MINISTRY OF HEALTH

REPUBLIC OF BENIN

NATIONAL GUIDE TO IMPLEMENTATION OF PROPHYLAXIS PRE-EXPOSURE TO HIV

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PREFACE

In 2016, the Joint United Nations Program on HIV/AIDS set itself the objective to end the AIDS epidemic by 2030. The screening of people living with human immunodeficiency virus (HIV) as well as treatment with ARVs are tools important to achieve this objective. Pre-exposure prophylaxis (PrEP) is one of the strategies to control the epidemic of HIV infection. Based on treatment prevention of people at risk, it consists of the administration of active drugs against HIV before potential exposure. PrEP offers a remarkable opportunity to prevent acquisition of HIV by people at risk.

It is with this in mind that the National Council for the Fight against HIV/AIDS, Tuberculosis, malaria, hepatitis, sexually transmitted infections and epidemics (CNLS TP), in its integrated national strategic plan (PSNIE) 2020-2024 as well as the Program Health for the fight against AIDS (PSLS), in the policy document, standards and procedures of management of PLHIV revised in 2019, have made PrEP one of the important axes of HIV prevention in Benin.

PrEP involves the use of antiretroviral drugs (ARVs) by people HIV negative. Several authors through clinical trials have demonstrated the effectiveness of PrEP in men who have sex with men (MSM) and women transgender (TG), serodiscordant couples, heterosexual men and women and injection drug users (IDU).

PrEP is provided as one component of a package of health interventions. HIV prevention including regular HIV testing, promoting the use of condoms and their distribution, screening and management of sexually transmitted infections communicable diseases (STIs), counseling services aimed at reducing risks. It is worldwide recognized that PrEP constitutes an important means of this set of interventions and that it should be offered to people at high risk of HIV infection in the part of a combined approach to HIV prevention.

The Ministry of Health (MS), as part of the quality approach in the health sector, has been engaged for several years in the standardization of activities through the development and establishment of normative documents. This document, which is a national guide to implementing implementation of HIV pre-exposure prophylaxis (PrEP) will make it possible to standardize interventions within the framework of this approach throughout the national territory.

Based on WHO recommendations, this guide, reinforced by the most recent data about PrEP, contains national recommendations for health professionals and socio-community actors in Benin with regard to the indications as well as advice on the modalities relating to the use of PrEP.

It seems judicious that those involved in the fight against HIV/AIDS infection in Benin, in particularly those involved in the provision of PrEP services appropriate this working tool to quality interventions and the well-being of our populations.

Health Minister

Benjamin IB HOUNKPATIN

THANKS

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SUMMARY

LIST OF ACRONYMS AND ABBREVIATIONS

ANRS: National Agency for Research on AIDS and Viral Hepatitis

ARV: Antiretrovirals

COVID-19: Coronavirus disease 2019

MSM: Men who have sex with men

HIV: Human immunodeficiency virus

CI: Confidence interval

IPERGAY: Preventive Intervention of Exposure to Risks with and for Gays

IPrEx: Preexposure prophilaxis initiative

STI: Sexually Transmitted Infection

WHO: World Health Organization

UNAIDS: Joint United Nations Program on HIV/AIDS

PrEP: Pre-exposure prophylaxis

PEP: Post Exposure Prophylaxis

PLHIV: Person living with HIV

ART: Antiretroviral treatment

TDF/FTC: Tenofovir/Emtricitabine

TG: Transgender

TS: Sex worker

IDU: Injection drug users

HAV: Hepatitis A virus

HBV: Hepatitis B Virus

HCV: Hepatitis C virus

HIV: Human Immunodeficiency Virus

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SUMMARY

The HIV epidemic remains concentrated among key populations in Benin with a prevalence low in the general population (1.2% in 2012) but high among key populations. According to the ESDGs carried out within these key populations, HIV prevalence is 7% among MSM (2017); 8.5% among PS (2017); 2.2% among IDUs (2017) and 21.9% among Transgender (year 2020).

All operational plans developed in Benin have recommended the adoption of strategies innovative and differentiated with the aim of removing bottlenecks in implementation and catch up on coverage of HIV services among adults (especially key populations and pregnant women). The WHO having recognized growing the potential of PrEP as an additional HIV prevention option and having asked countries to consider how PrEP could be implemented on most effectively possible, Benin has defined the broad outlines of PrEP in the document policy, standards and procedures for the care of PLHIV.

This guide describes in an operational manner the implementation of Pre-Prophylaxis Exposure (PrEP) in a medical setting and the role that communities must play.

In Benin, PrEP is indicated for all people aged 18 and over who are not using systematically wear a condom during sexual intercourse and who are at high risk of contract HIV.

The groups concerned are:

- MSM and transgender women;
- Serodifferent heterosexual men and women;
- Sex workers.

The eligibility criteria generally include:

- HIV seronegativity;
- No suspicion of acute HIV infection;
- Significant risk of HIV infection;
- Normal renal function;
- No contraindication to PrEP medications (e.g. TDF/FTC);
- Willingness to use PrEP as prescribed, including periodic testing HIV testing.

Oral PrEP can be offered to MSM as a daily regimen (continuous PrEP) or diet depending on events (PrEP on demand). Regarding couples serodiscordant and HCWs having vaginal sex, continuous PrEP is the option recommended.

One FTC/TDF tablet per day is the recommended regimen for continuous PrEP. THE tablet can be taken with or without a meal. Regarding on-demand PrEP, for To cover a single risk, you need four tablets taken in three doses as follows:

- 1st dose: Two tablets of the TDF/FTC combination taken at the same time between 2 hours and 24 hours before sexual intercourse;
- 2nd dose: One tablet of the TDF/FTC combination to take for approximately 24 hours (at longer or less 2 hours) after the first dose;
- 3rd dose: One tablet of the TDF/FTC combination to be taken for approximately 24 hours (at longer or less 2 hours) after the second dose.

This process should be repeated for each period of potential HIV exposure.

In Benin, the offer of PrEP to eligible populations will be provided by treatment sites. care of PLHIV accredited by the PSLS and for whom the providers will benefit from a specific training and adequate support. These sites are integrated into the training public and private health facilities at all levels of the health pyramid. The combination (TDF/FTC) being an antiretroviral drug, only authorized health workers in the structures care providers for PLHIV are authorized to prescribe PrEP. Community agents (peer educators, mediators, etc.) will play a supporting role during implementation of PrEP. This role is broken down as follows:

- Raising peer awareness with PrEP awareness tools;
- Distribution of male and female condoms and lubricating gels;
- Distribution of HIV self-tests;
- Raising peer awareness of PrEP regimens;
- Sensitization of peers and members of identity associations on the orientation and supporting clients on PrEP;
- Offer of adherence support (nutritional support, psychological support, monitoring of compliance with tablet intake, management of side effects, etc.)
- Community follow-up (search for those lost to follow-up, home visit).

INTRODUCTION

Despite the remarkable progress made in the treatment of HIV, the annual number of new infections worldwide have stood at 2 million for several years; with approximately 1.5 million new infections for the year 2020. Thus, a large number of people are still at high risk of HIV infection. Among key populations with high risk include sex workers (SW), men who have sexual intercourse with men (MSM), transgender people (TG), injecting drug users (UDI). This reality shows that it is imperative to continue efforts to expand access to effective HIV prevention interventions while continuing to scale up access HIV treatment programs for people living with HIV. There Pre-exposure prophylaxis (PrEP) is an effective HIV prevention intervention. She involves the use of antiretroviral (ARV) drugs by HIV-negative people to HIV in order to prevent acquisition of the virus. Several clinical trials have demonstrated the effectiveness of PrEP in MSM and transgender women, serodiscordant couples, heterosexual men and women. PrEP is provided as one component of a package of HIV prevention interventions including regular HIV testing, promotion of the use of condoms and their distribution, screening and care sexually transmitted infections (STIs), counseling services aimed at reducing risks and harm reduction interventions. It is globally accepted that the PrEP is an important tool in this set of activities and should be offered to people at high risk of HIV infection as part of an approach combined HIV prevention. Key populations (TS, MSM, TG) and couples serodiscordant to HIV can benefit from this new intervention by referring to the sites dedicated to PrEP in Benin. This explains the development of this guide, which aims the harmonization of provider practices in the provision of PrEP on all care sites for PLHIV.

1. GENERAL

1.1. Context and rationale

The HIV/AIDS epidemic has continued to progress throughout the world, despite the efforts of the different sectors involved in the fight against this pandemic. According to UNAIDS at the end of 2020 around the world, about 84% of people living with HIV knew their status, 73% were receiving antiretroviral treatment and 66% had successfully suppress the viral load minimizing the risk of infecting other people. That being said, between

the peak of 1997 and 2020, new HIV infections decreased by 52%; between the peak of 2004 and 2020 virus-related deaths decreased by 64%, anti-retroviral treatment (ART) made it possible to save nearly 20 million lives. This progress was achieved thanks to the efforts considerable efforts deployed by national HIV programs supported by the civil society and international development partners. Due to the shortcomings suffer from HIV services, UNAIDS estimated in 2020, 680,000 the number HIV-related deaths and 1.5 million the number of new infections [1].

