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National Technical Guidelines for Pre-Exposure Prophylaxis

National Technical Guidelines
for
Pre-Exposure Prophylaxis





आलोक सक्सेना
अपर सचिव एवं महानिदेशक

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Foreword



राष्ट्रीय एड्स नियंत्रण संगठन
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In the last 30 years, India has been able to successfully control the HIV epidemic. As we move towards the last mile, new and innovative efforts, strategies and techniques would need to be devised. Keeping the Sustainable Development Goal of ending AIDS as public health threat by 2030, it will be difficult for routine activities to yield desired results. One innovative prevention strategy is Pre Exposure Prophylaxis, for which WHO recommends "oral pre exposure prophylaxis (PrEP) containing Tenofovir (TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches".

The National AIDS Control Organisation under the Ministry of Health & Family Welfare, Government of India adopted a multi-stage consultative process to develop evidence based National Technical Guidelines on Pre Exposure Prophylaxis. The process started with the Asia-Pacific meeting on Prevention Strategies in 2018. An Expert Group on PrEP was constituted in 2019 under then Special Secretary & DG, NACO under whose guidance and constant watch began the work on the Technical Guidelines. The National Programme is centred around the communities and the main purpose behind the Technical Guidelines is to provide correct, ready and easy information on PrEP and its use. The National Technical Guidelines on PrEP talk about key considerations related to statutory disclosures for prospective users, consent, initiation of PrEP, triggers for entry, exit and re-entry, adherence, evaluation and periodicity.

NACP prides itself in its prevention programme implemented through the social contracting model and active involvement of communities. Against the backdrop of increase in at-risk populations, increase in the use of online and internet-based platforms and achieving the "last mile" in HIV/AIDS epidemic control, PrEP can prove to be an effective tool as an additional preventive option in the existing prevention strategy. However, we must not forget that condoms are still the time-tested line of defence, which protects not only against HIV but also STI, Hepatitis, cervical cancer and contraception. Further, a good communication and counselling package centred around PrEP is important.

I congratulate all stakeholders who have been actively engaged in the development of the National Technical Guidelines on PrEP. We have benefitted greatly from your experience and valuable insights. Critical perspectives from community, civil society and private providers helped finalise the National Technical Guidelines. Our partners have been an integral part of the journey and we look forward to this robust collaboration.

I congratulate National AIDS Control Organisation (NACO) for coming up with these National Technical Guidelines on PrEP through a rigorous and collaborative process. I am pleased that the Technical Guidelines are being published at this opportune time and will aid in accelerating progress towards reducing HIV incidence across India.

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निधि केसरवानी, भा.प्र.से.
निदेशक

Nidhi Kesarwani, I.A.S.
Director



Preface

The National AIDS Control Organisation (NACO), Ministry of Health & Family Welfare, Government of India encourages identification of newer and innovative strategies that will aid in improvement of outcomes among at-risk, Key and vulnerable populations. In order to address the emerging challenges pertaining to achieving the "last mile" in HIV/AIDS epidemic prevention and control, NACO has developed the National Technical Guidelines on Pre Exposure Prophylaxis (PrEP). The purpose of the National Technical Guidelines on PrEP is to provide correct information on PrEP to both providers and users.

The National Technical Guidelines on Pre Exposure Prophylaxis (PrEP) have been developed based on the recommendations of the Expert Group on PrEP, Working Groups on PrEP, and have been validated by the Technical Resource Group on ART. The expected outcome from the National Technical Guidelines is to provide a platform for correct and robust information on PrEP. One of the major advantages of PrEP is that it offers an additional preventive measure in the existing basket of prevention strategies. It is not a lifelong therapy and can be initiated under period of high-risk and can be discontinued under situations or periods of low-risk.

The National Technical Guidelines, a collaborative exercise saw active engagement of senior officials, officers and programme managers from NACO and State AIDS Control Societies, experts, academia, private providers, representatives from the community and civil society. The National Technical Guidelines bring together all available evidence which has been considered in drafting the guidelines. I extend my best wishes to everyone and hope that the National Technical Guidelines serve and benefit providers and users of PrEP.

My heartfelt thanks to all the members involved in developing these National Technical Guidelines.

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Message

The National AIDS Control Programme is evidence led public health programme. NACP aims to keep HIV negative individuals negative through a package of preventive services implemented by TI NGOs under social contracting. With communities at the heart of the national AIDS response, these National Technical Guidelines on Pre Exposure Prophylaxis have been developed. It is expected that the national guidelines will serve to provide correct information on the use of Pre Exposure Prophylaxis.

The development of the National Guidelines has been a consultative process involving various stakeholders, actively engaged with the programme. It has been a noteworthy and fruitful collaboration which saw all the evidence from published reports, technical documents, real-world findings from implementation and demonstration projects brought to the team / Experts for consideration and reference.

NACO is pleased to bring these technical guidelines to the fore, which will be beneficial for all PrEP and potential users and providers. The global and local recommendations on Pre Exposure Prophylaxis and Post Exposure Prophylaxis including PEP for sexual assault, have been taken into consideration. We are hopeful that the myths and misconceptions around PrEP and PEP prevalent among users and providers, are taken care of, by referring to this document.

I wish to reiterate NACO's full and continued commitment and support to all efforts undertaken by the National AIDS Control Programme. Through evidence based prioritisation, active community engagement and innovations, the Sustainable Development Goals of 2030 will be achieved.

Shobini

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Acknowledgment

The National Technical Guidelines for Pre-Exposure Prophylaxis (PrEP), the first of its kind, come at an opportune time, developed to provide correct information on PrEP to both providers and users in India. The journey of the National Technical Guidelines has gone through various consultations. The process began in 2019 with the constitution of the Expert group on PrEP under the chairpersonship of the then SS&DG, NACO, Shri Sanjeeva Kumar. We extend our heartfelt thanks to Sir for his overall guidance. We extend our heartfelt thanks to Additional Secretary & DG, NACO, Shri Alok Saxena for his vision, guidance and constant support in this endeavour. We are also thankful to Ms. Nidhi Kesarwani, Director, NACO and Dr. Shobini Rajan, DDG, NACO for overall support in the development of the National Technical Guidelines for PrEP.

We are grateful to all the Expert Group members and esteemed members of the Working Groups for their invaluable technical support, inputs and for their driving force at every step of this journey. We take this opportunity to thank Dr. R S Gupta and Dr. Naresh Goel, Chairpersons of the Working Groups on PrEP. We are thankful to UNAIDS, USAID, CDC, WHO SEARO, WHO India, ICMR, India HIV/AIDS Alliance, SAATHII, The Humsafar Trust, DMSC, Ashodaya, IDUF, PWN+, NAATKA, NNSW, AINSW, INFOSEM, NCPI+ and all other experts.

During the process of development of National Technical Guidelines for PrEP, we had the support from private providers, civil society and community representatives – whose critical insights contributed to drafting and finalisation of the guidelines. We thank each and everyone for sharing their experience and knowledge on issues around PrEP.

Special thanks to all our partners for contributing to the National Technical Guidelines for PrEP, in particular to the team of Johns Hopkins University for all the support extended in the development of the guidelines. Special thanks to UNAIDS for extending support towards designing and printing of the document.

We would like to thank all Heads of Divisions and officers of other Divisions from the National AIDS Control Organisation and also State AIDS Control Societies (SACS) for their active inputs in finalising this guideline. We acknowledge the role of Research and Evaluation Division under Strategic Information in bringing out these National Technical Guidelines. We are confident that all stakeholders will benefit from these guidelines.

Chinmoyee Das

LIST OF ABBREVIATIONS

HIV	Human Immunodeficiency Virus
PLHIV	People Living with HIV
MSM	Men Having Sex with Men
PWID	People Who Inject Drugs
FSW	Female Sex Workers
NACP IV	Phase IV of the National AIDS Control Program
TI	Targeted Intervention
NGO	Non-Governmental Organization
ART	Anti-Retroviral Treatment
NACO	National AIDS Control Organization
TDF	Tenofovir Disoproxil Fumarate
FTC	Emtricitabine
3TC	Lamivudine
DTG	Dolutegravir
TAF	Tenofovir alafenamide
PrEP	Pre Exposure Prophylaxis
WHO	World Health Organization
PEP	Post Exposure Prophylaxis
TaSP	Treatment as Prevention
HCT	HIV Counselling and Testing

BCC	Behaviour Change Communication
STI	Sexually Transmitted Infection
OST	Opioid Substitution Therapy
NSEP	Needle and Syringe Exchange Programme
TG/Ts	Transgender/Trans
SAE	Serious Adverse Events
TB	Tuberculosis
STD	Sexually Transmitted Disease
HBV	Hepatitis B
HCV	Hepatitis C
ICTC	Integrated Counselling and Testing Center
LGBTQ	Lesbian, Gay, Bisexual, Transgender, and Queer

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Introduction

India has the second-largest HIV burden in the world, with an estimated adult prevalence of 0.22% and 23.19 lakh people living with HIV (PLHIV) in 2020. During the 90s, India seemed to be following a trajectory to have one of the largest HIV epidemics in the world. A timely and concerted response to the epidemic, however, led to a considerable decline in the incidence of HIV in the country. Currently, the country is estimated to have an annual HIV incidence of 0.04 per 1,000 uninfected population¹. However, the burden of HIV is comparatively much higher in key populations, that is, men who have sex with men (MSM), transgenders, people who inject drugs (PWID), and female sex workers (FSWs). Thus, Phase IV of the National AIDS Control Programme (NACP IV) focused on reducing the burden of HIV in key populations.

As part of its prevention strategy, India has adopted the social contracting model through the targeted intervention (TI) approach in order to reach out to the hard-to-reach populations. The programme engages 1400+TI non-governmental organisations (NGOs) that provide services to over 10 million most at-risk populations across the country. Evidence gathered through clinical trials and observational studies, however, suggests that treatment is the most efficacious prevention tool and PLHIV, who are virologically suppressed, are not at risk of HIV transmission. Moreover, there is a strong correlation between the number of PLHIV on Anti-retroviral Treatment (ART) and HIV incidence. It means that higher the number of people on ART, lower the incidence of HIV. With this fact in mind, the National AIDS Control Organisation (NACO) adopted the test and treat strategy in 2017. Subsequently in 2020, aligning its efforts with the evidence-based strategies advocated by international bodies, it replaced the first-line regimen with a fixed-dose combination of tenofovir (TDF), lamivudine (3TC) and dolutegravir (DTG). Currently, there are over 540 ART centers dedicated towards delivering ART to approximately 1.5 million PLHIV across the country.

Despite these advances, the epidemic seems to have plateaued in the last four to six years, thereby bringing to the fore, the dire need to adopt novel and innovative strategies like partner notification for early detection, newer preventive strategies and linkages to care, and proven bio-medical interventions to control the epidemic. In this context, Prevention and Pre-exposure Prophylaxis (PrEP) can prove to be highly effective. PrEP is a medication that can be taken to reduce the risk of HIV acquisition by an individual who engages in risky practices. In 2016, the combination of TDF/emtricitabine (FTC) for use as PrEP was approved by the Drug Controller General of India. However, it is also important to note that PrEP is not 100% efficacious and adherence to PrEP is critical to ensure its efficacy.

As part of the combination prevention approach, the World Health Organisation (WHO) recommends that people at substantial risk of HIV should be offered oral PrEP containing TDF as an additional prevention choice. Substantial risk of HIV is defined as an incidence of HIV typically considered to be higher than three per 100 person-years in the absence of PrEP. However, unlike many Sub-Saharan African settings, HIV/AIDS is concentrated among high-risk group populations and is heterogeneous in its spread. Even among key populations, an HIV incidence of over 3% is rarely observed (except among PWID). Thus, from a programmatic perspective and to maximise the cost-effectiveness of the PrEP programme, it is critical to adopt and implement a case-based approach, wherein each case is assessed for PrEP suitability based on a risk-scoring system. It is also important to acknowledge the fact that there has been an increase in the number of risk groups over the recent past. The last decade has witnessed an increase in the use of online and internet-based platforms. The increasing use of virtual

¹India HIV Estimates 2020

spaces like Grindr, Tinder, and Planet Romeo, particularly among the MSM population, has made it relatively easier to identify and connect with sexual partners. While anecdotal evidence suggests that a huge proportion of this population are PrEP users, there is a dearth of evidence on PrEP users and private sector practitioners. This makes it imperative for the country to formalise the guidelines for a proper and efficient use of PrEP.

PrEP: a Brief Note

PrEP refers to the use of antiretroviral medication to reduce the risk of acquiring HIV, especially among individuals who are at high risk of HIV. Research suggests that if used correctly and consistently, it can reduce the risk of HIV by over 90% among those who are sexually exposed and by around 70% among those who inject drugs. However, it is important to note that only HIV negative individuals can use PrEP, while people who are already tested HIV positive need to be immediately referred/linked to the care and treatment centers.

The virus causes an infection, when it enters the body, infects the immune cells, replicates within these immune cells, and then spreads throughout the body to infect other cells. PrEP interferes with the pathways that the virus uses and thus prevents the infection.

When PrEP is taken consistently and correctly, antiretroviral drugs enter the bloodstream, the genital and the rectal tissues. Once the drug reaches optimal levels in the body and tissues, and is consistently maintained at that level, it prevents replication of the virus within the immune cells, and protects individuals from acquiring HIV.

One of the major advantages of PrEP is that it is an additional preventive measure to the existing prevention strategy. Moreover, it is not a lifelong measure and can be initiated under high-risk periods and can be discontinued under situations or periods of low-risk. It can prove to be substantially effective in reducing the risk of HIV among individuals who are unable to negotiate condom use with their partner(s), PWID who are not able to obtain new injection equipment or people who do not use condoms or new injection equipment consistently for some reason.

Purpose of the National PrEP Technical Guidelines

The goal of the National PrEP Technical guidelines is to provide correct information on PrEP and its uses among both providers and users. Since PrEP is already in use in the country, PrEP use may decrease HIV incidence in India by broadening the options of HIV prevention across all populations. The main aim of this document is to provide correct information around PrEP in India.

The National PrEP guidelines principally focus on the following strategies to integrate PrEP with the health services in India:

- **Broadening the options for HIV prevention** by providing PrEP as an additional tool and an appropriate measure for populations who are at-risk of acquiring HIV.
- **Review the evidence and make recommendations** on PrEP eligibility, optimal regimen choices, baseline assessments, monitoring and counselling of patients on PrEP, guidelines for discontinuation of PrEP and service delivery modalities. These guidelines apply to both private sector practitioners as well as at the level of public sector.
- **Integration with existing services** to optimise implementation and cost-effectiveness. PrEP can be incorporated into the existing facilities by taking advantage of the staff and available resources.
- **Capacity building of healthcare providers** by documenting and communicating evidence-based guidelines to healthcare providers. This will enable them to provide quality services and support individuals on PrEP.

