly effective means of preventing HIV infection. Oral PrEP preparations containing TDF should be offered as an additional prophylaxis for people at significant risk forHIV infection, in combination with other METHODS of HIV prevention.

PrEP involves the use of the following oral medications by HIV-negative people to prevent HIV infection:

- Tenofovir disoproxil fumarate (TDF)
- TDF in combination with emtricitabine (TDF/FTC) or lamivudine (TDF/3TC)
- TAF in combination with emtricitabine (TAF / FTC).

It should be noted that TAF/FTC is currently only recommended for MSM and transgender women (the effectiveness of this regimen on vaginal contact has not yet been sufficiently studied). due to the fact that among MSM who took TDF to treat viral hepatitis were

CASES of HIV infection have been detected,at the present time taking one TDF is not the preferred mode of PrEP for MSM.
Individuals using PrEP should be aware that the protective effect of PrEP can only be achieved after taking a sufficient number of doses. Pharmacological studies have shown that to achieve the maximum level of protection during receptive sexual contact, it is necessary to take the drug for 7 days; it takes 21 days to achieve the maximum level of protection during vaginal contact and the injection route of transmission. Eon achieving the maximum degree of protection, in parallel with PrEP, it is important to use additional protection measures (condoms and sexual practices without penetrating contact)

Adherence to PrEP throughout the period of application is a major factor in the effectiveness of PrEP.

3.1. Indications and contraindications for PrEP

Testimony	Contraindications
• HIV-negative status • No suspected acute HIV infection • Significant risk of HIV infection/Client's desire to receive PrEP without providing information about the risk of HIV infection • Willingness to use PrEP in accordance with doctor's recommendations , including regular HIV testing	• HIV infection • Signs/symptoms of acute HIV infection, probable recent HIV infection. • Estimated creatinine clearance less than 60 ml / min (if known) • Allergies or contraindication to any drug used in PrEP

3.2. Assessment of personal circumstances and risks prior to the appointment of PrEP

PrEP should be granted to all persons who have evidence of PrEP. Prior to practising PrEP, it is necessary to assess personal circumstances, perceived risk and desire to prevent possible HIV infection. It is preferable that the questions for evaluation focus on people's behaviour rather than their sexualidentity. It is important for PrEP service providers to show empathy and understanding when providing support to all people who are willing and able to benefit from PrEP.

Criteria for determining the significant risk of infection with VF:

The client is sexually active in a population with high HIV prevalence (or with representatives of any segment of the population or a certain key group) and reports any of the following facts that have occurred **in the last6 months**:

- Vaginal or sexual contact without a condom with several partners;
- Sexual contact without a condom with a partner exposed to one or more hiv risks;
- STI in the anamnesis (according to the results of laboratory tests or syndromic treatment of STIs, from your own words);
- The use of post-exposure prophylaxis (PEP) in the anamnium;
- Cases of sharing injection equipment with other persons;
- Had or has an HIV-positive sexual partner who has not received effective HIV treatment.

3.2.1. Questions for assessing personal circumstances and risks prior to the appointment of PrEP

Over the past six months:

- "Do you think you're at high risk of contracting HIV?"
- "Have you had sex with one or more partners without condoms?"
- "Have you been trained in safe sexual practices in contact with multiple partners?"
- "Have you had sex with someone whose HIV status you don't know?"
- " Have you injected drugs ?"
- "Did you take drugs using shared co-injection tools?"
- "Have you had partners who are at risk of contracting HIV sexually or through drug use?"
- "Have you had sex with an HIV-positive partner?"
- "Would you be diagnosed with a sexually transmitted infection?"
- "Did you use or want to use PrEP or PEP to prevent HIV?"

3.2.2. Questions for discordant couples

- " Does your sexual partner receive ARVs ?"
- "Has your partner been getting ARVs for more than six months?"

- "Are you sure your sexual partner is taking ARVs daily as prescribed by your doctor?"
- "Do you know when your partner's last viral load (HV) test was done and what the result was?"
- "Do you plan to have a baby with your partner?"
- "Do you use a condom during every sexual encounter?"

3.2.3. Additional factors for identifying situations of increased vulnerability to HIV

Have you had situations that may indicate an increased risk of HIV infection, such as:

- "Have you had sex with a new partner?"
- "Have you ended a long-term relationship or are you now looking for a new partner?"
- "Did you receive money, housing, food or gifts in exchange for sexual intercourse?"
- "Were you forced to have sexual intercourse against your will?"
- "Have you used injectable drugs or hormones using injection equipment with other people?"
- "Have you used psycho-stimulants or drugs?"
- "Have you lost a source of income, which is why you have to provide sexual services for income, food or shelter?"