In order to achieve the new 95-95-95 objectives (the three 95s) proposed on a global scale, we will have to redouble our efforts to avoid the worst-case scenario of half a million deaths additional cases in sub-Saharan Africa, the increase in the number of cases of HIV infection due to interruptions in HIV services during the COVID-19 pandemic and the slowdown in public health action to combat HIV. Interventions should be focused on populations that are insufficiently covered, particularly key population groups and their sexual partners who represented, in 2020, more than 65% of all new cases HIV infection worldwide among 15-49 year olds. If in sub-Saharan Africa key populations and their partners accounted for 39% of new infections in 2020, the situation is more worrying in Eastern Europe, Central Asia, the Pacific, Western and Central Europe, North America, the Middle East and North Africa, where these groups accounted for 93% of new cases [1].

Several studies have reported the effectiveness of PrEP and in all of these studies, its effectiveness on acquisition of HIV is optimal among those who use it continuously; she is slightly higher among MSM (92%) than among heterosexuals (90%) [2-3]. The whole thing first randomized trial of PrEP among MSM was a multi-country study (Peru, Ecuador, South Africa, Brazil, Thailand and the United States) entitled iPrEx (“Pre-Exposure Prophylaxis Initiative"), the aim of which was obviously to assess the safety and efficacy of the daily intake of Truvada® (TDF/FTC) as a measure to prevent the acquisition of HIV. This study, conducted from 2007 to 2009, reported a low effectiveness of Truvada® at 44% (95% CI: 15-63) [4]. PrEP basically gained momentum from two other trials randomized. The first in England from 2012 among MSM at high risk of acquisition of HIV and whose therapeutic regimen is based on daily intake of Truvada® versus that of a one-year deferred intake (Pre-exposure Option for Reducing HIV in the UK: immediate or Deferred) known as the PROUD study and which reported an effectiveness of 86% (90% CI: 64-96%) [5]. The second is the Franco-Canadian ANRS trial (Agence Nationale de Recherches

on AIDS and viral hepatitis), IPER§/GAY (Preventive Intervention for Exposure to Risks with and for Gays) started in 2012. This is an on-demand PrEP trial, either taking PrEP only at the time of exposure to sexual risks versus taking placebo. This trial reported that on-demand PrEP decreased by 86% (95% CI: 40-98%) the risk of being infected with HIV [6]. The results of this trial in its so-called “in-process” phase open” similar to a PrEP demonstration project, the post-trial follow-up phase is even more spectacular than those of the test phase itself. These results confirm the very good effectiveness and very good tolerance of PrEP to prevent the risk infection among MSM. Indeed, the relative reduction in HIV incidence under PrEP at the demand is 97% (95% CI: 81-100) [7]. At the end of this study, it is reported that the MSM who were interested in PrEP were mostly those at very high risk of acquiring HIV similarly to those randomized in the phase of the trial itself [8]. The open phase following the IPrEx randomized trial further reported that risky sexual behaviors of HIV acquisition are associated with a high rate of PrEP initiation, adherence greater therapy and persistence on PrEP (retention on PrEP both long as risk behaviors for HIV acquisition). For this phase, the efficiency of PrEP varied according to the level of therapeutic adherence and was 84% (95% CI: 21-99%) for 2-3 doses of Truvada® pills per week, and 100% for a dose of at least 4 pills per week [9].

Through the Ashodaya PrEP project carried out in India among sex workers, no HIV seroconversion was observed in HCWs adherent to the third (M3) and sixth (M6), similarly a decrease in the prevalence of STIs was reported during the same study recommending the scale-up of PrEP among HCWs [10]. The same observation was reported on the reduction of STIs in HCWs during an effectiveness demonstration study of PrEP in Benin, however in this study, PrEP was shown to be useful for TS but on condition that they are adherent [11].

The SEARCH randomized trial carried out in Kenya and Uganda among serodiscordant couples, people working in the transport or fishing industries and individuals considered at risk of HIV acquisition, showed a 76% reduction in the incidence of HIV in women who have been on PrEP (TDF/FTC) compared to the placebo group. By elsewhere in the ECHO study conducted from 2015 to 2018 with 75% of participants coming from South Africa, the reduction in HIV incidence was 55% among women using contraceptives [12].

The WHO consolidated guidelines in November 2015 [13] recommended the use antiretroviral drugs for the treatment and prevention of HIV infection. These recommendations follow clinical trials that have demonstrated the effectiveness of PrEP as additional tool of a diversified prevention strategy. Review of data in 2015 established that pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate (TDF), an ARV drug, administered alone or in combination with emtricitabine (FTC), is effective in preventing HIV transmission in all cases and within of all populations according to the proposed schemes. The update of recommendations (2015) includes a new recommendation on the use of oral pre-exposure prophylaxis (PrEP) to block HIV acquisition. The WHO has expanded the scope of these previous recommendations to offer PrEP to targeted key populations. HIV PrEP is now recommended for all populations at substantial risk of HIV acquisition, tentatively defined as an HIV incidence rate of more than three cases per 100 person-years in the absence of PrEP. As part of a combination of approaches to HIV prevention, pre-exposure prophylaxis (PrEP) to oral TDF must be added to the choices regarding prevention available to people at substantial risk of acquiring HIV (strong WHO recommendation).

According to data from the fourth edition of the demographic and health survey, Benin displays an HIV prevalence of 1.2% among people aged 15 to 49 in the population general [14]. This figure hides the disparities that exist between geographical areas but also between specific groups within the general population. The epidemic remains concentrated in key populations. According to biobehavioral studies carried out in key populations in 2017, HIV prevalence is 7% among MSM [15], 8.5% among TS [16] and 2.2% CDI [17]. With regard to transgender people, the study carried out in 2021 has revealed an estimated prevalence of 21.9% [18].

In Benin, MSM have little knowledge of PrEP. But once well informed, the majority of they seem ready to use it if it is available. “The free availability of the medicine and its accessibility in MSM networks are important facilitators” [19].

Operational plans developed in Benin recommended the adoption of innovative strategies and differentiated with a view to removing bottlenecks in implementation and catch up on coverage of HIV services to key populations. Despite the increasing availability of HIV testing services in Benin, much effort remains

to be done to reach the goal of the first 95. Following the recommendation of the WHO in 2015 that “oral pre-exposure prophylaxis (PrEP) should be offered as an additional prevention choice for people at high risk of infection with HIV in the bundle of combined HIV prevention approaches", and taking into account the evidence demonstrated by studies on the effectiveness of PrEP, Benin has defined the major lines of PrEP implementation in the document of standards and procedures for taking into account care of PLHIV (2019 edition). It is within this framework that the PSLS, with the support of the WHO and of UNAIDS is committed to designing the national guide necessary for the operationalization of Pre-Exposure Prophylaxis (PrEP) by the various stakeholders in Benin.

1.2. Goals

1.2.1. Main objective

Have a standard reference document for the implementation of PrEP in Benin

1.2.2. Specific objectives

- Describe the stages of implementing PrEP in Benin;
- List the target beneficiaries of PrEP in Benin;
- Describe the PrEP modalities available in Benin;
- Describe the roles and responsibilities of the different actors involved in the implementation PrEP implementation in Benin.

1.3. Concept definitions

“Pre” = before

“Exposure” = act that can lead to HIV infection

“Prophylaxis” = preventive treatment to prevent infection from occurring.

Pre-exposure prophylaxis (PrEP) is a new HIV prevention strategy. He involves offering to a person who does not have HIV, who does not systematically use the condom during sexual intercourse and who is at high risk of contracting HIV, a active medication against this virus in order to avoid contamination. This principle is not new : PrEP protects against HIV just like certain drugs protect against malaria or like A birth control pill prevents unwanted pregnancy. PrEP is part of a combined prevention strategy combining screening and early treatment of STIs, screening repeated HIV, counseling with distribution of condoms and lubricants. take in account the

different routes of HIV transmission, PrEP strategies will need to be adapted to each risk group.

This preventive treatment is accompanied by a reinforced monitoring system and must be used in as part of a diversified prevention strategy. Taking this treatment, in strict compliance of the prescription, makes it possible to obtain a blood concentration of antiretrovirals reducing the risk of contracting HIV if the subject comes into contact with an infected person [20]. Several results from clinical trials have proven the effectiveness of this strategy with a relative risk reduction ranging from 44% to 97% depending on the studies. The effectiveness is strongly dependent on treatment compliance [20,21]. This strategy is recommended by the World Health Organization for people at high risk of HIV infection [22]. **Post-exposure prophylaxis or PEP** consists of taking emergency antiretroviral drugs after taking a risk such as an accident of exposure to biological fluid or an accident of sexual exposure. It is recommended to initiate ART during post-treatment exposure within a maximum period of 48 hours after exposure to the risk for a period of a month. Do not confuse PrEP with PEP.