- **Increasing awareness** through communication campaigns that can be organised to improve people's awareness of PrEP and individuals willing to take PrEP can be referred to PrEP prescribers for improving access.
- **Creating an enabling socio-economic environment:** by improving the level of awareness and access among populations who are at the highest risk of acquiring HIV so that it is easily accessible to all sections of the population.

This document outlines the strategies to roll-out PrEP as an accessible HIV prevention tool. It focuses on increasing the capacity of healthcare providers to prescribe and manage PrEP, ensure that appropriate settings are used as access locations for PrEP across a wide array of general and high risk populations, and generate demand across populations with an emphasis on online and virtual strategies. The implementation of these guidelines will enable us to integrate PrEP with a variety of health services, thereby accelerating progress in reducing HIV incidence across India.

References

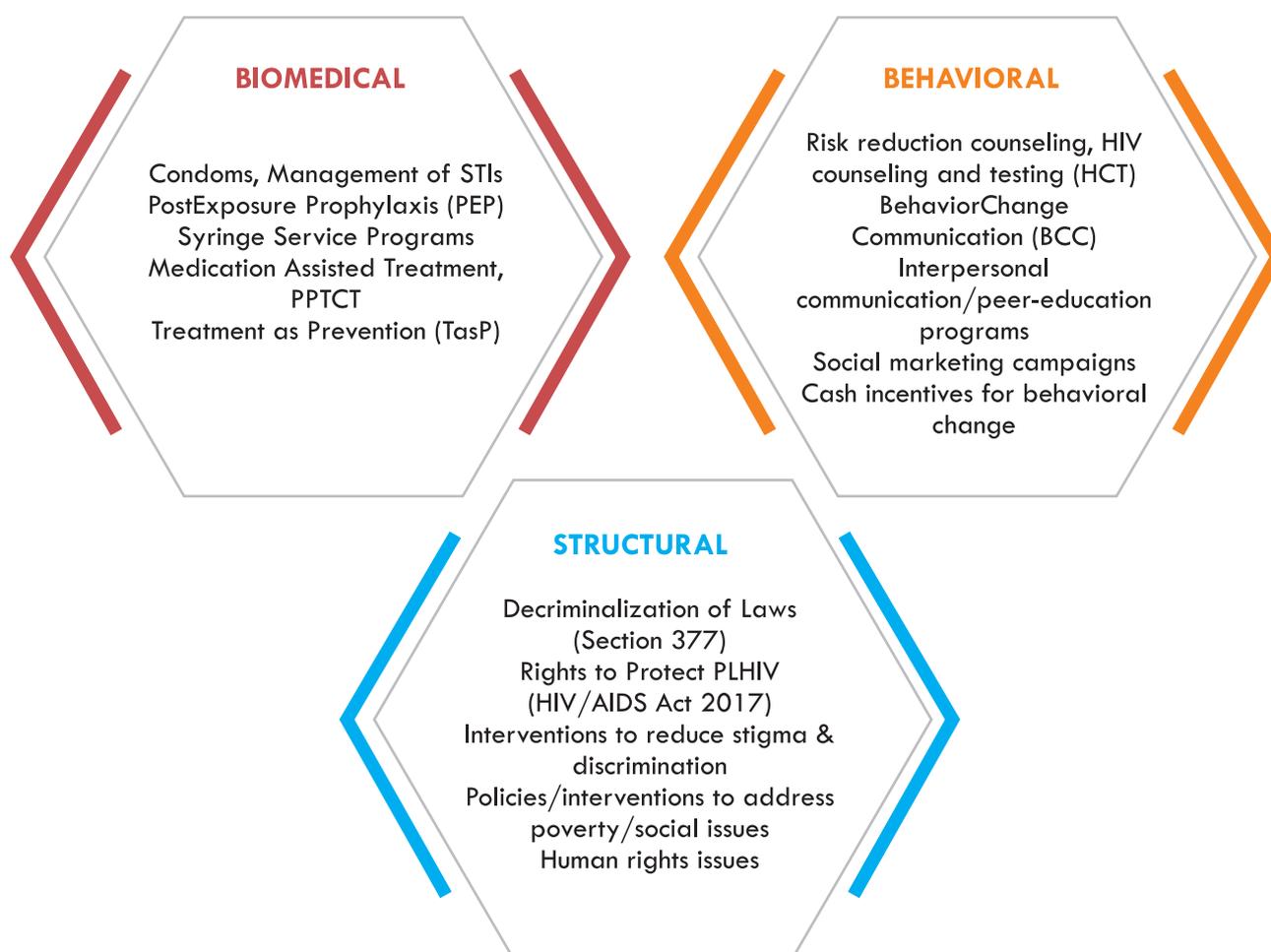
Krakower, D.S. and K.H. Mayer, The role of healthcare providers in the roll out of preexposure prophylaxis. *Curr Opin HIV AIDS*, 2016. 11(1): p. 41-8.

Combination Prevention

Several interventions to reduce the risk of HIV infection have been carried out in India since the beginning when the first few cases of HIV and AIDS were detected. However, none of these interventions could prove to be hundred percent efficacious. Hence, there is a need to combine complementary interventions to improve the overall efficacy of prevention programmes. This approach of combining various evidence-based prevention interventions tailored to the specific needs of communities and countries is commonly referred to as “combination” prevention.

HIV prevention interventions can be broadly classified under one of the three categories namely: biomedical, behavioural and structural. Figure 1 given below highlights the various evidence-based interventions that are commonly included as part of the combination prevention package. Figure 2 provides a basket of choices for HIV prevention.

FIGURE 1: HIV Prevention Evidence Based Interventions



Why do we need PrEP?

1.5 million people were infected with HIV in 2020, around two thirds (65%) of these were among the key populations and their partners². The burden of HIV infection is 19-fold higher among MSM and 49-fold higher among transgender women as compared to the general population. The high rates of HIV incidence are seen among MSM across all regions. High HIV prevalence is seen among sex workers in Africa; more than 20% in Nigeria, more than 50% in South Africa and Zimbabwe. Estimates from South Africa reveal 5.6% HIV prevalence among girls aged 15–19 years, further increasing to 17.4% for young women aged 20–24 years.

Evidently, there is an urgent need for new preventive strategies like PrEP to reduce the new infections over and above the provision of traditional preventive methods. Along with this, the treatment for all those infected is required.

In order to achieve an epidemic control in India, it is important to draw upon the elements from various strategies and tailor the program to target specific populations.

While building a prevention programme for MSM in India, it is essential that components from all three categories (behavioural, biomedical and structural) are considered in terms of availability, accessibility and affordability. Access to HCT should be an essential first step coupled with management of STIs and risk-reduction counseling to promote condom use. All MSM living with HIV should be on suppressive (Anti Retroviral Treatment) ART via the >500 ART centers and decentralised models across the country. These essential set of services are widely available across the country and can contribute greatly to control the HIV epidemic among MSM in India. PrEP should be considered an add-on to this set of evidence-based efficacious interventions that are already available and should not be considered as a replacement.

Similarly, among PWID, OST and NSEP are already available as part of the National AIDS Control Programme in addition to HCT, STI management, condoms and ART.

The addition of PrEP to this package of services could further help in controlling susceptible HIV epidemic. Mindful execution of existing and new services is required.

India has made dramatic strides in the HIV program over the past three decades – yet, we need to keep evolving with the epidemic to maintain a sustained response to the epidemic. It has become apparently evident that “one size does not fit all” and there is a need to have a bouquet of services that can be tailored to population and/or sub-national geographies. PrEP is one such service that can be considered in addition to the existing services to fast-track HIV/AIDS epidemic control in India.

FIGURE 2: HIV Prevention Basket



²UNAIDS 2021 Global AIDS Update/epidemiological estimates

Evidences

Several trials have been conducted to compare and establish the efficacy of various drug combinations for use as PrEP agents. Table 1 given below summarises the Phase 3 randomised clinical trials to date that have evaluated PrEP in various populations globally, which have contributed to the global evidence for PrEP. Most PrEP trials to date have been conducted among MSM and TG population globally and heterosexual populations in Sub-Saharan Africa. Till date, there is only one trial of PrEP among PWID from Thailand. Point to be noted here is that there have been no Phase 3 trials of PrEP in India.

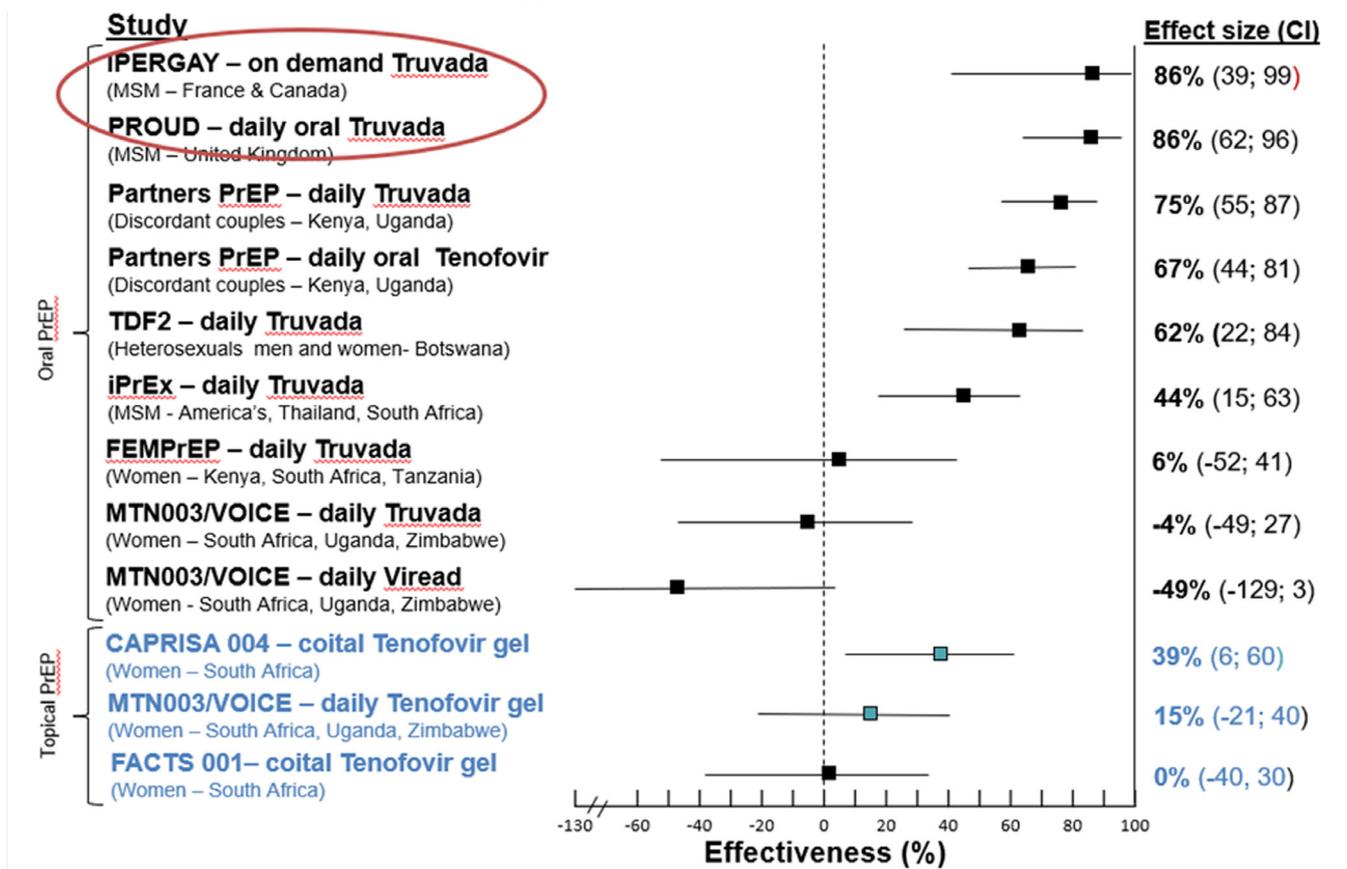
Overall, the efficacy of PrEP was found to vary from not efficacious to 86% - the strongest predictor of efficacy of PrEP was adherence. A linear association has been observed between adherence and PrEP efficacy. In the two trials (FEM-PrEP and VOICE) that were terminated for futility among heterosexual populations, the observed adherence was ~30%. There is evidence for the efficacy of both TDF and a combination of TDF/FTC for use as PrEP agents. Most recently, data from the DISCOVER trial demonstrated the non-inferiority of TAF/FTC compared to TDF/FTC as a PrEP regimen which was recently approved by the US Food and Drug Administration for use in men and transgender women. **There have been no Phase 3 trials of combinations using TDF/3TC or TAF/3TC for use as a PrEP regimen.** Several trials reported concomitant reductions in risk-taking practices during the course of these trials.

TABLE 1: Summary of Evidence from Phase 3 Clinical trials for PrEP

Trial Name (Reference)	Study population	Study location	PrEP regimen	Control arm	Efficacy	Adherence	Comment
iPrEX (Grant RM; N Engl J Med 2010;363:2587-2599)	MSM/TG	USA, Peru, Ecuador, Brazil, Thailand, South Africa	TDF/FTC	Placebo	44%	51%	<ul style="list-style-type: none"> In participants with >90% adherence, efficacy was 77%. An increase in risk reducing-behaviours, specifically increased condom use and decreased number of partners, was reported in both arms.
FEM-PrEP (Van Damme L; N Engl J Med 2012;367:411-422)	Heterosexual women	South Africa, Kenya, Tanzania	TDF/FTC	Placebo	N/A	21–37%	<ul style="list-style-type: none"> Adherence was too low to evaluate efficacy. Drug discontinuation of 1.7% rate was reported from hepatic or renal abnormalities.

Trial Name (Reference)	Study population	Study location	PrEP regimen	Control arm	Efficacy	Adherence	Comment
TDF-2 (Thigpen MC; N Engl J Med 2012;367:423-434)	Heterosexual women and men	Botswana	TDF/FTC	Placebo	63%	84%	<ul style="list-style-type: none"> Efficacy was 78%, when restricting the analyses to seroconverts within 30 days of last dose. Participants in the control arm had a significant decline in bone mineral density compared to placebo. In both groups, reported number of sexual partners declined.
Partners PrEP (BaetenJM; N Engl J Med 2012;367:399-410)	Serodiscordant, heterosexual couples	Kenya, Uganda	TDF/FTC	Placebo	75%	82%	<ul style="list-style-type: none"> Both TDF and TDF/FTC combinations were efficacious in men and women. No significant differences in efficacy by gender.
			TDF		67%		
VOICE (MarrazzoJM; N Engl J Med 2015;372:509-518)	Heterosexual women	Uganda, South Africa, Zimbabwe	TDF/FTC	Placebo	N/A	29%	<ul style="list-style-type: none"> Inefficacy of the drugs was attributed to poor adherence. Self-reported adherence across arms (~90%) was much higher than adherence based on tenofovir detected in plasma (~30%).
			TDF		N/A	30%	
PROUD (McCormack S; Lancet 2016;387:53-60)	MSM	United Kingdom	TDF/FTC	Deferred treatment	86%	~100%	<ul style="list-style-type: none"> No difference in STI incidence was detected between groups.
Bangkok Tenofovir Study (Choopanya K; Lancet 2013;381:2083-90)	PWID	Thailand	TDF	Placebo	49%	84-87%	<ul style="list-style-type: none"> Among those with detectable TDF in plasma, efficacy was 70%. Both injection and sexual risk behaviours declined.
DISCOVER (XXXXXXX)	MSM/TG	United States, Canada, Western Europe	TAF/FTC	TDF/FTC	TBA	TBA	

Overall evidence for PrEP



Several studies have reported a PrEP start-up syndrome which consisted of symptoms such as nausea, vomiting, headache and dizziness. However, most of these symptoms subside within the first month of PrEP use. Peremptory, there was no difference in serious adverse events (SAEs) between the PrEP and placebo arms. As has been observed with prolonged use of TDF, many PrEP studies also observed a decline in renal function and bone mineral density (among PrEP users compared to placebo. Bone mineral density returned to normal upon discontinuation of PrEP and no increase in risk of fracture was observed. In the DISCOVER trial, the combination of TAF/FTC was demonstrated to have a relatively better safety profile as compared to TDF/FTC.