Note e: *If the answer "yes" received from a representative of REAG or UGN to any of the questions should immediately begin discussing the risks of HIV infection and the benefits of PrEP. If a person themselves express a desire to receive PrEP, but does not disclose information about their risky behavior, it is also necessary to immediately begin to discuss the risks of HIV infection and the benefits of PrEP.*

3.3. Conducting PrEP

PrEP should be applied daily during periods of significant risk of HIV infection and can be stopped with little or no risk of infection. Situations that determine the beginning or end of risk periods will vary by region, demographic, sociocultural practices, and individual factors .

3.4. Rule out HIV infection before PrEP

All people at significant risk of HIV infection and people who may meet the criteria for PrEP should be encouraged to be tested for HIV. A rapid HIV test should be performed on the same day that PrEP begins and is desirablebut at the point of care. HIV testing will be conducted in accordance with the national HIV testing algorithm. In the case of a positive HIV test result, it is urgent to refer the person to start ART.

If a client has signs or symptoms of acute viral syndrome (acute HIV infection), PrEP should be delayed for four weeks, followed by retesting, which provides the time needed to detect possible seroconversion. Acute HIV infection is the initial stage of HIV disease, characterized by the manifestation of acute viremia. This stage develops in about 40-90% of infected individuals. Symptoms appear within 2 to 4 weeks of HIV infection. Mostpatients with acute HIV infection experience flu-like symptoms, such as fever, pharyngitis, headache, myalgia, as well as an increase in L/NODE, rash, nausea and vomiting, hepatosplenomegaly. These symptoms are not characteristic symptoms. HIV, they can manifest themselves in many other viral infections.

In the future, after the appointment of PrEP, HIV testing is recommended to be carried out after 1 month and then every 3 months.

3.5. Commitment to PrEP

Adherence to PrEP is a critical factor in reducing the risk of HIV infection. As the use of PrEP has increased, interventions to promote adherence to PrEP have become increasingly important. Adherence support should be based on reporting to the patient the high efficacy of PrEP if used correctly and adhered to. Individual counseling is useful for coordinating daily medication with the usual way of life (time of rising, going to bed and eating). Customers should not be compelled to use PrEP. It is necessary to maintain support in the discussion and monitoringof commitment (not to reprimand clients for poor adherence or refuse to dispense the next doses of medication) and to have a constructive discussion that can help the client in finding solutions to difficulties in complying with the impulse. In cooperation with the attending physician, with

With the prior consent of the client, peer counsellors and PEER counsellors provide the necessary psychological and social support to clients using PrEP. Research results indicate that adherence is higher among individuals who understand that they are at risk. HIV infection, and motivated to take PrEP.

3.6. Side effects

In 10% of cases, people who start PrEP may experience side effects in the first few weeks of using the drugs. These side effects include nausea, abdominal cramps, headache , etc. They are usually minor, occur without taking any action, and do not require discontinuation of PrEP. Adherence to PrEP in people who have been informed in advance of these initial side effects may be higher.

3.7. Monitoring of kidney and liver function

Tenofovir disoproxyl fumarate (TDF) may be accompanied by a slight decrease in the design glomerular filtration rate (rSCF) at the initial stage of PrEP. This usually doesn't progress. PrEP is not indicated for use if rSCF <60 ml / min.

If not determinedin the laboratory, the rSCF can be calculated using the Cockcroft-Gault formula:

rSCF = [140-age (number of years)] x body weight (kg) x f

where f=1.23 for men and 1.04 for women / [72 x serum creatinine (μmol/L)].

The determination of creatinine is recommended at the beginning of PrEP, quarterly for the first 12 months of PrEP, and then once a year. The lack of results in determining the level of creatinine should not prevent the onset of PrEP.

It is also recommended to test individuals receiving PrEP for hepatitis B virus surface antigen (HBsAg). Tenofovir disoproxyl fumarate (TDF) is active against HBV at the same dose as for PrEP. Discontinuationof PrEP in individuals with HBV (as well as discontinuation of active treatment of HBV) can lead to virological and clinical relapse. Individuals with detectable HBsAg and elevated ALT levels more than twice as high as the upper limit or clinical signs of cirrhosis need long-term therapy for HBV. In cases where HBsAg is not detected and there is no information about vaccination in the past, clients are advised to vaccination against hepatitis B

(although PrEP may bepre-delivered even if hepatitis B vaccine is not available or the client refuses to be vaccinated).)