TasP: Treatment as Prevention, is treatment as a means of prevention and concerns HIV-positive people. Initiated as soon as possible after diagnosis, it aims to achieve an undetectable viral load in observant subjects, thereby limiting the risk of contamination of HIV-negative partners, it is used less since the advent of the treaty all (Test and Treat) [22, 23].

The **TDF/FTC combination** is the only medication currently available for PrEP in Benign. It is an antiretroviral treatment that combines two anti-HIV molecules: emtricitabine and tenofovir disoproxil fumarate.

Globally, research continues to identify other drugs as well. effective than Truvada® for PrEP, as well as other routes of administration (gel, injections, implants) [24].

It is important to remember that PrEP like PEP only protects against HIV, not others. sexually transmitted infections such as gonorrhea, condyloma, chlamydia, hepatitis B/C, syphilis, etc. nor pregnancy. When taking PrEP it is therefore essential to have regular check-ups for STIs and to have good control over contraception [22].

1.4. Legal and policy framework

1.4.1. Regional and international instruments

United Nations member states have adopted a series of ambitious new goals set out in the political declaration on HIV and AIDS: “Ending inequalities for defeat AIDS by 2030”. If the international community respects these objectives, 3.6 million new HIV infections and 1.7 million AIDS-related deaths will be avoided by 2030 [25].

Political declaration calls on countries to provide access to prevention options effective and people-centered HIV treatment for 95% of all people exposed to a risk of contamination in all populations, age groups and situations geographic areas relevant to the epidemic. It also urges countries to ensure that 95% of people living with HIV know their HIV status, 95% of people who know their HIV status are on treatment and 95% of people on treatment have an undetectable viral load.

The political declaration highlights a worrying situation: key populations (gays and others men who have sex with men, sex workers, consumers injecting drugs, transgender people,:,, in prison and in closed environments) are more likely to be exposed to HIV and face violence, stigma, discrimination, as well as laws limiting their freedom of movement or access to services. Member States agreed on a target of ensuring that less than 10% of countries have restrictive legal and policy frameworks leading to the prohibition or limiting access to services by 2025 [25].

Since 2015, the WHO has published recommendations encouraging the provision of PrEP containing Tenofovir as an additional prevention option for all people at substantial risk of contracting HIV. Using TDF with FTC for HIV prevention has been approved in France, Kenya, South Africa and the United States of America [26].

In recognition of these orientations, during the high-level meeting entitled “Call for Dakar to reinvent the response to the HIV pandemic: a renewed commitment to end to AIDS in West and Central Africa. which was held from October 31 to November 2, 2021, the heads of state of Senegal, the Democratic Republic of Congo, the first lady of Sierra Leone, health ministers from 15 countries, civil society leaders from the region and

multilateral and bilateral partners in the global response to HIV, and to fill the gap delay, several recommendations were issued including " **Updating policies health to align them with the most recent scientific data to respond to the HIV pandemic »** . This recommendation includes PrEP as a prevention tool combined against HIV [27].

1.4.2. National instruments

The Constitution of December 11, 1990, as amended by Law No. 2019-40 of November 7 2019, in its articles 8 and 26, stipulates that the right to health is a major issue for the development of our society.

Law No. 2005-31 of April 5, 2006 relating to the prevention, care and control of HIV/AIDS in the Republic of Benin organizes HIV interventions and it is to this law that refers to the document of standards and procedures for the care of PLHIV revised in 2019 which integrates PrEP as a complementary HIV prevention measure.

Law No. 2020-37 of February 3, 2021 protecting the health of people in Republic of Benin in its article 3 aims to guarantee the realization of the right to health for all

The National Health Policy (PNS): which aims to translate Government policy into the health sector, ensuring the improvement of the quality of life of populations

1.5. Methodology for developing the PrEP implementation guide

The guide was developed by a consultant recruited by WHO and UNAIDS and made available of the PSLS. This consultant, after a PSLS scoping session, met the main stakeholders national response to HIV including beneficiaries and TFPs to collect their guidance on the specificities to be added to the document alongside the recommendations of the WHO. The consultant presented to the members of the CNSSP the broad outlines of the document to be develop and received their comments. Taking into account all orientations including those of the CNSSP, a draft of the guide was proposed by the consultant. Following the filing of this draft, the CNSSP set up a technical work team (ETT) which carried out its review before submission to CNSSP advisors. The document reviewed by the ETT was studied during the second ordinary session of the CNSSP held from February 21 to 24, 2022.

The observations of the CNSSP were taken into account by the consultant and the final document submitted to be validated by all stakeholders.

2. MAIN PROVISIONS

2.1. Indications for PrEP

In Benin, PrEP is indicated for all people aged 18 and over who are not using systematically wear a condom during sexual intercourse and who are at high risk of contract HIV.

The groups concerned are:

- MSM and transgender women
- Serodifferent heterosexual men and women
- Sex workers

The eligibility criteria generally include:

- Seronegativity
- No suspicion of acute HIV infection
- Significant risk of HIV infection
- Normal kidney function
- No contraindications to PrEP medications (e.g. TDF/FTC)
- Willingness to use PrEP as prescribed, including periodic testing HIV testing

Each target group must meet specific criteria.

2.1.1. MSM and transgender women

PrEP is recommended for MSM and transgender women if they have had anal sex unprotected by a condom in the last six months and that one of the following situations applies:

- Syphilis or other bacterial, viral or parasitic anal STI, particularly if This was diagnosed within the last six months;
- Sexual relations with an HIV-positive partner when the risk of HIV transmission HIV is significant (untreated partner or treated partner whose viral load is detectable, for example);
- A history of use of more than one post-exposure prophylaxis (PEP);
- Consumption of psychoactive substances during sexual relations;
- Having had unprotected sexual intercourse with two or more partners during the last six months.

The consumption of a psychoactive substance during sexual relations has been associated with a greater risk of having anal sex without condoms [22].
PrEP can be considered on a case-by-case basis when risk-taking meets the criteria. listed above is anticipated in the short term.

2.1.2. Serodiscordant heterosexual men and women

PrEP is recommended for serodiscordant heterosexual couples having sex vaginal and/or anal sex not protected by a condom when, for the partner HIV positive, the risk of transmitting HIV is significant (untreated partner or partner treated with a detectable viral load, for example).

Pre-exposure prophylaxis for the HIV-negative partner of a serodiscordant couple can be considered if attempts at conception are undertaken while adherence to treatment antiretroviral treatment is not optimal or the viral load remains detectable.

PrEP may provide additional protection for serodiscordant couples to some extent. number of situations:

- ART can take up to six months to suppress the viral load. In studies in serodiscordant couples, PrEP provided useful protection before withdrawal complete viral infection of the partner during this period;
- The HIV-negative partner has doubts about the effectiveness of his or her spouse's treatment, or he/she has other partners in addition to the HIV-positive one under treatment;
- There were failures in the regular taking of treatment by the partner HIV positive, or the couple does not communicate openly about taking treatment and viral load test results.

2.1.3. Sex Workers

Sex workers (SW) who had sex without a condom during the last six months should be advised and evaluated with a view to to undertake PrEP especially towards their “boy friends” (boyfriend or partner TS) but also in relation to possible risks of accident of exposure to liquids biological prevention to possible breakage of condoms.

PrEP is recommended for HCWs as long as they have had sexual relations
protected by a condom or in case of breakage of the latter during the last six months and
one of the following situations applies:

• Syphilis or another bacterial, viral, or parasitic STI, particularly if
This was diagnosed within the last six months;

• Sexual relations with an HIV-positive partner when the risk of HIV transmission
HIV is significant or with a “boy friend” of unknown status (untreated partner or
treated partner whose viral load is not suppressed, for example);

• A history of use of more than one post-exposure prophylaxis (PEP);

• Consumption of psychoactive substances during sexual relations;

• Have had two or more casual sexual partners in the last six months with
unprotected sex.

PrEP can be considered on a case-by-case basis when risk-taking meets the criteria.
listed above is anticipated in the short term.

The table below summarizes the indications for PrEP.