PrEP Failure and anti-retroviral drug resistance

It has been observed that PrEP is not 100% effective. Across the clinical trials, there have been several cases of incident HIV infection in the PrEP arm. Most of these cases were attributable to non-adherence and therefore, these participants were infected with wild-type of HIV virus. There have also been instances of individuals being infected with drug resistant forms of the virus. The most common mutations observed among these infections was the M184V mutation that confers resistance to FTC/3TC – the K65R, which is associated with TDF resistance was rarely found. There have been very few cases (~2) of true PrEP failures, i.e., the participants had adequate drug levels implying optimal adherence and was infected with wild-type virus. This further highlights the importance of combination prevention and the need for counselling clients to use condoms even while on PrEP.

Real-world experience

Baeten and colleagues recently reviewed PrEP data from 46 demonstration projects globally. All clients in these programmes were on a combination of TDF/FTC. A total of 91 incident HIV infections were observed cumulatively. Across all these studies, translating to an incidence of 0.6% was observed. Of these 91 infections, 27 occurred beyond 30 days after the last dose of PrEP was given and therefore, could not be considered as infections while on PrEP. Another 17 infections were observed within 3 months of starting PrEP, thereby suggesting that these individuals could have been infected prior to the initiation of PrEP. These findings highlight the importance of timely monitoring of clients on PrEP, especially, the clients, who are newly initiated on PrEP and also among clients who discontinue PrEP. Overall, the incidence of HIV infection observed in these demonstration projects were comparable to the incidence observed in the PrEP arm of the Phase 3 trials implying real-world benefits of PrEP use.

Pre-Exposure Prophylaxis

Pre-Exposure Prophylaxis (PrEP) refers to use of anti-retroviral medication, to reduce chances of getting infected, by people at risk of acquiring HIV infection. PrEP is for use by HIV negative persons while those already infected need to be linked immediately to care and treatment centres.

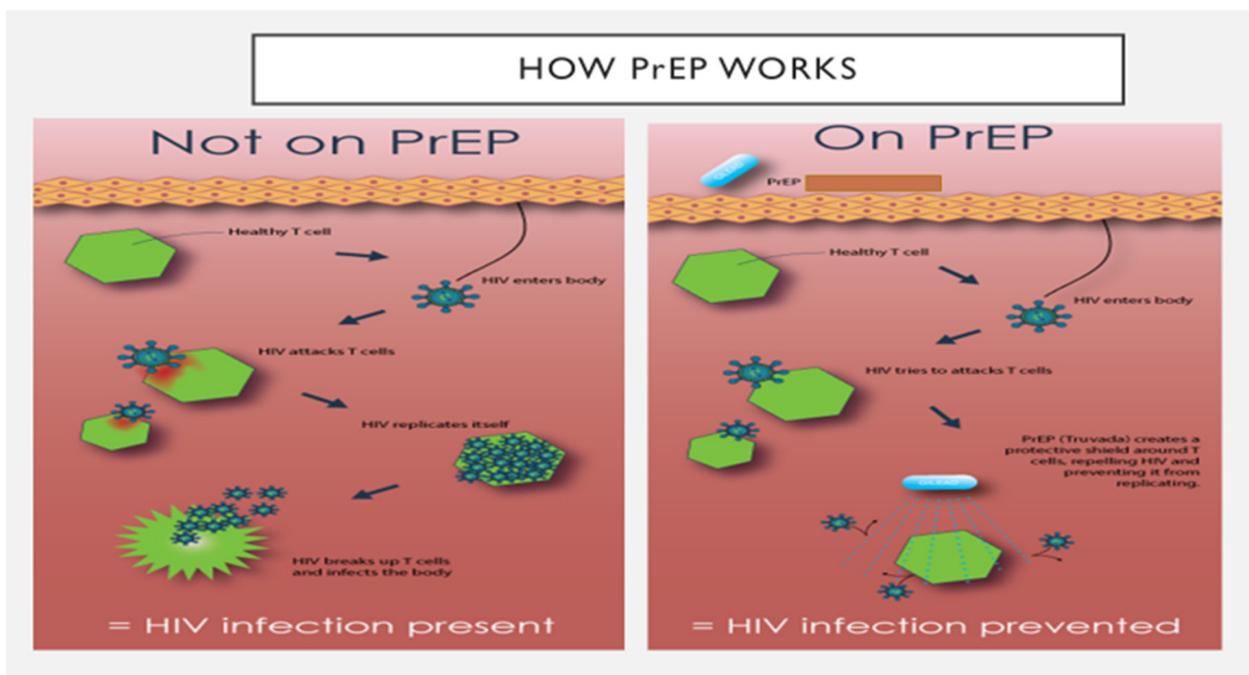
PrEP is highly effective and provides significant protection against HIV infection. Studies suggest reduction in risk of HIV infection by over 90% with sexual exposure and around 70% with intravenous drug usage, when used correctly and consistently.

The PrEP Mechanism

PrEP interferes with the pathways that HIV uses to cause an infection. For HIV to cause an infection, the virus must enter the body, infect immune cells, replicate within these immune cells and then spread throughout the body to infect other cells.

When PrEP is taken consistently and correctly, antiretroviral drugs get into the bloodstream and genital and rectal tissues. Once the drug levels in the body and tissues reach an optimum level and are maintained consistently then, it prevents HIV from replicating within the immune cells. In this way, PrEP helps to prevent an infection in human body.

Current evidence suggest, that, it takes at least 7 days of consistent use of PrEP to achieve the optimum level for protection in anal receptive sex while at least 20 days of consistent use of PrEP, for protection in vaginal receptive sex.



Why need PrEP

The goal of PrEP is to reduce the acquisition of HIV infection, ultimately reducing morbidity and mortality.

Therefore, it is important that prescribing clinicians ensure the following:

- Regimens used are proven to be safe and effective.
- Prescription is provided to uninfected individuals meeting the recommended criteria.
- Proper instructions are provided for its correct and consistent usage.
- HIV risk reduction support is provided.
- Clients are monitored regularly for HIV infection, medication toxicities, sexually transmitted diseases and condom usage.

Benefits of PrEP

The major advantage of PrEP is that it adds another effective HIV prevention option to the list of prevention strategies. It is not to be consumed lifelong, rather, can be started during periods of higher risk and stopped during lower risk periods.

In addition, it can be extremely useful to provide an additional method to help protect people, who are unable to negotiate condom use with their partner(s) or, people, who inject drugs but, are not able to obtain new injection equipment, or people, who do not use condoms or new injection equipment consistently, for whatever reason.

However, it must be noted that PrEP does not eliminate the risk of HIV infection and it does not prevent STIs or unintended pregnancies. It should, therefore, be offered as part of a combination prevention package that includes risk reduction counselling, HIV testing, condoms and lubricants, STI screening and treatment, contraception, needle exchange and opioid replacement therapy.

Regimens recommended

Combinations of two anti-retroviral drugs are recommended for use as Pre-Exposure Prophylaxis. The recommended regimens include:

Tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg

1 tablet daily

Tenofovir disoproxil fumarate (TDF) 300 mg + lamivudine (3TC) 300 mg

1 tablet daily

Currently, USFDA has recommended one more regimen for use as PrEP. This combination is recommended for people who are at risk through sex, *excluding people at risk through receptive vaginal sex*. This regimen is not recommended for people at risk due to injecting drug use and for people assigned female sex at birth.

Tenofovir alafenamide (TaF) 25 mg + emtricitabine (FTC) 200 mg

1 tablet daily

“Decision on drugs to be used will be as per recommendation of the TRG on ART of NACO”

Clinicians may use any of the above options based on availability and preference.

Clinicians should educate and counsel potential PrEP users about PrEP and conduct an individualised risk benefit assessment. PrEP should only be offered after thorough assessment to establish eligibility, readiness for effective use, required follow-up and absence of contraindications.

Eligibility for PrEP

PrEP shall be offered to sexually active HIV-negative individuals who are at substantial risk of acquiring HIV infection. It is important that a careful evaluation is done for assessing the risks and benefits before prescribing PrEP to individuals.

To be eligible for PrEP, persons must meet all the following criteria:

- **Confirmed HIV negative**, using rapid antibody testing, following the HCTS algorithm on the day of PrEP initiation.
- **At substantial risk** of acquiring HIV infection (listed below)
- **No contraindication** to use of any medication used for PrEP
- Does not have a current or recent (within past one month) illness suggestive of acute HIV infection along with history of probable exposure for HIV.
- Assessed as **ready to adhere** to PrEP and willing to attend follow-up evaluations including repeated HIV testing and monitoring.

Substantial risk:

Indicators for substantial risk of HIV infection may vary from person-to-person and in the same person at different times. Following are some factors putting people at substantial risk of HIV infection:

- HIV negative partner in sero-discordant relationship, when the HIV positive partner is-
 - Not on ART
 - Not virally suppressed
 - Not adherent to ART
- Engaging in anal or vaginal sex, either receptive or penetrative, with multiple partners with inconsistent or without using condoms in last six months.
- Engaging in transactional sex.
- People unable to negotiate condom use during intercourse with partner of unknown HIV status.
- History of any sexually transmitted infection in the last six months by laboratory testing or self-report or syndromic STI treatment.
- History of repeated use of non-occupational post exposure prophylaxis.
- A person having perceived risk of HIV infection and demanding PrEP.
- History of sex whilst under the influence of alcohol or recreational drugs as a habit.

- Intravenous drug abuse.
- Sero-discordant couples trying to conceive.

The risk assessment requires that providers have developed sufficient client rapport to effectively assess risk based on these self-reported behaviours.

The above list includes people, who are likely to be at the highest risk of getting HIV. These criteria can be used to identify PrEP candidates but should not be used to deny someone access to PrEP. While considering PrEP, practitioners must make decisions on a case-to-case basis, using local epidemiologic data and patient-reported risk behaviours/exposures.

Acute HIV infection:

A person can develop resistance to the drugs used in PrEP, if already infected with HIV (and unaware of their positive status) at the time of starting PrEP. Though, as per the current available evidence, the chances of this are very low, still, drug resistance can limit a person’s future treatment options. Hence, it becomes important to ensure that patients are HIV negative before starting PrEP.

In addition to negative HIV test report, it is important to take into consideration, the window period of HIV, when antibodies are undetectable. Therefore, clinician should properly assess and analyse, for acute HIV infection in people at substantial risk or high probable exposure. Clinician should also solicit a history of non-specific signs and symptoms of viral infection during last one month or on day of initiating PrEP.

Severity of the acute HIV infection ranges from mild non-specific ‘viral’ or ‘flu-like’ symptoms to a severe infectious mononucleosis-like illness with immune dysregulation.

Symptoms	Signs
<ul style="list-style-type: none"> • Malaise • Anorexia • Myalgia • Headache • Sore throat • Sore glands • Rash • Fever 	<ul style="list-style-type: none"> • Fever • Lymphadenopathy • Hepato-splenomegaly • Non-exudative pharyngitis • Orogenital herpetiform ulceration • Truncal rash (maculopapular or urticarial) • Guillain-Barre Syndrome • Candidiasis

Contraindications to PrEP:

Following are the situations wherein PrEP should not be initiated or continued:

- Confirmed HIV infection
- Signs/symptoms of acute HIV infection
- Weight below 30 kg
- Altered renal functions (estimated creatinine clearance < 60 mL/min)
- Unwillingness/unable to take 3-monthly HIV testing, counselling and safety monitoring visits
- Unwillingness or unable to adhere to PrEP

Creatinine measurements vary from day-to-day, depending on hydration, exercise, diet, creatine use (used by body builders) and other factors. Therefore, if a single creatinine measurement is above the normal range, the measurement should be repeated before excluding that person from PrEP services (*WHO toolkit 2017).

To calculate creatinine clearance (if not reported by laboratory), clinician can use Cockcroft-GAULT EQUation.

Estimated Creatinine Clearance = Gender * (140-age)/(serum creatinine) *(weight/72)

Note

- For gender, use 1 for male and 0.85 for female
- For transgender persons, gender at birth is used if person is not on hormone therapy
- If transgender person is on hormone therapy for more than 3 months, current gender is used
- For age, use completed years
- Provide serum creatinine in mg/dL
- For weight, use weight in kilograms

Initiating Pre-Exposure Prophylaxis

The important steps to be followed before initiating PrEP in any person are:

Step – 1: *History taking*-sexual and medical history of the person

Step – 2: *Screening/Management of Sexually Transmitted Infection*

Step – 3: *Baseline investigations* including HIV

Step – 4: *Rule out Acute HIV Infection*

Step – 5: *Counselling* – Condom use, adherence, side effects and follow-up

Step – 6: *Written Consent*

Step – 7: *Prescribe PrEP*

History taking

Sexual History: The main objective of taking a sexual history of the person is to identify patients at substantial risk of HIV infection, who will benefit the most from pre-exposure prophylaxis (PrEP). It is recommended that clinician/ healthcare provider takes a detailed sexual history and strictly avoid making assumptions around sexuality or sexual practices or sexual partners based on social norms, appearance or age of the person being assessed.

However, some patients may not be comfortable talking about their sexual history, sex partners, or sexual practices. Clinician should try to put clients at ease and let them know that taking a sexual history is an important part of a regular medical examination, and ensure that confidentiality and privacy is maintained. Following are sample questions to determine risk factors:

Starting/initial questions	<ul style="list-style-type: none"> • Are you sexually active? • With men, women or both?
General screening	<p>In last six months-</p> <ul style="list-style-type: none"> • Have you had sex with more than one person? • Have you had sex without condom? • Have you had peno-vaginal; peno-rectal; or peno-oral sex or a combination of these practices? • Have you had sex with anyone who is HIV positive or of unknown HIV status? • Have you had symptoms of sexually transmitted infection or been diagnosed with STI? • Have you wanted to use PrEP or had used PEP?
For people who have a sex partner with known HIV status	<p>One must ask the partner:</p> <ul style="list-style-type: none"> • “Is he taking ART for HIV?” • “Has he been on ART for more than six months?” • “At least once a month, discuss whether your partner is taking HIV medication daily?” • “When was your partner’s last HIV viral load test? What was the result?”