3.8 Termination of PrEP

PrEP is usually used only during periods of risk, not for life.

PrEP can be terminated when the person taking PrEP is no longer at risk of infection, provided that this situation continues to persist in the future. Periods of risk can begin and end due to life changes, such as , for example, relationships with a sexual partner, alcohol and drug use, migration, etc.
Like PEP, PrEP can be discontinued 28 days after the last potential contact with HIV infection if a person has no significantrisk of HIV infection.
For people who are in a monogamous relationship with an HIV-infected partner who has complete and persistent viral suppression while taking ART, the risk of contracting HIV infection is very low. In this situation, it is advisableto discuss with the HIV-negative partner the possibility of stopping PrEP.

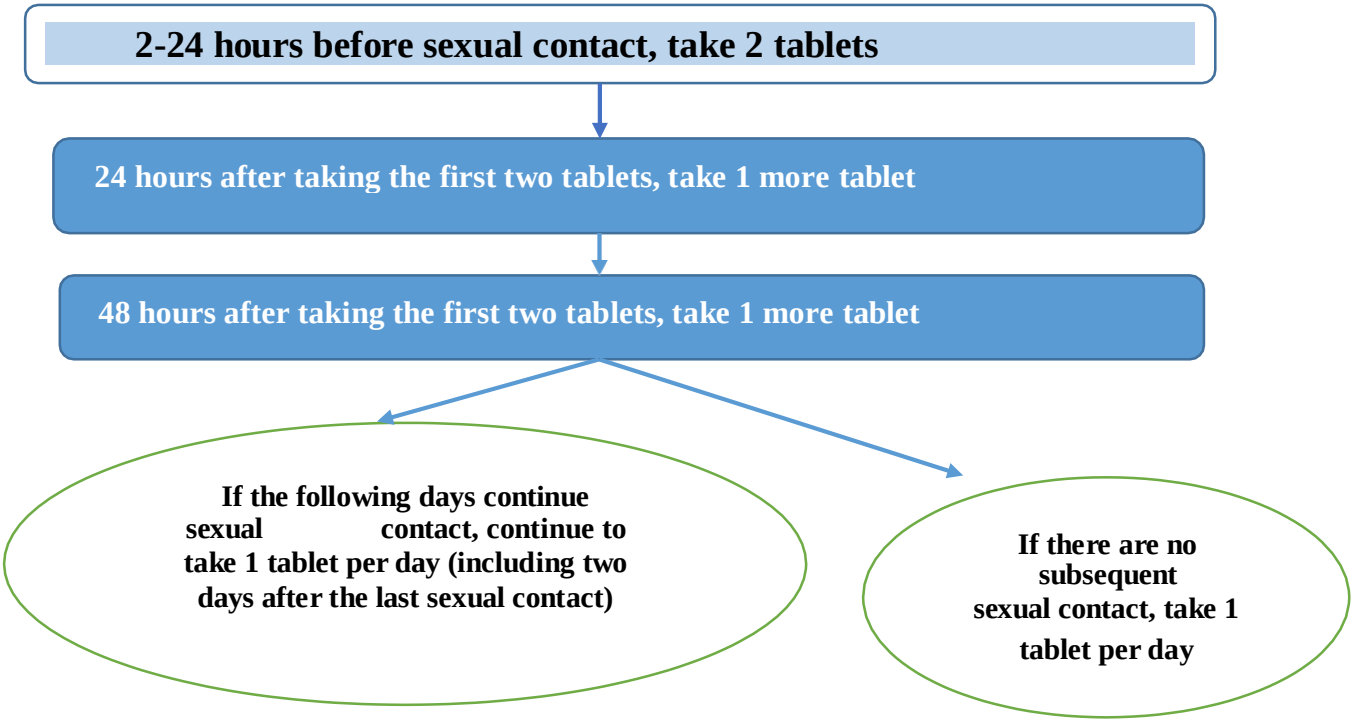
PrEP and women
All available data described in WHO guidelines support the use of PrEP in pregnant and lactating women who are at risk of HIV infection at all times. PrEP may also be seen as a way to reduce the risk of HIV infection at the time of conception if a woman planning a pregnancy is unsure of her partner's HIV status. Women taking hormonal contraceptives can safely use PrEP because PrEP is not affected by PrEP. on the effectiveness of hormonal contraceptives and hormonal contraceptives do not reduce the effectiveness of PrEP. PrEP does not protect against pregnancy. PrEP is safe and can be continued during pregnancy and breastreinforcement

3.9. Situational PrEP (PRSP) is currently only recommended for men who have sex with men (for all other groups, efficacy data are scarce to date). DMCP for MSM involves taking a double dose (two tablets that serve as a satiating dose) of TDF/FTC (or TDF/ 3TC) in the period from two to 24 hours before the alleged sexual intercourse, then the third andbletka 24 hours after taking the first two tablets and the fourth tablet 48 hours after taking the first two tablets.