Table I: Indications for pre-exposure prophylaxis

Population group	Terms	Recommendation
MSM and people transgender	Anal sex not protected by a condom in the last six months and one of the following situations: • History of syphilis or another bacterial, viral or parasitic STI, anal; • Sexual relations with an HIV-positive partner with a significant risk of HIV transmission; • History of use of more than one post-exposure prophylaxis; • Consumption of psychoactive substances during sexual relations; • • Having had unprotected sex with two or more partners during the six last months.	Recommended
	Exclusive stable relationship with only one HIV partner – or HIV+ whose risk of HIV transmission is negligible*	Not recommended

Population group	Terms	Recommendation
Sex workers	Sexual relations not protected by a condom during the last six months (especially with regard to their "boy friends" but also in relation to possible risks of accident of exposure to biological fluids in prevention of possible ruptures of condoms) and one of the following situations applies: • Syphilis or another bacterial, viral, or parasitic STI, particularly if it was diagnosed in the last six months; • Sexual relations with an HIV-positive partner with a significant risk of HIV transmission; or "boy friend" of unknown status (untreated partner or treated partner whose viral load is not suppressed, for example); • A history of use of more than one post-exposure prophylaxis (PEP); • Consumption of psychoactive substances during sexual relations; • Having had two or more casual sexual partners in the past six months with unprotected sex.	Recommended
Serodiscordant heterosexual men and women	Serodiscordant heterosexual couples having vaginal and/or anal sex unprotected by a condom when, for the seropositive partner, the risk of transmitting HIV is significant.	Recommended
	Preexposure prophylaxis for the HIV-negative partner of a serodiscordant heterosexual couple may be considered if attempts at conception are undertaken when adherence to antiretroviral therapy is not optimal or viral suppression is not confirmed.	Can be considered
	Unprotected vaginal or anal sex with one or more others partners of unknown HIV status who belong to a group in which HIV prevalence is high	Can be considered

*There is no evidence of transmission of HIV infection during sex oral, vaginal or anal without a condom when the person living with HIV is taking a antiretroviral treatment as prescribed and that their viral load, measured by tests consecutive laboratory tests is undetectable. In this context, the risk of transmission is negligible or almost zero [22].

2.2. PrEP contraindications [22,23]

Initiation of treatment with Emtricitabine / Tenofovir disoproxil (FTC/TDF) as part of PrEP is contraindicated in:

- People seropositive for HIV (or with unknown serology);
- People with signs of acute HIV infection (fever, rash, pharyngitis, lymph nodes, myalgia, arthralgia, diarrhea, vomiting etc.);
- People with known exposure to HIV in the past 72 hours;
- People infected with chronically active hepatitis B virus for the pattern of taking non-continuous PrEP (These people will need to take PrEP continuously);
- People with creatinine clearance less than 60 ml/min (disease renal);
- People with an allergy or contraindication to any medication in the regimen Prep.

2.3. The different methods of taking PrEP [22,23]

Oral PrEP can be offered as a daily regimen (continuous PrEP) or as a event-based diet (PrEP on demand).

In serodiscordant couples and HCWs having vaginal sex, PrEP continue is the recommended option.

For MSM and transgender women, PrEP can be offered continuously or on demand. MSM and transgender women should have the opportunity to decide which diet suits them best. On-demand PrEP may be appropriate for MSM and transgender women who have infrequent sex and find this more effective and convenient dosing regimen, (e.g., less than twice a week, on average) and are able to plan their sexual relations for at least two hours advance or can delay sexual intercourse for at least two hours after taking the loading dose of two tablets. However, on-demand PrEP is only recommended for the prevention of HIV contamination during anal sex. MSM and transgender women with other potential exposures to HIV should consider continuous oral PrEP or use other prevention methods for other types exhibition.

2.3.1. PrEP “Continuous intake”

It is the option recommended by the WHO due to its effectiveness. It is indicated for all target groups particularly MSM and transgender women with other potential exposures, serodiscordant couples and HCWs having sexual intercourse vaginal.

One FTC/TDF tablet per day is the recommended regimen. The tablet can be taken at class or outside of the meal. It is recommended to take it at the same time each day so to establish a routine:

- In people exposed to the risk of contamination in the context of relationships anal, it is recommended to consider that optimal protective activity is obtained after seven days of daily intake.

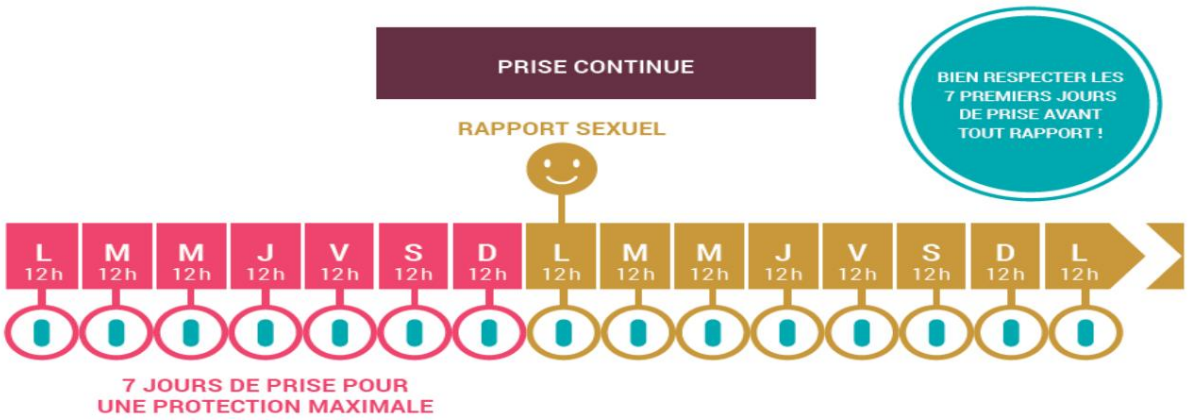

Figure 1: Continuous PrEP intake schedule

- In people exposed to the risk of contamination in the context of relationships vaginal, it is recommended to consider that optimal protection is obtained after 21 days of daily intake. It is for this reason that only the socket diagram continuous should be considered:
  - o For women and all people having vaginal intercourse;
  - o For people chronically infected with the hepatitis B virus on which tenofovir and emtricitabine have an antiviral action when taken daily, and for which the modification of this daily pattern can have effects deleterious.

NB: If you wish to stop continuous PrEP, taking it must be continued for 28 days after the last potential exposure.

2.3.2. “on-demand or intermittent” PrEP

On-demand PrEP may be appropriate for target groups who have relationships infrequent sexual intercourse and who find this dosage regimen more effective and practical, (for example example, less than twice a week, on average) and are able to plan their sex at least two hours in advance or may delay sex for at least two hours after taking the loading dose of two tablets. However, the On-demand PrEP is only recommended for the prevention of HIV acquisition during anal sex.

In MSM and trans women who do not have vaginal intercourse, the intake schedule “ on demand” can also be considered. This pattern requires anticipating sexual intercourse a few hours in advance. The advantage of this scheme is that it allows you to stop taking tablets during periods of less sexual activity or intercourse protected by a condom. To cover a single risk, you need four tablets taken in three doses as follows:

- **1st dose :** Two tablets of the TDF/FTC combination to be taken at the same **time** between 2 and 24 hours before sexual intercourse;
- **2nd dose :** One tablet of the TDF/FTC combination to take for approximately 24 hours (at **longer** or less than 2 hours) after the first intake;
- **3rd dose :** One tablet of the TDF/FTC combination to take for approximately 24 hours (at **longer** or less 2 hours) after the second dose.

  This process should be repeated for each period of potential HIV exposure

In case of further sexual intercourse, continue to take one tablet per day (same time, within 2 hours) and don't forget that you always need two doses spaced 24 hours after the last risky sex.

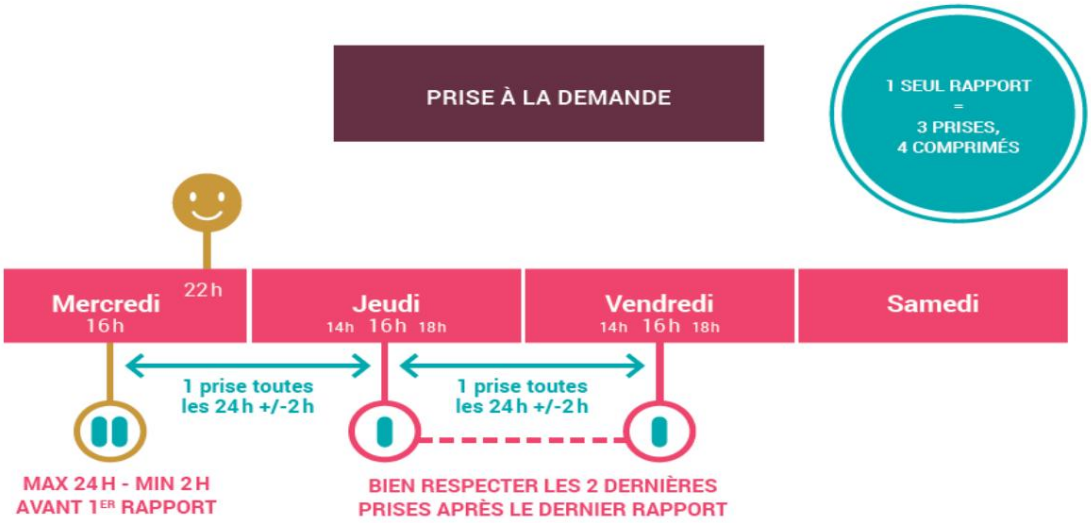

Figure 2: PrEP on-demand schedule

It is possible for a client on PrEP to switch from on-demand PrEP to continuous PrEP and vice versa.