Additional factors	<ul style="list-style-type: none"> • Started sex with a new partner, who is not known to be HIV negative • Ended a long-term relationship and are looking for a new partner? • Received money, housing, food or gifts in exchange for sex? • Been forced to have sex against your will? • Used recreational or psychoactive drugs?
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Medical history: Detailed medical history shall be taken of all probable PrEP users to identify the conditions which may aggravate the side effects or toxicity of drugs used in PrEP or requires other medications with potential drug-drug interactions. Medical history shall aim to identify the following information:

- Rule out acute HIV infection
- Screen for any comorbid conditions that can affect renal functions such as diabetes or hypertension
- Take complete history of any medications including past PrEP used by clients along with its indication
- Any mental health issues like depression, anxiety
- Any known allergies
- Menstrual and gynaecological history in females, including date of last menstrual period
- History of contraception used
- History of TB/exposure to TB/4S symptom complex
- History of Hepatitis B/Hepatitis C

In addition to these general points mentioned below, it may help to identify probable issues impacting adherence such as:

- Marital/relationship status
- Education, occupation and source of income
- Family support
- Alcohol, tobacco or smoking

STI Management and PrEP: All probable PrEP users have substantial risk of sexually transmitted infections as well and presence of sexually transmitted infection itself is a substantial risk for acquisition of HIV. Hence, it is important that all persons being assessed or considered for PrEP undergo a thorough screening for any sexually transmitted infection and if diagnosed, manage STI as per guidelines.

PrEP uptake may provide an opportunity to decrease the incidence of both HIV and other STIs if better programmatic coordination is achieved. Modelling shows that more frequent testing in MSM PrEP users can result in a reduction in STI incidence – for gonorrhoea and chlamydia. Reframing PrEP, HIV treatment and STI control programmes as sexual health initiatives may lead to greater success in achieving 2030 targets than focusing on specific infections.

Integration of STI and PrEP programmes can be viewed bi-directionally (not only integrating STI services into PrEP services but also considering STI clients as people also at risk for HIV and therefore potentially eligible for PrEP. Such an approach fosters synergies and efficiencies from a public health perspective.

Clients suspected of having STI usually present with one or more of the following complaints:

- Genital/ano-rectal/urethral/cervical discharge
- Genital ulcers: Vesicular and/or non-vesicular; recurrent/non recurrent
- Inguinal bubo
- Lower abdominal and/or scrotal pain and
- Genital skin conditions.

In case of presence of any of these signs/symptoms, person shall undergo appropriate diagnostic and management procedures.

In settings where laboratory set-up and facilities for clinical examinations are not available, syndromic approach for management is recommended. Syndromic management involves making clinical decisions based on a patient's symptoms and signs. It involves using algorithms for the common symptoms and signs of the STD syndrome, such as genital ulcer or vaginal discharge, to make decisions about the disease management. Following is the summary of seven common syndromes and recommendations as per the protocols mentioned in the National Guidelines:

S.N.	Syndrome	Possible causative organisms	Drugs and Kits recommended for use
1	Urethral discharge	Gonorrhoea and Chlamydia	KIT 1 Tab. Azithromycin 1 gm, single dose + Tab. Cefixime 400 mg, single dose • Follow up at 3rd and 7th day • Partner/s treatment
2	Cervical discharge syndrome	Gonorrhoeae, Trachomatis,	KIT 1 Tab. Azithromycin 1 gm, single dose + Tab. Cefixime 400 mg, single dose • Follow up -3rd, 7th and 14th day • Partner/s treatment
3	Painful scrotal swelling	Gonorrhoea and Chlamydia	KIT 1 Tab. Azithromycin 1 gm, single dose + Tab. Cefixime 400 mg, single dose • Follow up - 7th and 14th day • Partner/s treatment
4	Vaginal discharge	Trichomonas, Candida and Bacterial Vaginosis	KIT 2 • Tab. Secnidazole 1G, two tablets stat + • Tab. Fluconazole 150 mg, single dose Follow up schedule - 7th day Partner treatment only if partner/s are symptomatic

S.N.	Syndrome	Possible causative organisms	Drugs and Kits recommended for use
5. a	Genital ulcer: Non herpetic	Pallidum (syphilis), Haemophilusducreyi (Chancroid), K. granulomatis (Granuloma inguinale), Chlamydia trachomatis (Lymphogranuloma venerum).	
5. b	Genital ulcer: Non herpetic	Herpes simplex (Genital Herpes)	KIT 5 Tab. Acyclovir 400 mg tds X 7 days The partners of those with herpes should be examined and treated only if symptomatic.
6	Lower abdominal pain	Gonorrhoea, Chlamydia, Mycoplasma, Gardnerella, anaerobic bacteria	KIT 6 Tab. Cefixime 400 mg single dose + Tab. Metronidazole 400 mg bid X 14 days + Tab. Doxycycline 100 mg bid X 14 days Follow up schedule – 3rd, 7th, 14th and 21st day
7	Inguinal Bubo	Lymphogranuloma Venerium and Chancroid	KIT-7 Tab Doxycycline 100 mg bid X 21 days + Tab. Azithromycin 1gm single dose Follow up schedule - 7th, 14th and 21st day Partner treatment for herpes only if partner/s are symptomatic

***For further details please refer to the National Guidelines on Prevention, Management and Control of Reproductive Tract Infections including Sexually Transmitted Infections*

In a laboratory setting with availability of molecular diagnostic facilities, RPR/VDRL might be considered for syphilis screening while NAAT test for chlamydia and gonorrhoea. Wherever these molecular diagnostic tests are used, it is advisable to seek for sensitivity testing of gonococci. If there are these high end diagnostic facilities available, M-PCR testing (for Tp,Ng,Ct,Hd,HSV) is also needed. In women with a history of discharge, exclude trichomonal infection by doing simple normal saline wet mount test and if facilities are available, culture should be preferred. Whenever an STI is identified, treatment of partner/s must also be ensured.

Baseline investigations before starting PrEP:

Following table describes the recommended tests prior to initiation of PrEP. It is desirable that the tests shall be done on the first visit of client. In case the tests results are already available and older than a month, tests shall be repeated.

Investigations	Rationale
HIV test	<ul style="list-style-type: none"> • HIV test using algorithm in National HCTS guidelines • To assess HIV status clinically • If recent exposure (within 72 hours), consider PEP • If negative, screen for acute HIV infection • If symptoms or signs of acute HIV infection are found, postpone PrEP until symptoms subside and rapid antibody test remains negative at 2–4 weeks' follow-up • If positive, linkage to care and treatment services
Serum Creatinine	<ul style="list-style-type: none"> • To identify pre-existing renal disease • Calculate creatinine clearance using Cockcroft-Gault Equation. • If eGFR < 60 mL/min, do not start PrEP • Non availability of baseline creatinine should not delay initiation of PrEP • For clients with pre-existing risk factor for renal impairment (such as age > 65 years, diabetes, uncontrolled hypertension, glomerulonephritis, HBV and HCV infection), every effort should be made to obtain a serum creatinine prior to initiation of PrEP
HBsAg	<ul style="list-style-type: none"> • To assess Hepatitis B, specifically in MSM, TG/TS and IDU population • If negative, consider vaccination against hepatitis B • If positive, refer for further testing and management • HBV infection is not a contraindication, however close monitoring is required while on PrEP and after stopping PrEP
HCV antibody	<ul style="list-style-type: none"> • To assess Hepatitis C infection, specifically in MSM, TG/TS and IDU population • If positive, refer for assessment and treatment for hepatitis C
VDRL/RPR	<ul style="list-style-type: none"> • To rule out syphilis • If positive, further management as per national guidelines
STI screening	<ul style="list-style-type: none"> • Syndromic approach, in setting without lab facilities • Screen for syphilis –RPR/VDRL Test • In setting with availability of diagnostic facilities, <ul style="list-style-type: none"> - For MSM and TG/TS, NAAT testing is recommended for chlamydia and gonorrhoea using oral, rectal and urine specimen (M-PCR for Tp, Hd. HSV, Tv, Ng,Ct). - For females, NAAT testing is recommended for gonorrhoea (M-PCR for Tp, Hd. HSV, Tv, Ng,Ct) using vaginal specimen
Pregnancy testing	<ul style="list-style-type: none"> • Pregnancy is not a contraindication for PrEP • To guide antenatal care or contraceptive need

Source: WHO-Oral PrEP Tool app

Counselling prior to PrEP initiation:

Success of a public health intervention depends upon the effective and ongoing counselling throughout the intervention. Counselling prior to PrEP initiation should focus on increasing awareness around PrEP as a prevention choice and helping the clients to decide whether PrEP is right for them.

Once the client chooses PrEP as an option, the focus should be on preparing the client, explaining its use, limitations and making a specific plan for its consistent use.

A non-judgmental attitude will contribute towards open conversations where clients will be free to share accurate information on risk and concerns about PrEP.

The key message that should be delivered at this point includes:

- PrEP only helps to prevent HIV and does not offer protection against STIs (such as herpes, chlamydia, gonorrhoea or syphilis), blood-borne infections such as hepatitis B/C and pregnancy.
- Correct and consistent usage of condoms along with PrEP is essential for protection against HIV as well as prevents STIs and pregnancy.
- Along with PrEP, a person should be offered male/female condom and lubricant as well, along with instructions on correct and consistent use. The detailed instruction on condom use is placed as annexure.
- PrEP is effective only when taken regularly and consistently. A person using oral PrEP needs to take it as prescribed by their healthcare provider.
- They must also attend regular doctor's appointments. These regular visits are necessary in order to be tested for HIV and other STIs, monitored for drug side effects, and receive ongoing adherence as well as risk-reduction counselling.
- The drugs used for PrEP are safe to be used. However, a small number of clients may develop side effects. These are mostly self-limiting and wane within the first few weeks of use.
- For PrEP to work optimally, drug levels in the body need to be high enough to prevent HIV infection.
- Evidence suggests that it needs 7 days of daily dosage to reach adequate anal/rectal tissue levels, whilst it needs up to 21 days of daily dosage to achieve protective genital/rectal tissue levels of PrEP drugs.
- During this period, other protective precautions must be used, such as abstinence or condoms.
- PrEP is not required lifelong. Appropriate risk reduction counselling should be provided to eventually reduce or eliminate risk of HIV acquisition.



PrEP for HIV prevention. PrEP prevents HIV infection in men and women.



HIV testing. Individuals who are taking PrEP need to have regular HIV testing



PrEP for discontinuation. PrEP should be used when someone has a risk of getting HIV. When this risk is no longer there, PrEP can be stopped.



Side effects. Side effects from PrEP affect each person differently. Most side effects will lessen after the first 1-2 months of regular use. Once the body gets used to the medications.



Daily use. PrEP must be taken every day to prevent HIV infection.



Pregnancy. PrEP safe to use when trying to become pregnant



Adherence. Counselors can talk about the best strategies to help people take their daily pills. They help people find ways to take their pills during difficult times such as travel, in the face of stigma, or when there are new partners.



Condoms. When PrEP is used, condoms have a role to prevent other sexually transmitted infections and pregnancy as well as being another HIV prevention method

Informed consent should be obtained from the client or from the caregiver if the client is a minor, before initiating Pre-exposure prophylaxis (refer to Annexure-b: Consent Form)

Prescribing the PrEP

The PrEP initiation visit should be carried out as soon as possible after the baseline screening visit. It can be on the same day of baseline screening visit and must not take longer than one month. Clinician may get repeat HIV tests, on the day of initiating PrEP, if required.

It is necessary to educate the user about potential PrEP side-effects and their management, as well as signs and symptoms of acute HIV infection.

Clients shall be advised that they should return to their clinician in case of any side effect, signs of acute infection or any other health problem developed, even if the appointment is not scheduled.

Who can prescribe PrEP: PrEP must be prescribed by a registered medical doctor qualified in modern medicine only. It is preferred that clinicians prescribing PrEP undergo training on the national guidelines for the use of ARVs as PrEP:

■ What regimen is to be followed:

Given below is the recommended regimen that involves a fixed drug combination, to be taken at prescribed time and duration:

Fixed Drug Combination of	Dosage	Time and duration
Tenofovir disoproxil fumarate (TDF) 300 mg + Emtricitabine (FTC) 200 mg	1 tablet daily	Can be taken anytime during the day. To improve adherence, it is advisable to fix a time
Tenofovir disoproxil fumarate (TDF) 300 mg + Lamivudine (3TC) 300 mg	1 tablet daily	At first visit prescription should not exceed 1 month

The combination of Tenofovir alafenamide (TAF) 25 mg + Emtricitabine (FTC) 200 mg, 1 tablet daily, can also be used to prevent HIV infection among persons at risk through sex, excluding people at risk through receptive vaginal sex. The combination has not been studied yet for use in persons with risk of HIV through injecting drug use or persons with assigned female sex at birth.

■ **Where is PrEP available:** PrEP can potentially be offered in any healthcare setting that has a medical doctor trained on the national guidelines for use of ARVs as PrEP, and with systems and tools in place for the monitoring, documentation, and reporting of PrEP use.

Some limitations (do not) with regard to PrEP prescription: For clinicians prescribing PrEP	For PrEP users seeking prescription for PrEP
<ul style="list-style-type: none"> Do not prescribe for someone not in your care Do not use regimens/medications other than mentioned above 	<ul style="list-style-type: none"> Do not share medicines with friends/spouses Do not self-prescribe Do not take PrEP from untrained/unqualified persons

Summary:

Visit	Recommendations
Screening Visit	<ul style="list-style-type: none"> • Educate about the risks and benefits of PrEP • Assess risk and eligibility • Conduct HIV counselling and testing • Assess for HIV infection • Serum creatinine level • Hepatitis B and C • STI screen • Pregnancy test • Contraceptive counselling and offer services • Arrange follow-up visit as soon as possible not later than a month
Initiation	<ul style="list-style-type: none"> • Conduct HIV counselling and testing (if required) • Confirm eligibility (including investigation results and creatinine clearance calculation) • Commence hepatitis B vaccination if indicated • Provide STI treatment if indicated • Educate client about PrEP side-effects and management • Educate client about signs and symptoms of acute HIV infection • Discuss behaviours that reduces risk • Initiate a medication effective use plan • Provide condoms and lubricant • Provide one-month prescription and • Arrange follow-up date
Vaccination	<ul style="list-style-type: none"> • Hepatitis B • Human papillomavirus vaccine (and expand on this)

Source: WHO-Oral PrEP Tool app

Side Effects and Drug-Interactions

Drugs used for Pre Exposure Prophylaxis, as tenofovir (TDF/TAF), emtricitabine and lamivudine are generally better tolerated as they may cause side effects in some individuals. Major toxicities are rare during PrEP use and most of the side effects are mild and self-limiting. However, side effects caused by PrEP may affect adherence to their medication schedule.