SDCP is also described as a "2 + 1 + 1" DCP scheme - such a description can help inforConsider this approach as an alternative to daily intake PrEP for Men Practicing sex c Men. Scheme PrEP
"2 + 1 + 1" is the only SDCP scheme that has proven to be effective (and only when used by men who havesex with men).

The 2+1+1 SDCP scheme can be used in the case of single or rare sexual contacts. With continued sexual contact with a high risk of HIV transmission, it is recommended to continue daily use of PrEP for as long as the sexual contact lasts, plus another pill a day should be taken two more days after the last sexual contact.

Algorithm for the use of THE PRSP



Based on the available evidence, namely the results of a number of studies, WHO has included the possibility of situational use of PrEP for men who have sex with men in the current recommendations for oral PrEP.

Daily oral D-KP is still recommended for people at increased risk of HIV infection, including men who have sex with men. The following are cases where PRSP may be considered as an alternative to daily PrEP.

The PRSP has been highly effective in reducing the risk of HIV infection among men who have sex with men and has the following additional benefits:

• provides choice and convenience for MSM who are at increased risk of HIV infection for a short time or who practice sexual intercourse on average less than 2 times a week;

• A good option for PrEP for MSM, who can predict, plan or postpone their sexual contacts;

• reduces the number of tablets taken ;

• reduces costs due to fewer necessary pills, including costs for the client if he purchases PrEP drugs on his own.

It is possible to move from daily PrEP to DMCP and vice versa. If sexual contact lasts more than one day, the client can protect himself from HIV by taking one pill every day for the duration of the continuation of sexual contact and stopping taking PrEP 2 days after the last sexual contact. Conversely, if the client begins daily oral administration of PrEP, and then his sexual contacts become infrequent and predictable, he can switch to PRS.

HIV testing every 3 months is recommended for both those who take PrEP daily and those who use PrEP situationally. Typically, testing is done when customers apply for a new prescription for PrEP.

When the appointment of **the SDCP** may **be considered**

Who is suitable for the SDCP?	**Who is NOT suitable for THE SDCP?**
• men who have sex with men: – for which the PRSP can be more convenient and efficient – who have infrequent sexual contact (for example, on average less than 2 times a week) – who can plan sexual intercourse for at least 2 hours or can postpone sexual intercourse for at least 2 hours	• cisgender or transgender women • transgender men practicing vaginal/frontal sex • men who have vaginal or sex with women • people with chronic hepatitis B

IV. RESOURCES AND MATERIALS NEEDED TO IMPLEMENT AND IMPLEMENT PREP *(based on WHO recommendations, 2016)*

Institutions providing PrEP services	**Personnel:** - doctor - nurse - laboratory assistant - social worker, peer consultant **Equipment, equipment:** tonometer, phonendoscope, rostomer, scales. The ability to carry out yourself or redirect to other institutions to determine: a general detailed blood test, a general urinalysis, abiochemical blood test (*glucose, bilirubin and its fractions, ALT, AST, alkaline phosphatase, urea, creatinine),* ECG, serological testing for HIV and viral hepatitis B and C. **Availability of ARVs : TDF/FTC or TDF/3TC.**

4.1The list of data recommended for collection in health organizations:

Number of people receiving antiretroviral drugs for the first time for PrEP.
This indicator measures progress made in providing PrEP. Frequency of measurement: Every 12 months.
Breakdown of data:

- Gender and age
- Administrative-territorial units (city/district, region, republic)
- Key population groups - MSM, RS, PWID and their partners, partners of PLHIV.
- Vulnerable groups of the population - persons in prison, discordant couples,horses, labor migrants.

Institutions:

- AIDS Prevention and Control Centers
- PhC institutions, including OMCP
- Reproductive Health Centers
- IK (correctional colonies)
- Public organizations

V. LIST OF REFERENCES USED IN THE PREPARATION OF METHODOLOGICAL RECOMMENDATIONS

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