2.4. Prescribing PrEP

The offer of PrEP to eligible populations will be ensured by treatment sites for PLHIV accredited by the PSLS and for whom providers will benefit from training specific and adequate support. These sites are integrated into health facilities public and private at all levels of the health pyramid.

As the combination (TDF/FTC) is an antiretroviral drug, only health workers authorized PLHIV care structures are authorized to prescribe PrEP.

2.4.1. At the level of public and private health centers accredited by the PSLS (CS, HZ, CHD, CHUZ, CHU)

The activities listed below are those dedicated to PrEP offering sites. It is :

- Training of prescribers (midwives, nurses, doctors) on the modules of PrEP (client selection criteria, PrEP start-up assessment, start-up ARV, clinical and biological monitoring under PrEP, conditions for stopping PrEP);
- Training of prescribers (midwives, nurses, doctors) on the filling out PrEP monitoring-evaluation tools (eligibility register, register appointments, calculations of PrEP indicators;

- Training of providers on the methods of dispensing ARVs to clients under PrEP according to the regimen;
- PrEP prescription;
- Dispensing of PrEP;
- Clinical and biological monitoring of clients on PrEP
- Documentation of data related to PrEP;
- Calculation of PrEP indicators.

2.4.2. At the community level

Community agents (peer educators, mediators, etc.) will play a role support during the implementation of PrEP. This role is broken down as follows:

- Raising peer awareness with PrEP awareness tools;
- Distribution of male and female condoms and lubricating gels;
- Distribution of HIV self-tests;
- Raising peer awareness of PrEP regimens;
- Raising awareness among peers and members of identity associations on orientation and supporting clients on PrEP;
- Offer of compliance support
- Community follow-up (search for those lost to follow-up, home visits).

2.5. Schedule of initiation visits and readiness assessment

For most clients, PrEP can be started the same day. However, in some scenarios described in Table II, it is recommended to delay PrEP initiation.

Table II : PrEP initiation steps

Required initiation steps	Shares
HIV test (According to national guidelines HIV testing)	• Same-day HIV testing is suggested. If positive, the client should not be initiated on PrEP, but should be immediately referred and initiated on ART.
Counseling	• Assess whether the client is at substantial risk of contracting the HIV; • Discuss prevention needs and provide condoms and lubricating gels; • Discuss desire for PrEP and willingness to take PrEP; • Develop a plan for effective use of PrEP; • Assess fertility intentions and offer safer contraception or conception advice; • Assess the client's experience of gender-based violence (GBV); • Assess consumption of psychoactive substances (drugs, alcohol and other narcotics) and mental health problems. • Assess PrEP contraindications Consider: Although not part of the WHO counseling messages when starting PrEP, it is important that clients are informed and counseled about the possibility of side effects, what those side effects may be, and what do if they arise.
Search if customers exposed to HIV in the past 72 last hours	If a client reports exposure to HIV in the past 72 hours, investigate possible eligibility for PEP instead of PrEP • PPE scheme: **TDF/3TC/DTG (over 10 years or weight > 30 kg), TDF/3TC + LPV/r (under 10 years or weight < 30 kg) ;** • Educate clients on the difference between PEP, PrEP and ART and offer risk reduction counselling; • After 28 days of PEP, the client can switch from PEP to PrEP without interruption, if they are still HIV negative and at risk of HIV contamination.
Search if customers at risk of acute infection	If the client has signs and symptoms of HIV infection (fever, rash, pharyngitis, lymph nodes, myalgia, arthralgia, diarrhea, vomiting etc.); and possible exposure to HIV in the previous two weeks: • Delay PrEP. Provide counseling on risk reduction as well as screening, diagnosis and management of STIs; • Repeat the HIV test after four weeks; start PrEP if negative.
Search for contraindications of PrEP	Assess contraindications to PrEP. If there is no contraindication, administer PrEP for one month (consider distribution over several months depending on the situation)

Required initiation steps	Shares
Recommended initiation steps (if available)	**Action**
Evaluate the function renal (creatinine serum)	• If available, perform a baseline serum creatinine analysis before starting PrEP to ensure normal renal function (creatinine clearance ÿ 60 ml/min); • Given the low rates of creatinine abnormalities, creatinine should not be a barrier to PrEP initiation. If creatinine testing is not available, a targeted medical history review could be used to identify potential kidney problems; • For clients with pre-existing risk factors for kidney failure, every effort should be made to obtain a serum creatinine before starting PrEP. Risk factors include: age > 50 years, hypertension, diabetes mellitus, taking nephrotoxic drugs, any symptoms or signs suggesting renal insufficiency. In these cases, TAF is more indicated in these subjects [24]. Consider: Although urinalysis is not recommended by WHO, it is an indicator if creatinine testing is not available or if results are delayed. If the urinalysis is not normal, PrEP initiation would be delayed until the creatinine results come back. Note that albuminuria is better than proteinuria for early detection of renal disease/damage. Proteinuria indicates high protein in the urine (normal excretion should be <150 mg/day), while albuminuria is defined as "abnormal loss of albumin in the urine." Albumin is a type of plasma protein normally found in urine in very small amounts. Albuminuria is a very common (although not universal) finding in clients with chronic kidney disease; is the first indicator of glomerular diseases, such as diabetic glomerulosclerosis; and is typically present even before a decrease in glomerular filtration rate or an increase in serum creatinine. Serum creatinine should be used to estimate creatinine clearance using the following Cockcroft-Gault formula: **East. Creatinine clearance** = [[140 – age (year)] * weight (kg)] / [72 * Serum Cr (µmol / L)] (Multiply by 0.85 for women) NB: Creatinine 1mg/dl = 88.4 µmol/ *Interpretation:* *Usual values: Men = 120 ml/ min (+/-20ml/ min); Woman = 95 ml/ min (+/-20ml/ min)*
To research of Hepatitis Surface Antigen	• HBsAg negative: Explore and offer hepatitis B vaccination (in accordance with national hepatitis guidelines);

Required initiation steps	Shares
B (HBsAg) see "Considerations special" below)	• HBsAg positive: see section below on clients infected with hepatitis B.
Hepatitis C antibody test	If positive: consider referral for evaluation and treatment for hepatitis C. Remember that HCV infection is not a contraindication to PrEP.
Syndromic screening of STI	If STI, manage STI according to standard STI treatment guidelines.
Carry out the test pregnancy	Determine the date of the last menstrual period; perform a pregnancy test if indicated or requested by the client. Remember that neither pregnancy nor breastfeeding are contraindications to PrEP use.
Assess mental health status	• Screen for mental health problems, including depression and alcohol/substance abuse, that could increase risk or affect medication adherence. Prep ; • Make the link to follow-up mental health care. Clients with mental health issues should not be barred from receiving PrEP if they can use it effectively or with the help of a third party.
Search for special considerations related to hepatitis B	Clients infected with hepatitis B seeking PrEP: • Intermittent PrEP is contraindicated in clients suffering from chronic hepatitis B; • Continuous PrEP is not contraindicated in clients infected with hepatitis B; If the HBsAg result is positive, the client can be initiated on continuous PrEP. • Additional assessment may be considered for people with hepatitis B who are considering PrEP; • Clients infected with hepatitis B who are not interested in PrEP or who stop PrEP should be referred to care services for appropriate management or treatment. Consider: Clients starting PrEP who have hepatitis B infection may benefit from additional counseling to ensure they are aware of the need for continued treatment and if they want to stop taking PrEP for HIV prevention.

Required induction steps	Shares

ASSESSMENT OF READINESS BEFORE INITIATING PREP

1. HIV test is negative on the day of initiation of HIV Prep	[__] Yes	[__] No
2. Client is at substantial risk of HIV infection (or client has requested to use PrEP as an HIV prevention method)	[__] Yes	[__] No
3. Client has not been exposed to HIV in the previous 72 hours	[__] Yes	[__] No
4. The client is not suspected of having acute HIV infection	[__] Yes	[__] No
5. Client is willing/able to come to follow-up appointments	[__] Yes	[__] No
6. The client has no contraindications to PrEP medications (TDF, FTC)	[__] Yes	[__] No
IF "YES" TO ALL SIX QUESTIONS ABOVE, START PrEP		

2.6. Entry points for PrEP

The following services are potential entry points for PrEP:

- HIV testing services;
- STI screening services;
- Services related to sexual or gender-based violence;
- Gyneco-obstetrics or reproductive health services;
- HIV testing points in the community (clients tested within the community community can be referred for PrEP);
- PMTCT services: HIV-negative partners of pregnant women HIV-positive people can be referred for PrEP;
- PEP services (clients who have completed PEP can be referred for PrEP);
- Mental health service.