Side effects that may be experienced by PrEP users include:

Gastrointestinal side-effects: The gastrointestinal side-effects related to use of fixed drug combination of TDF/FTC and TDF/3TC in PrEP includes nausea, vomiting or abdominal discomfort. These generally are seen in 1 in 10 PrEP users and are mostly self-limiting, mild and wane off within few weeks. Rates of other GIT symptoms (bloating, abdominal tenderness, flatulence) are not significant. Supportive counselling and symptomatic treatment is often sufficient.

Renal toxicity: Proteinuria, decreasing glomerular filtration rate (GFR) and Fanconi's syndrome are known side effects / toxicity to tenofovir in the setting of HIV treatment. In PrEP trials, a modest and transient increase in serum creatinine and decreased GFR has been noted. Appx 0.5 to 1.5% PrEP users may have altered renal functions while on PrEP. Renal function needs to be measured prior to commencement and monitored in clients using PrEP by measuring serum creatinine and calculating the estimated creatinine clearance. These parameters should be measured at baseline, at month 1, month 4 and then every 6 months.

Clients with high risk situations like underlying renal disease, Age >65 years, BMI < 18.5 (or body weight < 50 kg), diabetes mellitus, hypertension, concomitant use of nephrotoxic drugs, should be followed more closely while on TDF containing PrEP.

Approximately one in every 200 PrEP users will have an elevation of serum creatinine during PrEP use. Approximately 80% of creatinine elevations are self-limiting (without stopping PrEP) and resolve when a separate specimen, collected on a different day, is tested. Such transient creatinine elevations are often due to dehydration, exercise or diet, or they could reflect a false positive creatinine test result. Creatinine elevations associated with starting PrEP usually reverse after stopping PrEP and do not re-occur when restarting PrEP. Common causes of chronic or severe renal insufficiency are diabetes mellitus, uncontrolled systemic hypertension, hepatitis C virus (HCV) infection, liver failure from any cause and pre-eclampsia during pregnancy.

Clients with creatinine clearance < 60 mL/min should not be initiated on PrEP and, if found during continuation, PrEP should be discontinued.

Decreased bone mineral density: Decreases in bone mineral density associated with TDF use have been a known factor among individuals receiving TDF containing treatment. These are also noticed among individuals using TDF in PrEP. However, these are very rare. There is no increased risk for fracture reported and these are reversed back to normal on stopping TDF.

Therefore, DEXA scan or any other investigations for assessing bone health are not required at time of initiation or continuation. However, in individuals with history of pathological or fragility bone fractures or have significant risk factors for osteoporosis should be referred or managed accordingly.

Drug-Drug interactions

Sometimes some drugs can affect blood levels of other drugs, which may increase side effects or make the medications less effective. Many drugs can affect tenofovir. This includes prescription and over-the-counter medicines, vitamins, and herbal products as well. However not all are clinically significant, however it is important that clients are being asked about concomitant use of any drugs/medicinal product.

Given below are some common drug-drug interactions:

	TDF/TAF	FTC/3TC
Buprenorphine	No dosage adjustment recommended.	No dosage adjustment recommended
Methadone		
Oral Contraceptives		
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir	Serum concentrations of these drugs and/or TDF may be increased.	
Aminoglycosides	Monitor for dose related renal toxicities	
NSAIDS		
Ledipasvir/sofosbuvir	Serum concentrations of TDF may be increased. Monitor for toxicities.	

Source: CDC-HIV-PrEP-Guidelines-2017

Follow-up and Monitoring

Follow-up and monitoring of clients initiated on PrEP is essential to ensure efficacy for HIV prevention. The major aim to track progress, monitor sexual and general well-being, assess adherence and to identify adverse drug reactions/toxicities.

Monitoring includes clinical monitoring as well as laboratory monitoring.

Clinical Monitoring

- To be done on every visit
- Assess for any side effects
- Ask for any new signs/symptoms suggestive of STI
- Take menstrual history to rule out pregnancy
- Ask for signs/symptoms suggestive of acute HIV infection
- In case signs of acute HIV infection present, clinician may elect to continue PrEP while awaiting results of follow-up HIV testing (2–4 weeks) or may decide to withhold PrEP until follow-up tests available.
- Note that, if PrEP has been taken consistently, breakthrough infection is unlikely. Withholding PrEP may put an effective user at greater risk for HIV acquisition.

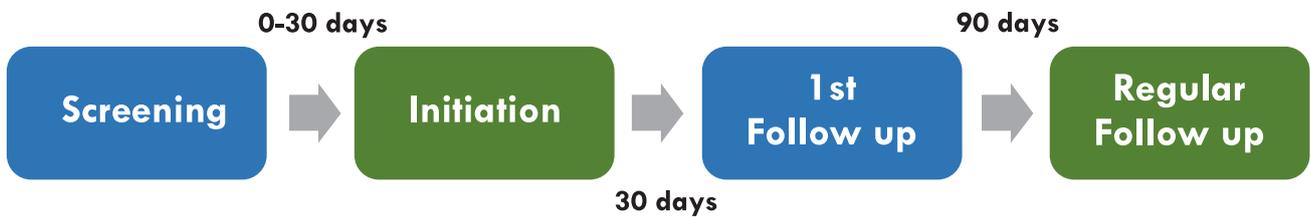
Laboratory Monitoring

- HIV testing using national HCTS guidelines at 1 month of PrEP, then every three months
- Serum creatinine and estimated creatine clearance at 1 month of PrEP, 4 months of PrEP and then every six months
- More frequent monitoring of serum creatinine may be done, in cases with conditions affecting kidneys, such as diabetes, hypertension, etc.
- STI screening: as per the signs/symptoms
- Hepatitis C antibody: every 12 months may be offered to clients e.g. MSM ,TG/TS or IDU

Repeat pregnancy testing for women who may become pregnant. However, it should be noted that pregnancy is not a contraindication for starting/continuing PrEP.

Frequency of visits:

- It has been observed that the rate of discontinuation is highest among first four weeks hence it is recommended that after initiation of PrEP, next date should be preferably after 4 weeks (1 month's prescription)
- After this, visits can be done every three months.



- For certain populations, such as the PWID, more frequent monitoring may be required. Physician may take decision on case-to-case basis.

Counselling while on PrEP

Counselling of the clients while they are on PrEP is a crucial aspect of the overall care. The aim of counselling during this phase is to encourage the clients to maintain optimum adherence to medication, follow suggested algorithms for visits and testing, answer any queries around PrEP and remove misconceptions.

Following are the important steps for counselling during PrEP:

- Understand the history of condom use and risk behaviour
- Assess the adherence to PrEP during each visit and adherence must be reinforced through counselling at all visits. Adherence evaluation can be done through pill count and self-report
- Adherence to daily PrEP medication can be a challenge. Adherence counselling should be implemented at each visit where PrEP prescriptions or distributions are made. Users need to be made aware of the fact that drugs only work if present at adequate levels in tissues and, preferably, that drug levels should be adequate before and after exposure to HIV has occurred.
- The use of cellphone reminders, pillboxes and linking of pill taking with daily routine activity can improve PrEP adherence. Clinicians and clients could use any of these or other strategies to ascertain an effective use of PrEP medication. Any trained healthcare worker can provide adherence counselling. A client-centred approach is recommended.
- It is clear that PrEP is effective only if taken regularly. More than 95% adherence should be expected for optimum results. Clients with adherence below 80% should be offered enhanced adherence counselling.
- Include user-focused effective use counselling at every contact. Provide a clear explanation of the benefits of effective use. In a neutral manner, ask if the user has any challenges that may make taking PrEP difficult. Also explore possible facilitators on pill taking. Include identified facilitators when developing strategies to improve effective use of PrEP.
- Risk reduction is an important aspect that must be included in counselling : Risk reduction counselling is a behavioural intervention that attempts to decrease an individual's chances of acquiring HIV and other STIs and should be implemented together with adherence counselling at follow-up visits for PrEP users.
- The main objective of risk reduction counselling is for clients to set a realistic goal for behaviour change that could reduce their risk of contracting HIV. This is most effective when it is non-prejudicial, and user centred. Risk reduction counselling can be provided by any trained healthcare provider and should address the following points:
 - Explore the context of the user's specific sexual practices and assist in recognising which of their behaviours are associated with high risk of HIV infection. Clinicians should also be aware that clients might not always perceive their own risk, or may be in a state of denial on the issue.
 - Identify the sexual health protection needs of the user and reflect on what their main concerns appear to be.
 - Identify strategies with the user that can manage their concerns or needs.
 - Agree on which strategies the user is willing to explore, and guide the user to decide on how to implement the strategy.

Some Key Considerations and possible ways to manage:

Key considerations/issues	Techniques to manage
<p>Client does not want to use a condom</p>	<ul style="list-style-type: none"> • Do not be judgemental about patient preferences. • Explain that this is a valid choice and avoiding condom use can have potentially negative consequences. • Explain that PrEP prevents HIV but not STIs. • Explain that PrEP prevents HIV but not pregnancy. • Confirm a regular STI screening and management plan. • Confirm an effective and acceptable contraception plan where indicated.
<p>Client with signs / symptoms / diagnosis of STI</p>	<ul style="list-style-type: none"> • Reiterate the importance of condom use • Explain that though STIs are curable, they may cause complications and increase the risk of HIV infection • Refer for management of STIs
<p>Client skips doses occasionally</p>	<ul style="list-style-type: none"> • Reiterate the importance of adherence • Appreciate the client for reporting • Explain that if a dose is missed, it should be taken whenever you remember • Mention that it is safe if occasionally two doses are taken by mistake • Suggest mechanisms like reminders / alarms
<p>Client with poor adherence (<80%)</p>	<ul style="list-style-type: none"> • Do not be judgemental about poor adherence • Appreciate the client for reporting and discussing • Explain that PrEP is effective only if taken regularly • Elicit information of probable barriers • Suggest possible mechanisms to overcome it • If required, link to peer support groups

Discontinuation of PrEP

Unlike Antiretroviral therapy, PrEP is not required lifelong. The major aim of PrEP is to cover the risk period and simultaneously efforts must be made to make behavioural changes and incorporate risk reduction methods in the lifestyle.

The duration of PrEP use may vary from individual to individual and time to time, depending on risk assessment at different periods in life and may get affected by factors like breakups, travelling, emotional vulnerabilities, ability to adherence, etc.

Discontinuation of PrEP may be categorised as completion of PrEP course (for that episode) or stopping (due to medical advice or client's own will)

Completion of PrEP

PrEP can be termed completed, for a particular case, when the risk status of client changes from substantial risk to low/no risk. The criteria for these include:

- In sero-discordant couples, the HIV positive partner is virally suppressed AND is adherent to treatment for last six months
- The risk status changes from substantial risk to low or no risk
- Client enters in mutual monogamous relationship
- Consistent and correct use of condoms for last three months and willingness to continue the same with both regular and non-regular partners
- No signs/symptoms of sexually transmitted infection in last three months

Decision for completion of PrEP shall be done only after a detailed and frank conversation and discussion between the provider and client on all the aspects.

Clients completing PrEP shall be advised to continue it for 28 days since the last potential exposure.

Laboratory investigations required at the time of completing PrEP

- Rapid HIV antibody test
- Serum Creatinine

Any person who completes PrEP shall be counselled six monthly and an annual follow-up in order to assess risk status. Clients shall also be explained about the risk status and advised to report back anytime if risk increases or is perceived.

Anyone can be re-started on PrEP if required. While re-starting the PrEP course, it shall be considered as a fresh episode and following procedure needs to be taken up with the client:

- Assessed for eligibility again
- Undergo baseline clinical and laboratory assessment including HIV & STI testing, and
- Receive preparedness counselling

Conditions to stop or discontinue the PrEP

In certain situations, clinician may need to stop PrEP, in between the ongoing course due to medical reasons or at times because of client's non-adherence/reluctance to continue with PrEP.

Medical grounds to discontinue PrEP On medical grounds, despite continued risk, PrEP should be stopped if ANY of the following is noted:

- Diagnosis of HIV infection
- Renal toxicity (creatinine clearance below 50 ml/min)
- Intolerable toxicities

In such situations, PrEP shall be stopped immediately, and restarting is not recommended. These clients shall be:

- Counselling for risk reduction behaviour
- Followed up every three to six months for HIV testing and STI screening, while risk remains elevated

Client related issues

There may be situations, wherein, client-related factors impact the efficacy of PrEP. These include:

- Continued non-adherence to PrEP, despite efforts of improving it
- Not willing / unable to follow regular testing requirements
- Client is not willing to continue with PrEP

In these situations, the clinician shall put all efforts towards improving compliance and adherence by understanding the barriers, involving peers or professional counsellors. However, in case no improvement is noticed, then PrEP can be discontinued. Client may also be advised to continue PrEP for at least 28 days after the last potential exposure to HIV.

An important step in such a situation is that the clients should be offered with counselling for risk reduction, barrier method and regular follow-up. They shall be advised to report back, in case of:

- Willingness to start PrEP
- Signs / symptoms of STI
- Signs of acute HIV infection
- HIV diagnosis

Upon discontinuation for any reason (completion/stopping), the following should be documented:

- HIV status
- Reason for discontinuation
- Adherence
- Reported sexual behaviour

Special Situations

There are situations that call for special attention and care of clients under PrEP. Patients with certain clinical/special conditions requires special attention and follow-up by the clinician. These include:

Pregnancy

PrEP may be initiated or continued during pregnancy in women at substantial risk of HIV acquisition. If a sero-discordant couple desires pregnancy, PrEP can be one of the strategies for safer conception. Clinicians should educate HIV-discordant couples who wish to have a child about the potential risks and benefits of all available alternatives for safer conception and if indicated, make referrals for assisted reproduction therapies.

The clinicians should also discuss with them about the available information related to potential risks and benefits of beginning or continuing PrEP during pregnancy so that an informed decision can be made. Once the decision of taking PrEP is taken, clinician must ensure that:

- The HIV positive partner is on ART and virally suppressed
- PrEP is initiated at least 20 days ahead of unprotected sex
- Most fertile period may be advised to the couple for increasing chances of conception

Breastfeeding

PrEP may be initiated or continued during breastfeeding in women at substantial risk of HIV infection. If a woman becomes infected with HIV during breastfeeding, the risk of transmission to the infant may be higher because of high viral load during sero-conversion. Therefore, PrEP should be initiated or continued in women who are at substantial risk.

Hepatitis B

Hepatitis B vaccination is recommended for people at substantial risk of HBV or HIV infection. Vaccination should be considered if there is no documented history of a completed vaccine series for HBV. PrEP can be provided whether or not HBV vaccination is available. For clients with HBV infection, following care is recommended:

TDF is active against HBV infection through the same dose used for PrEP, TDF is recommended for treatment of HBV infection in people for whom treatment is indicated. However, not all people with chronic HBV infection have treatment indications. Indications for treatment of HBV can be assessed in a variety of ways depending on which laboratory tests are available.