2.7. Prescribing and monitoring methods for clients on PrEP

Regular monitoring of people on PrEP is necessary. Medical monitoring is carried out at a minimum one month after the initiation of PrEP continuously then every 3 months to ensure

the effectiveness and tolerance of the treatment. The duration of the prescription should not exceed one month at the first visit, and three months thereafter, to allow for serological screening of HIV.

Before starting PrEP, a first visit should be offered to prescribe tests paramedical. Based on the results, the provider will assess whether PrEP is a strategy adapted to the client and if he does not present medical contraindications, then he will prescribe (or no) a first order of the TDF/FTC combination. A month later then every three months, regular monitoring will:

- Get regular HIV testing: indeed if the client contracts HIV, PrEP is stopped for the benefit of ART in order to reduce the risk of developing drug resistance and to fight effectively against HIV with appropriate antiretroviral treatment;
- Regularly check up on STIs: PrEP does not prevent other STIs (gonorrhea, condyloma, chlamydia, hepatitis B/C, syphilis, etc.). It is therefore recommended to make a regular monitoring (clinical and/or biological) of STIs every three months at least and as soon as that there are symptoms, to use the syndromic management algorithm for STIs in case of unavailability of biology. Vaccinations may also be offered (hepatitis B);
- Look for possible side effects to manage
- Evaluate compliance, or even reinforce it in the event of irregular intake.
- Have kidney function checked preferably every 6 months [28]. It's important to take into account other treatments taken by the client which may in the long run impact kidney function or interfere with optimizing the concentration of the combination TDF/FTC.

The table below presents the different biological follow-up assessments under PrEP.

Table III : Initial biological assessment when starting PrEP and follow-up assessment

Exams organic	Initial	M1 M3 M6 M9 M12					Follow up
Creatinine and flow filtration glomerular estimated	X (the no availability does not prevent the initiation of the Prep)	X*		X*		X*	X*
HIV X serology		XXXXX					X**
HBV X serology (the	no availability does not prevent the initiation of the Prep)						Once per year or in case indication clinical
HCV X serology (the	no availability does not prevent the initiation of the Prep)						
Urine analysis	X					X	

*Monitoring kidney function after 2 to 4 weeks of treatment, at 3 months of treatment and every 6 months thereafter. The frequency of renal monitoring must be increased in people with risk factors for impaired renal function;
** Any HIV seroconversion during treatment with emtricitabine/tenofovir disoproxil fumarate must be reported on the seroconversion monitoring form.

The minimum assessment is free and depends on the availability of inputs made available to the sites by the PSLS for the PrEP offer. The cost is charged to several funding sources:

- Subsidies made available to the PSLS by the technical and financial partners of same as the Beninese State (inputs);
- The resources of health establishments involved in PrEP (human resources).

All acts carried out outside the minimum free package are the responsibility of the customer

2.8. Condom use and PrEP [11,22].

The condom is an effective tool in HIV prevention, when used correctly and systematically. It is also the only tool that protects against both HIV and certain

STIs and which prevents unwanted pregnancy. PrEP is not incompatible with condom, it can even be used as a complement. In fact, PrEP is aimed as much at people who have occasional difficulties with the condom than to people who do not never use. PrEP also allows a person to protect themselves when their partner unwilling/unable to use a condom. PrEP, particularly “on demand”, thus complements perfectly use condoms and vice versa.

It is often recalled that PrEP is added to a range of prevention tools among which :

- The use of condoms and lubricating gels;
- Regular screening for HIV and other STIs (and their treatment);
- The use of post-exposure prophylaxis (PPE) in cases of emergency;
- The use of single-use materials for IDUs.

2.9. Community sensitizers and educators

Implementing PrEP does not just involve providing medications. THE services offering PrEP must also:

- Provide information on PrEP and other prevention, care and services HIV treatment;
- Provide regular HIV testing as well as testing and treatment for other sexually transmitted infections (STIs);
- Provide support for adherence and compliance;
- Refer to treatment all people who test positive for HIV or who have become HIV-positive while taking PrEP.

Community education can shape appropriate PrEP demand and help achieve and to inform the people who could benefit the most.

Peer educators can provide information about PrEP directly to communities that could benefit from it. They can help people who are at risk significant amount of HIV infection in their community to make informed decisions about whether or not to start PrEP.

Peer educators are peers who have good interpersonal skills and communication and are able to provide information on how to recognize risks, basic information about PrEP and other prevention options, as well as strategies for adhesion.

2.10. Support in PrEP consultation [22].

The international recommendations (WHO, 2015) follow several clinical trials that have demonstrated the effectiveness of PrEP as an additional tool in a prevention strategy diverse. The notion of support is also part of certain reports, opinions and PrEP clinical trials.

- The ANRS-IPERGAY trial places community support at the heart of its device. It includes in particular classic counseling type interviews, interviews collectives, motivational interviews and a monitoring system (by email, telephone, SMS) throughout the duration of the test. Test results and satisfaction results encourage support during the PrEP consultation outside of a clinical trial [6].
- Morlat report: an expert report recommending support. The group of experts recommends, in its report on the medical care of people living with HIV updated in 2015, that the dispensing of PrEP be carried out with “a accompaniment (counselling) aimed at adherence to this method of prevention and adoption in terms of safer sexual practices with regard to all STIs” [21].

Objectives and fields of action of community support [21,22].

All studies have shown that one of the main challenges of PrEP is good compliance. treatment over time. The support interviews offered to people in complement to the medical consultation therefore have as their primary objective help with compliance:

- Understand the grip pattern;
- Think about how to adapt the grip pattern to the reality of the person's life, to oversights sockets;
- Provide information on how the medication works;
- Question the motivations for using PrEP;
- Identify the barriers but also the factors facilitating the use of PrEP;
- Question sexual decision-making in the context of PrEP;
- Systematically associate the use of PrEP with a heightened perception of risk.

Beyond compliance and medical monitoring strictly linked to PrEP, the second objective of the community accompanist is to propose to the person a follow-up of his sexual health

on PrEP. Indeed, PrEP is intended for populations highly exposed to HIV and who may possibly present other problems that could impact their health:

- Frequent STIs;
- Use of drugs in a sexual context (intravenously);
- Social problems including social isolation;
- Psychological problems (low self-esteem);
- Psychiatric disorders;
- Sexual disorders (erectile disorders, sexual hyperactivity);
- Sex work;
- Discrimination.

The guide will therefore be able to discuss all these questions with the person but also discuss their sexual practices, their pleasure, their personal development, their integration into a care pathway, what PrEP has or has not changed in his life. He must be able to identify, in the speech of the person, what can be an obstacle to taking into account quality charge and therefore to identify possible sexual (or other) health needs.

Community support for PrEP

The support offered here is inspired by the experience capitalized during the ANRS trial IPERGAY, reduced in its aspects linked to research but enriched with the experience of first PrEP consultations [6].

Community support must be carried out regularly (at least once a year). months) during the first 6 months of PrEP and optionally thereafter depending on the customer needs. This support must be provided during dedicated consultation times on PrEP and in the service when possible. If there is no dedicated PrEP consultation. It will be necessary to offer tailored support to customers.

- **The accompaniment during the first consultation** according to the organization of the service, can start on the day of prescription **(D0)** or during an appointment a few days or weeks upstream during which the examinations prior to starting PrEP are prescribed. In both cases, it is at this meeting that the customer discovers the service and that the provider trained will determine compliance with the criteria regarding the client. The first visit is a key stage of the journey, this is why it is preferable to see the customer upon arrival in the service and after the first medical consultation. If conditions do not permit it, it

it is recommended to see the client after the consultation and to mix in the same interview the following points :

- **Before the consultation :** The guide welcomes the client, introduces himself, explains his role, the principle of support and sets the framework for the interview (confidentiality, non-judgment, familiarity possible, etc.). It's about putting the customer at ease so that they express themselves without taboos and in complete freedom. He then ensures what the client knows about PrEP, how he plans to take it, what he understands about the issues, what the PrEP involves in terms of follow-up and answers their questions. This time of exchange and listening allows the client to complete their knowledge and to pre-evaluate whether this tool really meets their needs.

- **After the consultation:** The guide will return with the client on his first interview, on the choice of the trained provider (PrEP or not), on their state of mind and on the points that remain to be clarified.

  In the event of refusal, he will make sure to direct the customer and possibly offer him a other sexual health type monitoring.

  If agreed,

  - the trained provider will prescribe PrEP (and subject to test results conclusive medical evidence);
  - The guide will return to the preferred grip pattern;
  - The guide will ensure that they are understood correctly. He will explain to her continuation of the support;
  - The guide will offer an exchange of contact details (telephone and/or email), as during each interview;
  - The guide will provide the client with other prevention tools (condoms, lubricating gels, etc.), information documents.

- The attendant must also remind people of the benefit of post-exposure prophylaxis. (PPE) if you forget to take it and explain to the person how to access this tool at within the service that provides HIV care. He may also inform and direct them to other sexual health offers;

- Support during the first 6 months: During the following 3 meetings (M1, M3 and M6), the guide will offer a counseling interview after the consultation medical. This interview will allow us to look back on the first months of taking: compliance, adverse effects, last sexual relations, change in risk taking, good being global, acceptance of PrEP in family and friend circles, integration in a regular care course etc… He will be able to return to the intake schedule, and support the strengthening of compliance and the linking of PrEP to other tools of prevention ;

- The attendant will not have access to the client's medical file or to the results of the tests carried out. However, he remains available to the person to talk about it. in particular when the latter informs him of other results of biological analyzes or when of seroconversion to HIV. During each interview he will make available to the person other prevention tools (condoms, lubricating gels, etc.) as well as documents of information ;

- Support after the first 6 months: It is proposed that the support be redesigned according to the needs of the person. It is up to the guide and the person to define together how to continue community support during the coming months:

  - o Classic follow-up (every 3 months, in parallel with medical consultations);

  - o Lightening of the device, for example: once every 6 months; on demand (keep contact with the person); only remotely (email, calls); total stoppage of accompaniment (by specifying that the person can return at any time in the course). The optional nature of support after 6 months must not prevent the companion from remaining reactive when requested by the person.

- Remote accompaniment: The accompanist will offer the person follow-up at distance in order to help him on his journey. Concretely he will give him a number mobile phone or a WhatsApp number or an email address. Of course, this is not not from the personal telephone number of the companion but from a professional number which will be shared within the team of guides. The customer can contact the support person outside of the consultations to ask them all types of questions in relationship with PrEP or its monitoring. Furthermore, it will be made clear that this is neither a penalty nor an emergency number, and even if it must be rapid, the response will not be

necessarily immediate. If the client agrees to give their contact details, the guide may also communicate the dates of collective discussion times on PrEP or even call him if he didn't show up for his appointment.

This support work can be done by the doctor or other personnel. caregivers (nurse, psychologist midwife, etc.), but the community approach is complementary to the medical or psychological approach. She must be benevolent and without judgement. In a multidisciplinary context, it is easier to talk about sexuality and combined prevention by diversifying listening and approaches. The guide community, through its greater proximity to people's experiences, through its listening and mastery of the counseling technique can facilitate the confidence building of the person and therefore his free expression. The multidisciplinarity of those involved in the person's journey can make it easier to express your difficulties. Thus, it has often been observed that a customer can say some things to the doctor, others to the nurse and still others to the companion. If the guide collects information that seems important or even essential to him for good follow-up, he will encourage the customer to inform the service provider or if the customer does not dare do, and with his agreement, he can inform the healthcare team. By its greatest availability, before, after and outside consultations thanks to remote monitoring, the guide facilitates the client's journey and allows for better retention in care. Finally, as medical time is often limited, the community support worker, by ensuring well-identified tasks that complement those of other actors, can save a lot of time for the healthcare team.

Qualities required for a PrEP support person

Being a PrEP companion during consultations means:

- Be able to commit to a minimum amount of time;
- Be regularly available to establish a relationship of trust with the staff of care on the one hand and then with PrEP users on the other hand;
- Be available for PrEP consultations;
- Be available for discussion with healthcare staff;
- Be available to users outside formal times (by SMS, social networks, mail…);

- Have the scientific and lay knowledge necessary to be able to respond to the questions from users;
- Have a good understanding of grip patterns;
- Be able to exploit personal and community experience;
- Be able to guide the user;
- Be the bridge between the medical environment and everyday life;
- Maintain an ethical posture: respect for medical confidentiality, confidentiality, respect autonomy;
- Establish links with the person that are different from those established with the medical community: familiarity possible, adapted vocabulary register, non-prejudicial discussion on the sexual practices, use of products;
- Have the potential required to work with the medical community;
- Respect consultation times;
- Be able to accept the medical decisions of the trained provider (refusal of prescription);

Being a PrEP companion during consultations does not mean:

- Be available on demand, immediately, all the time. It is necessary to establish a relationship of trust with the person, to be available during consultations and to ensure follow-up, permanence but also to establish rules: a client can be followed by different attendants, the establishment of schedules for calls (on a line dedicated).

The support person does not announce the results of STIs or seroconversion, he does not prescribe or does not exempt from the TDF/FTC combination. However, some information may have a interest in being shared with the medical team if they are important for treatment medical. In these cases, it is appropriate to ask the customer for their permission to share data concerning him.

To provide PrEP support, there is no specific dedicated training.
However, each guide will have to validate certain steps. Indeed, one of the particularities of the PrEP support action is that it is carried out jointly with nursing staff, in a hospital setting.

Necessary prerequisites: Be a volunteer or employee (Initial Training), no training specific is required. However, training can provide knowledge and

know-how useful for PrEP support (counseling, Risk Reduction, etc.),
Training in counseling is strongly recommended.

3. FINAL PROVISIONS

3.1. Monitoring and evaluation

To monitor the implementation of PrEP, several tools will be developed by the PSLS and made available to the actors. It is :

- Risk assessment and PrEP eligibility form;
- PrEP eligibility assessment register;
- PrEP establishment file;
- Register of patients on PrEP;
- Seroconversion follow-up form;
- Monthly PrEP activity report;
- Quarterly PrEP cohort activity report.

The following four core indicators for PrEP are a suggested minimum set for monitoring of the PrEP program in Benin, and aim to evaluate participation, continuation treatment and its safety. Each indicator measures an important aspect of implementation of PrEP and can be used to assess progress and flag areas that may warrant further further investigation.

The four key indicators are:

- Percentage of people eligible for PrEP who were offered PrEP and who have started oral antiretroviral PrEP within the last 12 months;
- Percentage of PrEP users who continued oral PrEP for three months consecutive after starting PrEP in the last 12 months;
- Percentage of people who received oral PrEP who stopped or interrupted PrEP due to severe ARV-associated toxicity in the past 12 months;
- Percentage of people who became HIV positive among people who received the PrEP at least once in the past 12 months and having had at least one test HIV monitoring.

Indicator 1: Percentage of eligible people who started oral antiretroviral PrEP in the last 12 months

Definition of the indicator	Percentage of eligible people who started oral antiretroviral PrEP in the last 12 months
Preview	This indicator measures PrEP participation/uptake The group of people starting oral PrEP includes those who started PrEP for the first time and those who may have stopped taking it. PrEP and restarted PrEP during the reporting period
Numerator	The number of people who started oral PrEP in the last 12 months.
Denominator	Number of people recently offered PrEP after having met the eligibility criteria in the last 12 months
Calculation	Numerator*100/denominator
Methodology collection of data	The numerator includes people who received PrEP for the first time, and those who had previously stopped PrEP and restarted it during the first reporting period. Regular PrEP users who continue PrEP should be excluded from the numerator and denominator, the numerator should only count each individual once in a given reporting period The denominator is generated by counting the number of people who were offered PrEP after meeting eligibility criteria. An individual should only be counted once in a given reporting period, even if they started PrEP more than once after periods of discontinuation. Age is defined as the age when the person starts PrEP.
Frequency	Data must be collected continuously, aggregated periodically (monthly)
Disaggregation	• Age (18-24, 25-49 and 50+ years) • Sex (male, female) • Type of Key Populations • Partners of PLHIV • Applicable PrEP model: (Continuous or on-demand)

Indicator 2 : Percentage of PrEP users who continued oral PrEP for three consecutive months after starting PrEP in the last 12 months.

Definition of the indicator	Percentage of PrEP users who continued oral PrEP for three consecutive months after starting PrEP in the past 12 months.
Preview	This indicator measures **continuation of PrEP** among people who start PrEP and also assesses loss to follow-up
Numerator	Number of people who continued PrEP for three months consecutive after starting PrEP in the last 12 months
Denominator	Number of people who started oral PrEP in the past 12 months
Calculation	Numerator*100/denominator
Data collection methodology	The numerator is generated by counting the number of people who started oral PrEP in the past 12 months and continued PrEP for 3 consecutive months. People who initiated PrEP include people who received PrEP for the first time, and those who had previously stopped PrEP and are restarting it during the relevant period. The denominator is generated by counting the number of people who started oral PrEP in the past 12 months. An individual should only be counted once in a given reporting period, even if they were offered PrEP more than once, as may occur if a person starts, stops, and restarts PrEP during the same reporting period.
Frequency	Data must be collected continuously, aggregated periodically (monthly)
Disaggregation	• Age (18-24, 25-49 and 50+) • Gender (male, female) • Type of Key Populations • Partners of PLHIV • Applicable PrEP model (Continuing)

Indicator 3: Percentage of people who received oral PrEP who stopped or discontinued PrEP due to severe ARV-associated toxicity in the past 12 months.