- Clients with HBV infection should be referred to appropriate facility and should be managed as per National Guidelines for treatment of Hepatitis.
- When HBV treatment is stopped, occasionally HBV infection can flare in the following one to three months. Such flares are often limited to elevations in serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST), although decompensation of liver function can occur.
- Flares in HBV infection are treated by restarting treatment. The risk of hepatitis flares after stopping HBV treatment is higher in people with liver fibrosis. Therefore, additional assessment can be considered for people with HBV infection who are considering PrEP.

Management of HIV Positive Cases

HIV testing is an integral step in the PrEP process. Clinicians must remain vigilant about signs and symptoms of acute HIV infection at all times and in all cases. A person can be screened HIV positive during any of the following situations:

- Baseline screening
- While on PrEP, every 3 months
- At Discontinuation
- After Discontinuation

Such infections are generally found to be pre-existing or due to no or inconsistent use of PrEP. A client screened positive anytime should be provided the following services:

- **HIV confirmation:** Any client who is screened reactive while testing for/during/after PrEP, should be linked to an Integrated Counselling and Testing Center (ICTC) and follow confirmatory HIV testing as per National HIV Counselling and Testing Services (HCTS) Guidelines.
- **Counselling:** Pre and Post-test counselling should be provided to such clients, regarding their HIV positive status, healthy lifestyle and ways to prevent further transmission.
- **Linkages to Care, Support and Treatment:** Clients diagnosed HIV positive should be linked to Care, Support and Treatment services under the government or to a clinician trained / experienced for provision of Antiretroviral therapy (ART), as soon as possible. These services shall include:
 - CD4 testing
 - Baseline evaluation
 - Antiretroviral therapy

****For details, please refer to National GUIDELINES for Antiretroviral therapy**

- For clients who are already on PrEP, it is recommended that transition of two drug PrEP course to three drug ART should be immediate and without any gap. This should not be delayed for results of CD4 or any other investigations. Even in cases wherein confirmation is expected to be delayed by hours or days, transition to three drug ART can be started without waiting for results.
- As per current evidence, baseline resistance testing or using regimens other than tenofovir based regimens is not recommended. Clients diagnosed positive after exposure to PrEP, should be monitored closely with viral load testing.
- **Index Partner(s) testing:** Clients diagnosed positive should be counselled for and/or linked to services for identification of sexual and injecting partners who may have been recently exposed to HIV. Such partners shall be offered HIV testing, considered for non-occupational post-exposure prophylaxis, and counselled about their risk-reduction. Once diagnosed negative, such partners can be offered PrEP if found to be at substantial risk.

Service Delivery

PrEP implementation can be integrated in any setting that meets the conditions for initial evaluation and initiation. Since there is a definite need for close clinical and lab monitoring, The National Guidelines on PrEP recommend that specific criteria should be met for service delivery that can be understood through the Q/As given below:

Who can prescribe PrEP?

Since the drugs used for PrEP are included in schedule H, it is mandatory that these should be prescribed by a registered medical doctor qualified in modern medicine. It is desirable that the doctor prescribing PrEP should be trained in National Technical Guidelines for PrEP.

Who can provide counselling related to PrEP?

Counselling needs specific skills along with a non-judgemental and empathetic approach. It is desirable that counselling related to PrEP is provided by a healthcare worker who is adequately trained on all the aspects of PrEP. The health care worker who can provide counselling for PrEP include:

- Counsellor
- Medical Doctor
- Staff Nurse
- Peer

A trained peer is often the best option. Sharing of real-life experiences helps the client to understand pros and cons effectively.

What are the key requirements for laboratory testing?

The physical setting of laboratory may not be necessarily required at the site providing PrEP services. However, it is recommended that services from an accredited or recognised laboratory are available through linkage. To avoid any linkage loss between 'referred for' testing and 'actual testing', it is advisable that sample collection shall be available in the same premises. Hence to meet laboratory requirement basic needs include:

- Linkage to an accredited/recognised laboratory
- Phlebotomist
- Bio-medical waste management system

What are the specific documents required for prescribing PrEP

- Valid ID proof for establishing identity and confirming age (in case of minors)
- Complete address along with contact details like telephone numbers
- Written consent

- Patient record to document all the events that should be maintained with providers (refer to Annexure-e)

These documents are desirable for prescribing or continuation of PrEP. However, inability to produce these at first visit should not result in delay in services. These can be collected at the first visit/subsequent visits, wherever feasible. In case, the address related document is not available, options of verifying address through a field visit by peer may be considered. Providers should ask for any change in address or contact details at every visit.

Service Delivery sites

Following is the list of sites recommended for PrEP initiation or continuation:

Setting	HIV clinics
Description	This includes ART centres in government setting as well as infectious disease / HIV clinic in private sector.
Ideal for	These settings are primarily best for clients whose spouse / partner is known HIV positive.
Strength	The existing experience of dealing with antiretroviral drugs, its use and monitoring along with availability of qualified staff are the major advantage of these settings.
Improvisation required	Focus should be on making services friendly to marginalised populations such as clients among sexual minorities and clients engaged in transactional sex / drug abuse. Waiting time or turnaround time due to existing workload of treating HIV positive clients also needs to be considered and efforts are required for decongestion of facility.
Consideration	May not be ideal for general population or HIV-negative clients with high risk. Attached stigma to a “HIV clinic” may also hamper access by some population

Setting	STI Clinics
Description	These include “Suraksha Clinics” in government settings and skin and venereal disease clinics in the private sector
Ideal for	People with signs or symptoms of sexually transmitted infections(STIs) are the major focus population for PrEP use and risk reduction counselling.
Strength	Coverage of population with high risk of HIV and STI transmission. Availability of qualified and experienced staff like doctor and counsellor in dealing with anti-retro viral (ART) drugs and STI management. Experience with partner tracking, testing and treatment.
Improvisation required	Focus should be in making services friendly to the marginalised populations such as clients among sexual minorities and clients engaged in transactional sex or drug use.
Consideration	May not be ideal for sero-discordant couples. Attached stigma may also hamper access by some population

Setting	Primary / General Health Care
Description	This includes primary / general health institutes and any OPD based clinics in private settings
Ideal for	The population with perceived stigma to the clinic designated for sexually transmitted infections or HIV
Strength	Availability of a qualified staff (medical practitioner/ doctor) and the aspect of integration of HIV services to general health under universal coverage
Improvisation required	Focus should be in making services friendly to the marginalised populations such as clients among sexual minorities and clients engaged in transactional sex or drug use. Additional training shall be required for continuous follow up.
Consideration	May not be ideal for sero-discordant couples / marginalised groups.

Setting	Community based setting
Description	This includes settings established by the community and for the community. Examples are Targeted Intervention sites, LGBTQ Drop-in centres, Support groups
Ideal for	These are ideal for marginalised groups
Strength	Strong peer support is the greatest strength along with available resources for continuous tracking and follows up
Improvisation required	Availability of a qualified and trained healthcare personnel needs to be ensured
Consideration	These setting shall focus on the specific groups for whom they are specialised

Post Exposure Prophylaxis

Post exposure prophylaxis (PEP) for HIV refers to the comprehensive management, including use of antiretroviral medication, instituted to minimize the risk of infection following potential exposure to HIV.

This includes first aid (if required), counselling, risk assessment, relevant laboratory investigations based on informed consent of the source or exposed person, and depending on the risk assessment, the provision for short term (4 weeks) of antiretroviral drugs, with follow up and support including maintaining confidentiality.

Exposure, which may place a person on risk of HIV infection can be occupational as well as non-occupational.

Occupational: refers to exposure to potential blood-borne infections (HIV, HBV and HCV) that occur during performance of job duties. This includes:

- A percutaneous injury (e.g. needle-stick or cut with a sharp instrument)
- Contact with the mucous membranes of the eye or mouth
- Contact with non-intact skin (when the exposed skin is chapped skin or afflicted with dermatitis)
- Contact with intact skin when the duration of contact is prolonged with blood or other potentially infectious body fluids

Healthcare workers are at an increased risk of occupational exposure to HIV through contact with contaminated blood and other body fluids containing HIV through needle stick injuries and injuries by other sharp objects or through non-intact skin and mucous membranes.

The term “Health Care Personnel (HCP)” is defined as any persons, paid or unpaid; working in healthcare settings who are potentially exposed to infectious materials (e.g. blood, tissue, and specific body fluids and medical supplies, equipment, or environmental surfaces contaminated with these substances).

HCP include emergency care providers, laboratory personnel, autopsy personnel, hospital employees, medical and nursing students and healthcare professionals at all levels. If required, PEP can also be given to public safety workers, including law enforcement personnel, sanitary workers, prison staff, fire-fighters, workers involved in needle exchange programmes, healthcare providers in private setting and even to attendants of patients after proper evaluation of exposure.

Non-occupational: refers to exposure to potential blood-borne infections (HIV, HBV, HCV) outside of the work place setting like unsafe sex, sexual assault. This includes:

- Contact with the mucous membranes of oral, genital or anal region.

The “**exposed person**” is the person who is potentially at risk of acquiring HIV infection due to exposure to blood or potentially infectious body fluids.

The “**source person**” is the person who is (either identified or not identified as) the possible source of contamination through blood or potentially infectious body fluids. If the sero-status of the source person is unknown, he or she may be counselled to provide informed consent for HIV testing. The source person may be a patient if a healthcare provider is exposed, or the perpetrator in the case of sexual assault, or the sexual partner during unsafe sex.

The decision regarding whether to provide PEP in cases of occupational/non-occupational exposure should be based on the clinical consideration of risk only. Providers should give information, services and education without discrimination. The provision of information regarding PEP should be confidential including information about HIV testing, PEP provision and the reasons for seeking PEP.

Written Informed consent needs to be obtained. Consent for HIV testing of source/exposed person in the context of HIV exposure and/or taking PEP, needs to be done in accordance with National HCTS Guidelines.

In special situations, where the individual has limited or no capacity to consent (e.g. children, or unconscious or mentally ill adults), a legally acceptable representative may be able to provide consent (e.g. parent/guardian/care taker).

Risk Factors:

Risk of exposure from different body fluids

Body fluids considered 'at-risk'	Body fluids considered 'not at-risk'
Blood	Tears
Semen	Sweat
Vaginal secretions, Cerebrospinal fluid Synovial, pleural, peritoneal, pericardial fluid	Urine & faeces
Amniotic fluid	Saliva
Other body fluids contaminated with visible blood	Sputum
	Vomit
	(Unless these secretions contain visible) blood

Source: National Technical guidelines on ART, NACO

Any direct contact (i.e. contact without barrier protection) to concentrated virus in a research laboratory requires clinical evaluation.

For human bites, clinical evaluation must include the possibility that the person bitten and also the person who inflicted the bite were exposed to blood borne pathogens. Transmission of HIV infection after human bites has been rarely reported.

Average risk of acquiring HIV, Hepatitis B, Hepatitis C after exposure

The average risk of acquiring HIV infection following different types of exposure is low compared to the risk of acquiring infection with HBV or HCV. In terms of occupational exposure, the important routes are needle stick exposure (0.3 % risk for HIV, 9-30 % for HBV and 1- 1.8% for HCV) and mucous membrane exposure (0.09% for HIV).

HIV transmission risk by different routes:

Route of exposure	Type (in %)
Blood transfusion	90- 95
Perinatal (without any intervention)	15- 40
Sexual intercourse	0.1 to 10
Vaginal	0.05- 0.1
Anal	0.065- 0.5
Oral	0.005- 0.01
Injecting drugs use	0.67
Needle stick exposure	0.3
Mucous membrane splash to eye, oro-nasal	0.09

Source: National Technical guidelines on ART, NACO

Prevention of Exposure

Exposure to HIV is mostly accidental. However, there are specific steps which can be taken, especially for occupational exposure, which can decrease the chances of exposure.

To avoid exposure to HIV, universal precautions should be followed while handling possibly contaminated body fluids including the use of appropriate barriers such as gloves, gowns and goggles. Care with sharp equipments, including minimising blind surgical procedures and proper handling and disposal of sharps; safe disposal of contaminated waste; safe handling of soiled linen; and adequate disinfection procedures are equally important.

Guidelines also recommend universal Hepatitis B vaccination of non-immune 'at risk' groups including HCWs, police, prison staff and rescue workers.

Certain work practices increase the risk of needle stick injury such as:

- Recapping needles (most important)
- Transferring a body fluid between containers
- Handling and passing needles or sharps after use
- Failing to dispose off used needles properly in puncture-resistant sharps containers
- Poor healthcare waste management practices

Ways to protect oneself from needle stick/sharps injuries:

- Strict compliance to universal work precautions
- Avoid the use of injections where safe and effective alternatives are available e.g. oral, drugs
- Avoid recapping the needles
- Plan for safe handling and disposal of needles after use
- Promptly dispose of used needles in appropriate sharps disposal containers
- Report all needle stick and sharps-related injuries promptly to ensure appropriate follow-up care.

Steps for initiating PEP:

PEP should always be offered as soon as possible (and within 72 hours) after a high-risk exposure. However, following are the important steps that need to be followed:

Step 1: Management of exposed site (for occupational PEP)

Step 2: Establish eligibility for PEP

Step 3: Counselling for PEP Step 4: Laboratory evaluation Step 5: Prescribing PEP

Step 6: Follow-up

Step 1: Management of exposed site (for occupational PEP)

Skin	Unbroken skin	Eye	Mouth
<p>If the skin is pierced by a needle-stick or sharp instrument:</p> <ul style="list-style-type: none"> Immediately wash the wound and surrounding skin with water and soap and rinse Do not scrub Do not use antiseptics or skin washes Don't use bleach, chlorine, alcohol, betadine After a splash of blood or body fluids 	<ul style="list-style-type: none"> Wash the area immediately Do not use antiseptics 	<ul style="list-style-type: none"> Irrigate exposed eye immediately with water or normal saline Sit in a chair, tilt the head back and ask a colleague to gently pour water or normal saline over the eye If wearing contact lens, leave them in place while irrigating, as they form a barrier over the eye and will help protect it. Once the eye is cleaned, remove the contact lens and clean them in the normal manner. This will make them safe to wear again Do not use soap or disinfectant on the eye 	<ul style="list-style-type: none"> Spit fluid out immediately Rinse the mouth thoroughly, using water or saline and spit again Repeat this process several times Do not use soap or disinfectant in the mouth

Step 2: Establish eligibility for PEP

Must meet all of the following criteria:

- Exposed individual is HIV negative at baseline
- Exposure must have occurred within the past 72 hours
- Exposure must be “risk exposure” (at-risk type AND at-risk material)

At-risk types	At-risk material
<ul style="list-style-type: none"> mucous membrane non-intact skin, or percutaneous injury 	<ul style="list-style-type: none"> blood or bloody body fluids breast milk semen vaginal secretions synovial, pleural, pericardial, amniotic fluids CSF, or HIV cultures in lab

HIV status of the source should not be part of the risk assessment for PEP, because even if the source tests HIV negative by rapid antibody test, they may still be in the window period of acute HIV infection.