Definition of the indicator	Percentage of people who received oral PrEP who stopped or discontinued PrEP due to severe ARV-associated toxicity in the past 12 months.
Preview	This indicator measures the **prevalence of toxicity among clients on PrEP.** The main expected toxicities linked to the use of PrEP are bone and kidney toxicities associated with tenofovir in population groups with associated risk factors. Adverse drug reactions leading to discontinuation or interruption of PrEP should be routinely recorded in the appropriate PrEP registry for each PrEP client
Numerator	Number of people who received oral PrEP who stopped or discontinued it due to serious ARV-associated toxicity in the past 12 months
Denominator	Number of people who received oral PrEP at least once in the last 12 months.
Calculation	Numerator*100/denominator
Data collection methodology	The numerator is generated by counting the number of people taking oral PrEP who stopped or discontinued PrEP due to severe PrEP-limiting adverse toxicity in the past 12 months, defined as life-threatening illness, death, hospitalization or disability or any adverse effects of medication leading to discontinuation of PrEP. The denominator is generated by counting the number of people who received oral PrEP at least once in the past 12 months according to national guidelines or WHO standards/ UNAIDS
Frequency	Data must be collected continuously, aggregated periodically (monthly)
Disaggregation	• Age (18-24, 25-49 and 50+ years) • Gender (male, female) • Type of Key Populations • Partners of PLHIV • Applicable PrEP model (Continuous or on demand)

Indicator 4 : Percentage of people who became HIV positive among people who received PrEP at least once in the last 12 months and who had at least one follow-up HIV test

Definition of the indicator	Percentage of people who became HIV positive among people who received PrEP at least once in the last 12 months and who had at least one follow-up HIV serological test
Preview	This indicator measures **the percentage of people who are HIV positive after being prescribed PrEP.** HIV testing to determine PrEP eligibility is not included in either the numerator or denominator. The last HIV test recorded in the reporting period is counted.
Numerator	Number of people who had a follow-up + HIV test among people who received oral PrEP at least once during the last 12 months
Denominator	Number of people who received oral PrEP at least once during in the last 12 months and having had at least one follow-up HIV test.
Calculation	Numerator*100/denominator
Data collection methodology	The numerator is generated by counting the total number of people who had a follow-up HIV test among people who received oral PrEP at least once in the last 12 months and had at least one follow-up HIV test. The numerator should not include people who last used PrEP more than 12 months before the HIV test date The denominator is generated by counting the number of people who received PrEP at least once in the past 12 months and who had at least one follow-up HIV test during the reporting period. Only the most recent test result should be taken into account
Frequency	Data must be collected continuously, aggregated periodically (monthly)
Disaggregation	• Age (18-24, 25-49 and 50+ years) • Gender (male, female or transgender) • Type of Key Populations • Partners of PLHIV • Applicable PrEP model (Continuous or on demand)

3.2. Update

This PrEP implementation guide developed in accordance with the recommendations WHO 2015 will be updated with all stakeholders in the national response to HIV each publication of new recommendations by the WHO.

CONCLUSION

PrEP greatly reduces the risk of HIV infection in people who adhere to This intervention is part of a global combined prevention approach, which is based on several aspects which must be promoted without exception. To this end, let us cite the counseling as well as education on prevention of HIV infection, HIV testing and of STIs, treatment of infected people to prevent transmission, treatment pregnant women carrying HIV and finally, post-exposure prophylaxis. It is therefore important to promote rapid access to PrEP for people at risk to control the epidemic of HIV [22].

Tenofovir fenamide (TAF) is a new prodrug with a stronger safety profile interesting on the renal and osseous plans, under a serum concentration clearly lower and a high intracellular concentration presaging greater effectiveness at block virus entry into target cells. Its availability could possibly increase therapeutic adherence to PrEP (its combination with emtricitabine is known under the trade name Genvoya® [24,29].

Injectable prolonged-release molecules (Cabotegravir injectable /8 weeks) and under implant form (Islatravir orally offering protection for one month or in implant for protection lasting one year) provide hope for strong therapeutic adherence to PrEP. However, antiretroviral resistance could potentially have an impact negative on the effectiveness of antiretroviral options among PrEP users who contract HIV, because there is a potential overlap in resistance profiles between drugs antiretrovirals recommended for PrEP and first-line ART [29]. For example Truvada contains TDF which is found in first-line regimens [20]. For monitor the risk of acquiring HIV drug resistance among users of PrEP who contract HIV, the WHO now recommends that the scale-up of PrEP is accompanied by monitoring of HIV drug resistance according to the methods recommended by the WHO [22].

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CONTENTS

APPENDICES

PrEP counseling and education messages for clients

The table below outlines counseling and education messages for clients on PrEP.

Table IV: PrEP counseling and education messages for clients [22].

Subject	Key messages
What is PrEP?	PrEP is one of several HIV prevention options and, if possible, should be used in combination with condoms and other HIV prevention methods. It prevents the acquisition of HIV when taken as prescribed. PrEP is safe, but people who take PrEP should be tested to make sure they are not HIV positive before starting. PrEP does not protect against other STIs or prevent unwanted pregnancies.
PrEP is not not for life	You should take PrEP for as long as you feel you are at risk of HIV infection. Some people only need to take PrEP at certain times in their lives, while others have an ongoing need.
Starting and stopping the Prep	*For all people other than men whose only exposure to HIV is through sex with men:* PrEP should be taken daily for seven consecutive days before exposure for maximum effectiveness, then one PrEP tablet should be taken daily at around the same time. To safely stop PrEP, one PrEP pill should be continued daily for 28 days after the last potential exposure. *For men whose only exposure to HIV is through sex with other men:* For those on a **daily regimen :** Two pills of PrEP should be taken at least two hours before sex for maximum effectiveness. One tablet should be taken daily at approximately the same time thereafter. To safely discontinue PrEP, one PrEP pill should be taken daily for up to 28 days after the last potential exposure. For those following an **on-demand PrEP** regimen : Two PrEP tablets should be taken 2 to 24 hours before having sex for maximum effectiveness. One PrEP tablet should be taken every day at the same time as the loading dose until two days after the last potential exposure. This

Subject	Key messages
	This process should be repeated for each period of potential HIV exposure. PrEP can be stopped 28 days after the last possible exposure to HIV. Patients may consider stopping PrEP if they are no longer at significant risk of HIV infection. Ways to reduce risk include: adopting safer sex practices, such as not having vaginal or anal sex, or using condoms for all vaginal and anal sex; changing circumstances such as leaving the sex trade or stopping injecting drug use; or moving to a place where the prevalence of HIV infection is low. For people in a serodiscordant couple, the risk of HIV transmission is very low when the HIV-positive partner is virally suppressed on ART
Ways to support membership and observance	PrEP can be taken at any time of the day, with or without food. If you miss a daily dose of PrEP, take it as soon as you remember. Some people find it easy to remember to take their PrEP when they make it part of their daily routine and take it at the same time each day. For example, you can take PrEP when you brush your teeth (in the morning or in the evening), or when you watch a favorite TV show or listen to a favorite radio show. It helps to combine taking PrEP with a routine that makes you feel good. Consider: If the loading (starting) dose is taken less than two hours before sexual intercourse, or if it is missed, the client may be a candidate for PEP.
PrEP and alcohol or others recreational drugs	Alcohol and the use of psychoactive substances are not incompatible with PrEP. They can cause you to forget to take your PrEP, so make sure you take it before using any substances. (Note to provider: insist on compliance and dosing reminders)
PrEP, pregnancy and breastfeeding	• PrEP does not prevent pregnancy. Be sure to use modern contraception to avoid unwanted pregnancy; • Taking PrEP while you are pregnant or breastfeeding will not harm you or your baby; • You can use PrEP throughout pregnancy and breastfeeding. (Note to provider: assess family planning needs and offer, if appropriate)

Subject	Key messages
	(Note to provider: Offer PrEP to pregnant women at high risk for HIV first after all risks and benefits have been explained to the client.)
PrEP and others drugs	PrEP is safe and effective. It can be taken with hormonal contraceptives.
None protection against STIs other than HIV	PrEP does not prevent any other STIs. Use a condom correctly every time you have sex to protect yourself from other STIs.
Effects secondary	More than 90% of people will not experience any side effects. Sensitive subjects will show minor and mild signs, such as: • Gastrointestinal symptoms (diarrhea and nausea, loss of appetite, abdominal cramps and flatulence) • Dizziness • Headache These side effects are usually mild and go away without stopping PrEP. Typically, these symptoms begin within the first few days or weeks of using PrEP and last for a few days, and almost always less than a month. However, your healthcare provider can help you manage them.
Other ways to reduce HIV risk	To reduce your risk of HIV: • Adopt safer sexual practices, including consistent use of condoms; • Ensure that an HIV-positive partner in a serodiscordant couple has been on effective ART for at least six months, has an undetectable viral load and remains adherent; • Reduce the number of sexual partners; • Access substance harm reduction services psychoactive.
Switch between prevention options HIV	It is normal to start PrEP and decide later that you want to use another option to prevent HIV infection, such as condoms. Many people change methods as their needs change. I am here to help you make the best decision for you.

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