If a breastfeeding mother starts PEP because of HIV exposure, the infant does not require PEP or infant prophylaxis as well. The infant should continue breastfeeding.

Step 3: Counselling for PEP

For an informed consent, exposed persons (clients) should receive appropriate information about what PEP is and the risks and benefits of PEP. It should be clear that PEP is not mandatory. The client should understand details of the window period, baseline test, drugs that are used, their safety and efficacy and issues related to these drugs during pregnancy and breast-feeding.

He/ she should be counselled on safe sexual practices till both baseline and 3 months of HIV test are found to be negative.

Psychological support: Many people will feel anxious after exposure. Every exposed person needs to be informed about the risks and the measures that can be taken. This will help to relieve part of the anxiety, but some may require further specialised psychological support.

Special leave from work, if required, should be considered for a period of time e.g. 2 weeks (initially), then as required, based on assessment of the exposed person's mental state, side effects and requirements, the decision should be done as per assessment of the treating physician.

Step 4: Laboratory evaluation

HIV, HBV and HCV testing of exposed person within 6 days of an exposure is recommended (baseline sero-status). A positive HIV status at baseline may indicate the need to discontinue PEP and referral to HIV care and treatment. The decision whether to test for HIV or not should be based on the informed consent of the exposed person. In addition to these, pregnancy testing, serum creatinine and liver function test should be done.

****However, PEP SHOULD be offered even when lab tests are not available. Do not delay administration of PEP while waiting for lab RESULTS.**

Step 5: Prescribing PEP

Time of PEP: As post-exposure prophylaxis (PEP) for HIV has its greatest effect if begun within 2 hours of exposure, it is essential to act immediately. There is little benefit if more than 72 hours have lapsed but PEP can still be used if the health care worker presents after 72 hours of exposure. The prophylaxis needs to be continued for 4 weeks.

- Report exposure immediately to appropriate authority
- Never delay the start of therapy due to debate over regimen.
- In cases with exposure from person on ART, start available three drug regimens and seek opinion after that.

Regimen for PEP:

Three-drug regimens are preferred for PEP as under:

Client	Preferred regimen	Alternate regimen
≥ 10 years old and ≥ 30 kg body weight	TDF + 3TC + DTG (one tablet OD)	TDF + 3TC + LPV/r (TDF+3TC, one tablet OD and LPV/r, two tablets BD) TDF +3TC + EFV (one tablet OD)
Age 0-14 years and < 30 kg body weight (dosage as per treatment dosage)	ABC + 3TC + LPV/r (dosage as weight bands)	ZDV + 3TC + LPV/r ABC + 3TC +DTG (dosage as weight bands)

In case of a highly treatment experienced source, initiate first dose as per above guidelines and expert opinion should be sought.

If a breastfeeding mother starts PEP because of HIV exposure, the infant does not require PEP or infant prophylaxis as well. The infant should continue breastfeeding.

In cases of sexual assault, the same principles need to be followed in adults and adolescents. For children who have suffered assault and have to be administered PEP, the dosage should be as per age and weight bands and haemoglobin levels.

Step-5: Follow-up

A 28-day prescription of antiretroviral drugs should be provided for HIV postexposure prophylaxis following initial risk assessment (strong recommendation, low-quality evidence).

Enhanced adherence counselling is recommended for individuals initiating HIV post-exposure prophylaxis.

- Follow up the client at 7 days, 14 days, 28 days, and 12 weeks period after starting PEP
- Follow-up HIV testing at 4 weeks, if negative, test again at 12 weeks after which test as per the risk category
- Assess for and manage side effects due to PEP
- Monitor for acute sero-conversion illness. Within 3-6 weeks after exposure. if suspected, refer to treatment services.

Other services for sexual assault:

- STI prophylactic treatment to all (treat for vaginal/urethral discharge syndrome following the national STI algorithms)
- Emergency contraception for non-pregnant women
- Tetanus toxoid for any physical injury of skin or mucous membranes
- Referral to appropriate authority

Frequently Asked Questions

Topic	Question	Answers
Know PrEP	What is PrEP	<p>PrEP stands for pre-exposure prophylaxis. PrEP is an oral medication that provides protection from HIV. PrEP helps prevent HIV infection by stopping HIV from replicating inside your body.</p> <p>When taken correctly, PrEP is effective to prevent getting HIV from unprotected sex or injection drug use. It is much less effective when it is not taken regularly. You still need to use condoms if taking PrEP to prevent the transmission of STIs.</p>
	Does PrEP work?	<p>PrEP has been shown to reduce the risk of getting HIV from sex by over 90% if taken correctly. For injecting drug use, studies show PrEP reduces HIV risk by over 70%.</p> <p>When taken regularly, PrEP can provide a high level of protection against HIV, but it is important to still use condoms to protect against other STIs like syphilis and gonorrhoea. PrEP does not prevent pregnancy.</p> <p>It takes about 7 days of taking PrEP daily before it provides protection for anal sex, and 21 days for vaginal sex and injection drug use.</p>
	How does PrEP work?	<p>When HIV enters the body, it attacks healthy immune cells (https://www.avert.org/about-hiv-aids/what-hiv-aids). The HIV virus breaks up the immune cells and infects the body. PrEP stops the HIV virus from replicating within immune cells and spreading, thus preventing an infection.</p>
	How effective is PrEP in preventing HIV?	<p>PrEP has been shown to be highly effective in reducing the risk of getting HIV when taken daily. If PrEP is taken correctly, studies have shown that PrEP reduces the risk of HIV infection from sex by over 90%. PrEP has been shown to reduce the risk of HIV infection from injecting drugs by over 70%. Its efficacy reduces when taken inconsistently.</p>
	Who should be taking PrEP?	<p>PrEP should be taken by those who are HIV negative and are at-risk of getting HIV. You may be at risk for HIV and can consider taking PrEP if:</p> <ul style="list-style-type: none"> • You have had vaginal or anal sex in the past 6 months and: <ul style="list-style-type: none"> - You have multiple sexual partners and don't always use condoms - You have a sexual partner living with HIV (with an unknown or detectable viral load) - You have been diagnosed with a sexually transmitted infection in the past 6 months - You are considering getting pregnant with an HIV positive partner • You are a person who injects drugs and: <ul style="list-style-type: none"> - You have an injection partner living with HIV - You share needles, syringes, or other equipment to inject drugs

Topic	Question	Answers
	What are the side effects of PrEP?	<p>PrEP, like other drugs, may have side effects which are usually mild and temporary. Side effects can include:</p> <ul style="list-style-type: none"> • Diarrhea, nausea or headache - These symptoms usually go away in a few weeks. Sometimes, they can be avoided by taking the pill with food or at bedtime. <p>Less common side-effects, which are reversible, include:</p> <ul style="list-style-type: none"> • Reduced kidney function - It is important that kidney function is monitored at follow-up visits with your provider. • Reduced bone density - In very rare cases, PrEP may reduce bone mineral density (bone strength). <p>These symptoms return to normal when PrEP is stopped.</p> <p>If you are feeling any side effects from taking PrEP, please consult your doctor immediately.</p>
	How should I use PrEP?	The usage mantra for PrEP is 'One pill, Once a day'. Remember, PrEP should be taken under the supervision of a medical practitioner. Don't try to buy it over the counter or share the medicine with your friend or your partner.
	What is the recommended dosage of PrEP?	There are various combinations of drugs available for PrEP. Please consult your doctor. A qualified doctor will recommend an appropriate dosage for you. The same is provided in the National Technical Guidelines on PrEP.
	How can I stop PrEP?	Talk to your doctor before stopping or restarting PrEP. You should continue taking PrEP as long as you are still at-risk of HIV. Also, you shouldn't stop taking PrEP immediately if you think you are not at-risk of HIV anymore. PrEP should be continued for 28 days after an exposure to HIV.
	Does PrEP only work to prevent HIV, or does it work for STIs too?	PrEP is only effective for HIV prevention. PrEP can't provide protection against STI/STDs such as Syphilis, Gonorrhoea, Hepatitis B, Hepatitis C, or Chlamydia. The best way to protect against STIs is to use condoms regularly.
	Do I need to use a condom when I am on PrEP?	Yes. It is strongly advised that you use condoms along with PrEP as an additional protection against HIV and STIs, unless you are trying to get pregnant.
	I am on PrEP. Do I still need to test regularly for HIV?	Yes. PrEP provides protection from HIV only when the tablet is taken every day. This leaves some risk of contracting HIV, so it is important to get an HIV test every 3 months when on PrEP. If you become HIV positive while on PrEP, you should start taking treatment for HIV as soon as possible with the help and guidance from your doctor.
	What is the difference between PrEP and PEP?	PrEP (pre-exposure prophylaxis) is taken daily by HIV negative people to prevent acquiring HIV. PEP (post-exposure prophylaxis) is for people who may have been exposed to HIV to stop getting infected. PEP is for emergency situations and must be taken within 3 days of a possible HIV exposure.
Access PREP	How do I get started on PrEP?	PrEP should be taken only under the supervision of a qualified doctor. Your doctor will decide if you are eligible for PrEP and issue you a prescription.
	Where can I get PrEP?	With a valid prescription, a person can get pre exposure prophylactic medicines either from a public health setting or purchase from a pharmacy.

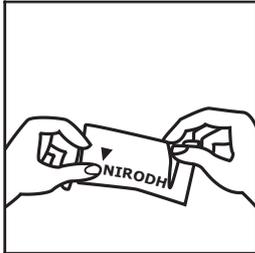
Topic	Question	Answers
	How do I know if I am eligible for PrEP?	The best way to know your eligibility for PrEP is to consult a doctor. You can also read the FAQ “How do I know if I am at risk for HIV” above. Your doctor will help you complete the required tests to see if you can start PrEP. If you are HIV positive, you are not eligible for PrEP.
Order PREP	How do I order PrEP?	With a valid prescription, a person can get pre exposure prophylactic medicines either from a public health setting or purchase from a pharmacy. PrEP is to be take only after doctor consultation.
	How can I start PrEP?	If you think you’re at risk of HIV, consult a qualified physician. To get started on PrEP, you need a doctor’s prescription.
Adherence	Do I need to take PrEP daily?	Yes. One tablet, once a day till your doctor asks you to stop based on the risk factors.
	How long should I be on PrEP?	You should continue to take PrEP if you continue to be at risk of HIV. If your risk of HIV changes, you should consult your doctor to talk about stopping PrEP.
	How many days before should I start taking PrEP before sex?	It takes about 7 days of taking PrEP daily before there is enough medication in your body to provide protection for anal sex. It takes 21 days of taking PrEP daily to provide protection for vaginal sex and injection drug use. Also, PrEP should be continued for 28 days after an exposure. Consult your doctor before stopping PrEP.
	Should I take PrEP every day even if I am not having sex every day?	Yes. You should take one pill every day even if you do not have sex every day. At least till 28 days after the risk exposure.
	What happens if I miss a PrEP dose?	If a dose is missed, PrEP should be taken whenever you remember. If two doses are taken by mistake, that is okay, only take one pill the next time.
Special Considerations	Can people living with HIV take PrEP?	No. PrEP is ineffective for people living with HIV. If a PrEP user is diagnosed positive, treatment for HIV should be started immediately.
	Can I use drugs and alcohol while taking PrEP?	There are no documented drug interactions with drugs and alcohol while taking PrEP. It is safe to use drugs and alcohol while on PrEP. However, physician may be consulted on this aspect.
	Is PrEP safe during pregnancy and breastfeeding?	PrEP is safe to take during pregnancy as well as for women who are breastfeeding. PrEP can be started or continued during pregnancy or breastfeeding.
	Can I take PrEP if I am on contraceptives?	Yes, it is safe to combine contraceptives and PrEP.
	Can I take PrEP if I take hormones?	There are no documented drug interactions with hormonal medication/pills. It is safe to be on PrEP if you are taking gender affirming hormones. However, physician may be consulted on this aspect.
	Can I take PrEP if I am on anti-depressants?	There are no documented drug interactions with anti-depressants. You can safely combine PrEP and anti-depressant medication. However, physician may be consulted on this aspect.

ANNEXURES

(a) Condom Demonstration

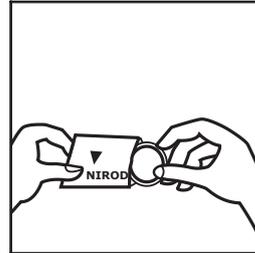
CONDOM DEMONSTRATION

1



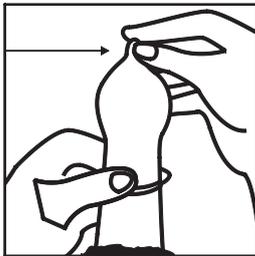
Check the expiry date of condom. Never use condom AFTER EXPIRY DATE.

2



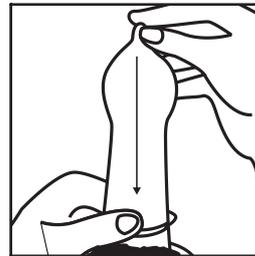
Open the condom packet by tearing it from one side. Roll out the condom by pressing on one side of the packet.

3



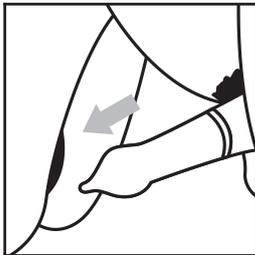
Press teat of the condom BEFORE putting it on tip of the Penis. Fix the condom on the tip with hand.

4



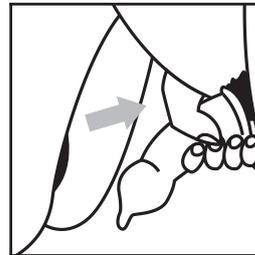
Start unrolling the condom on penis. Unroll it right up to the base of penis.

5



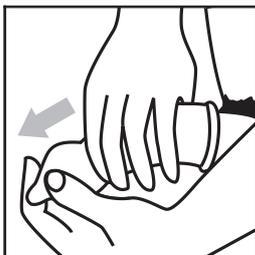
..... for SAFER SEX

6



After intercourse, withdraw the penis from the vagina, while the penis is semi-erect.

7



Hold onto the rim of the condom while withdrawing to prevent it from slipping off and the semen spilling into the vagina.

8



Tie knot at base of condom without spilling semen before disposing

(b) PrEP Consent Form

Consent form for starting Post exposure prophylaxis (PEP)

I (name) _____ address _____
agree to receive PEP drugs / regimen from the registered medical doctor (signed underneath) under the National Programme. Further, I fully understand the BELOW key information provided by the counselor/ Health staff on PEP.

- ✓ Post exposure prophylaxis (PEP) is not mandatory and not lifelong. It will be stopped by my health care provider once I have completed the 4 weeks course, instituted to minimize the risk of infection following potential exposure to HIV.
- ✓ The details of window period, baseline test, drugs that are used, their safety and efficacy.
- ✓ The importance of counselling, risk assessment, relevant laboratory investigations which is part of PEP treatment and will undergo the same.
- ✓ PEP is effective only when taken regularly and consistently. 100% adherence is essential for its efficacy and I will abide by the same.
- ✓ Attend regular follow up visit on 7th day, 14th day, 28th day, and 12 weeks after starting PEP.
- ✓ These regular visits are essential for HIV testing at 4 weeks, (if negative, test again at 12 weeks), monitoring for drug side effects, and for receiving counselling on adherence and risk-reduction.
- ✓ Will return to the clinician in case of any side effect / signs of acute infection / any other health problem develops, even if the appointment is not scheduled
- ✓ Aware of safe sexual practices till both baseline and 3 months HIV test are found to be negative.
- ✓ Receiving PEP involves sharing of essential information with CBO and NGO's approved by government to achieve the goals and objectives of the programme.

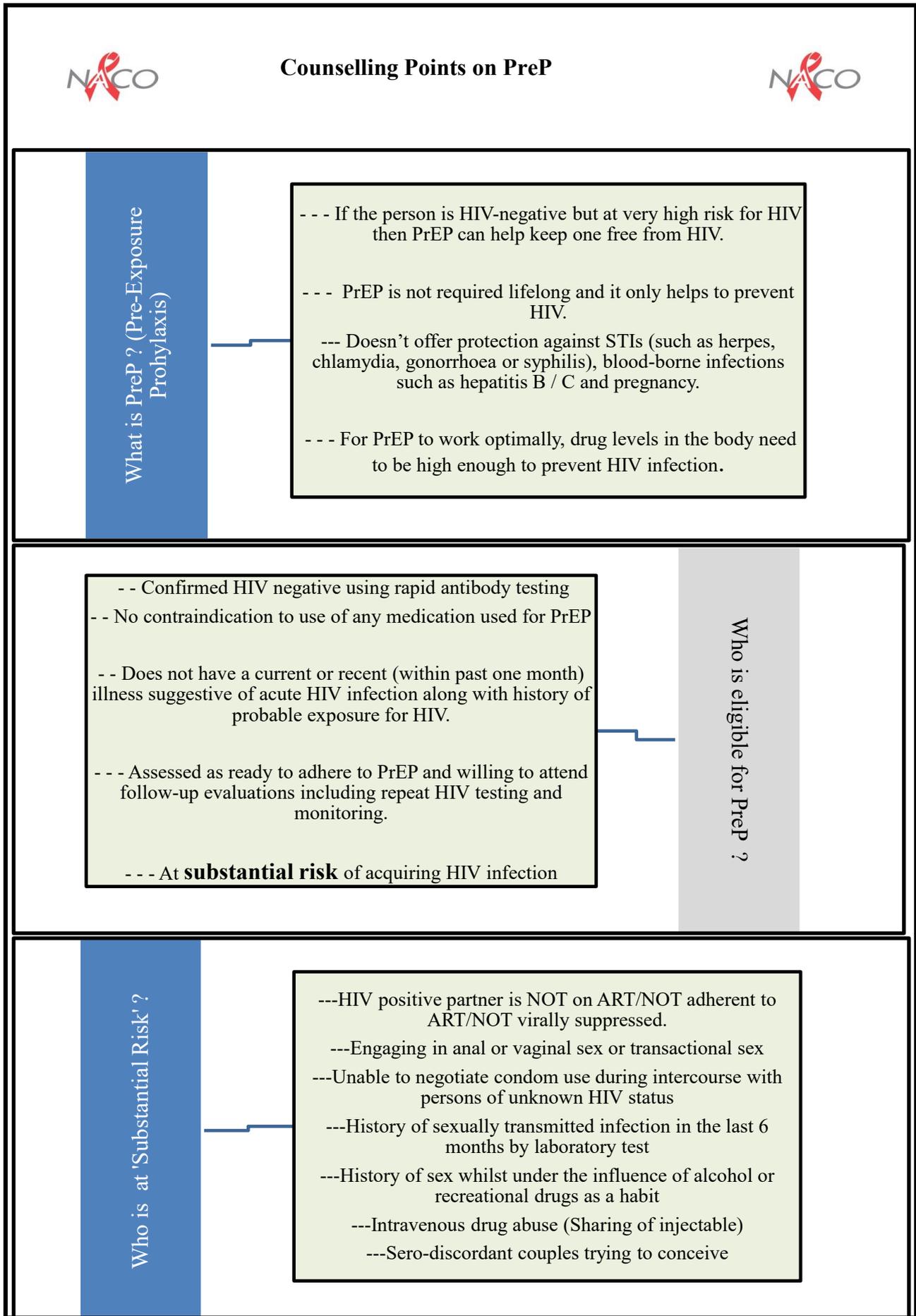
Note for health staff: In special situations, where the individual has limited or no capacity to consent (e.g. children, or unconscious or mentally ill adults), a legally acceptable representative may be able to provide consent (e.g. parent / guardian / care taker). PEP should be offered even when lab tests are not available. Do not delay administration of PEP while waiting for lab results.

Name & Signature of Medical Officer

Signature of PEP user/exposed individual

Date:

(c) Counselling checklist for PrEP



What if Client with poor adherence (<80%)?

- Do not be judgemental about poor adherence
- Appreciate client for reporting and discussing
- Explain that PrEP is effective only if taken regularly
- Elicit information of probable barriers
- Suggest possible mechanism to overcome it
- If required, link to peer support groups

- Reiterate the importance of adherence
- Appreciate client for reporting
- Explain that if a dose is missed, it should be taken whenever remembered
- Mention that it is safe if occasionally two doses are taken by mistake
- Suggest mechanisms like reminders / alarms

What if Client misses 'doses occasionally'?

Counselling on adherence

- Give emphasis during counselling on 100% adherence to PrEP for its efficacy. PrEP to be taken regularly and consistently.
- Note:** *Clients below 80% should be offered enhanced adherence counselling.*
- Use of cell phone reminders, pillboxes, and linking pill taking with a daily routine activity can improve PrEP adherence
- Help people find way to take pill during difficult times such as travel and in face of stigma.
- Correct and consistent usage of condoms along with PrEP is essential for protection against HIV as well as prevents STIs and pregnancy.

What if Client does not want to use condom ?

- Do not be judgemental about patient preferences.
- Explain that this is a valid choice but there are potentially negative consequences.
- Stress that PrEP prevents HIV but not STIs.
- Stress that PrEP prevents HIV but not pregnancy.
- Confirm a regular STI screening and management plan.
- Confirm an effective and acceptable contraception plan where indicated.

Whom should not be given PrEP?

- - Unwilling or unable to adhere to PrEP
- Confirmed HIV infection
- Signs / symptoms of acute HIV infection
 - Weight below 30 kg
- (estimated creatinine clearance < 60 mL/min)
- Unwilling / unable for 3-monthly HIV testing, counselling and safety monitoring visits

What is Importance of follow up visit ?

- - Regular visits are necessary in order to be tested for HIV and other STIs, monitored for drug side effects, and receive on-going adherence and risk-reduction counselling.
- The drugs used for PrEP are safe to be used. However, a small number of clients may develop side effects. These are mostly self-limiting and wane within the first few weeks of use.
- Side-effects includes nausea, vomiting or abdominal discomfort.

PreP in pregnancy and Breastfeeding?

- - PreP is safe when trying to become pregnant.
- Positive partner is on ART and virally suppressed
- PrEP is initiated at least 20 days ahead of condomless sex. Most fertile period may be advised to the couple for increasing chances of conception.
- PrEP may be initiated or continued during breastfeeding in women at substantial risk of HIV acquisition.

Precautions related to prescriptions

- -Do not share medicines with friends / spouses
- Do not self-prescribe
- Do not take PrEP from untrained / unqualified persons
- When the risk of HIV is no longer then only PrEP can be stopped.

Notes:

(d) PrEP Patient Card

Date of first visit _____ Name: Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender Weight: _____ Age: _____ Address: Phone No: _____ Unique ID of PrEP user: _____ Previous history of PrEP: Yes / No (If Yes) Number of PrEP courses taken: _____ HIV status: <input type="checkbox"/> Negative <input type="checkbox"/> Positive Date of HIV test: _____ Tick of the reason for initiating PrEP / Screening for substantial risk:	Facility Name: _____ Is creatinine clearance >60 ml/min: <input type="checkbox"/> Yes / <input type="checkbox"/> No Date of initial test result: _____ Any sign of Acute HIV infection during initial visit: Yes / No Tick the box for the PrEP Regimen provided: <input type="radio"/> Tenofovir disoproxil fumarate (TDF) 300 mg + Lamivudine (3TC) 300 mg 1 tablet daily <input type="radio"/> Tenofovir disoproxil fumarate (TDF) 300 mg + Emtricitabine (FTC) 200 mg 1 tablet daily <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Visit No</th> <th style="width: 25%;">Adherence (%)</th> <th style="width: 25%;">HIV infection (Yes/No)</th> <th style="width: 25%;">Any side effects (if any):</th> </tr> </thead> <tbody> <tr> <td>1st Month (After first pill pick up)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>3rd Month</td> <td></td> <td></td> <td></td> </tr> <tr> <td>____ Month</td> <td></td> <td></td> <td></td> </tr> <tr> <td>____ Month</td> <td></td> <td></td> <td></td> </tr> <tr> <td>____ Month</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Visit No	Adherence (%)	HIV infection (Yes/No)	Any side effects (if any):	1 st Month (After first pill pick up)				3 rd Month				____ Month				____ Month				____ Month			
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1 st Month (After first pill pick up)																									
3 rd Month																									
____ Month																									
____ Month																									
____ Month																									
Date when PreP completed / stopped: _____ Specify reason for stopping PreP: HIV infection <input type="radio"/> No risk of HIV infection <input type="radio"/> Any other (Specify below) <input type="radio"/>	Name & Signature of Medical Officer _____																								

(e) PrEP Provider Card

Unique ID of PreP user: _____ Facility Name / ID: _____

Provider Card – PreP

Name of the PreP User: **Sex:** Male Female Transgender **Weight:** _____ **Age:** _____
Address: **District:** **State:** **Important landmark:**
Phone No: _____ **Occupation of PreP User (Specify):** _____ **Name & Ph No of nearest contact person:** _____

Tick of the reason for initiating PreP / Screening for substantial risk:

- HIV positive partner is NOT on ART/NOT adherent to ART/NOT virally suppressed Engaging in anal or vaginal sex or transactional sex
- Unable to negotiate condom use during intercourse with persons of unknown HIV status History of sexually transmitted infection in the last 6 months by laboratory test or self-report or syndromic STI treatment
- History of repeated use of non-occupational post exposure prophylaxis History of sex whilst under the influence of alcohol or recreational drugs as a habit
- Person having perceived risk of HIV infection and demanding PreP Intravenous drug abuse (Sharing of injectable)
- Sero-discordant couples trying to conceive

History:

Previous history of PreP: Yes / No (If Yes) **Number of months PreP taken:** _____ **Source of PreP Treatment:** Public Private

Tick the box for the PreP Regimen was provided: Tenofovir disoproxil fumarate (TDF) 300 mg + Lamivudine Tenofovir disoproxil fumarate (TDF) 300 mg + Emtricitabine (FTC) 200 mg 1 tablet daily

Diabetic Status: Unknown Non-Diabetic Non-Diabetic **Hypertension:** Unknown Yes No **Other renal function illness:** _____

History of STI: Yes/No (If Yes) **specify STI:** _____ **Mental health issue:** - Depression / Anxiety/ other (Specify) _____ **Alcohol use:** Yes / No

History of Hepatitis B / Hepatitis C: Yes / No **History of Tuberculosis:** Yes / No or any contact person with tuberculosis treatment: Yes / No

Menstrual and gynaecological history in females, including date of last menstrual period: _____

Any other co-morbid condition affecting renal condition or allergy: _____

Baseline Investigations:

Test	Result	Remark	Test	Result	Remark
Serum Creatinine			Pregnancy testing		
HBsAg			VDRL / RPR		
HCV antibody			Any STI testing		

Current HIV status: Negative Positive Date of HIV test: _____ facility where HIV test conducted: _____

Tick the box for the PreP Regimen provided: Tenofovir disoproxil fumarate (TDF) 300 mg + Lamivudine Tenofovir disoproxil fumarate (TDF) 300 mg + Emtricitabine (FTC) 200 mg 1 tablet daily

Follow up:

Visit Number	Adherence (%)	HIV infection (Yes/No)	Side effects/ ADR (Specify if any)
1 st Month (After first pill pick up)		Yes / No	
3 rd Month		Yes / No	
Month		Yes / No	
Month		Yes / No	
Month		Yes / No	

If HIV positive; the name of the facility / ICTC linked to: _____ **Date of Referral:** _____

Details of ADR / adverse drug (if any):

Date of ADR	Details of symptoms	Action taken:	Outcome of adverse drug reaction

Outcome:

Date when PreP completed / stopped:

Specify reason for stopping PreP: HIV infection No risk of HIV infection Continued non-adherence to PrEP Intolerable toxicities
 Not willing / unable to follow, regular testing requirements Client not willing to continue Renal toxicity (creatinine clearance below 50 ml/min) Any other (Specify below)

Name & Signature of Medical Officer

(f) Self Assessment Checklist

Self-Assessment Checklist for Initiating PREEXPOSURE PROPHYLAXIS (PrEP)

Service Provider / Clinic name:

Place:

Name of the PrEP user: _____

A) I have confirmed ELIGIBILITY of this PrEP user with the following:

- Confirmed HIV negative using rapid antibody testing following the HCTS algorithm on the day of PrEP initiation
- Have done other required baseline investigations for STI, Pregnancy etc
- Identified that the patient is at substantial risk of acquiring HIV infection
- No contraindication to use of any medication used for PrEP (Confirmed HIV infection, signs / symptoms of acute HIV infection, Weight below 30 kg & Altered renal functions (estimated creatinine clearance < 60 mL/min)
- Doesn't have a current or recent (within past one month) illness suggestive of acute HIV infection along with history of probable exposure for HIV
- Assessed as ready to adhere to PrEP and willing to attend follow-up evaluations including repeat HIV testing and monitoring

B) Further, I have COUNSELLED the above eligible PrEP user with the following:

- PrEP only helps to prevent HIV and does not offer protection against STIs
- Correct and consistent usage of condoms along with PrEP is essential for protection against HIV as well as prevents STIs and pregnancy
- PrEP is effective only when taken regularly and consistently.
- They must also attend regular doctor's appointments. First visit after one month while the next after every three months.
- Information about PrEP use during conception and pregnancy (when indicated)

C) Emphasis on follow-up visits at least every 3 months that include the following:

- HIV status (including signs or symptoms of acute HIV infection)
- Side effects and advice on how to manage them
- Adherence and counselling to support adherence
- Check STI symptoms, HIV risk behaviour and counselling support for risk- reduction.

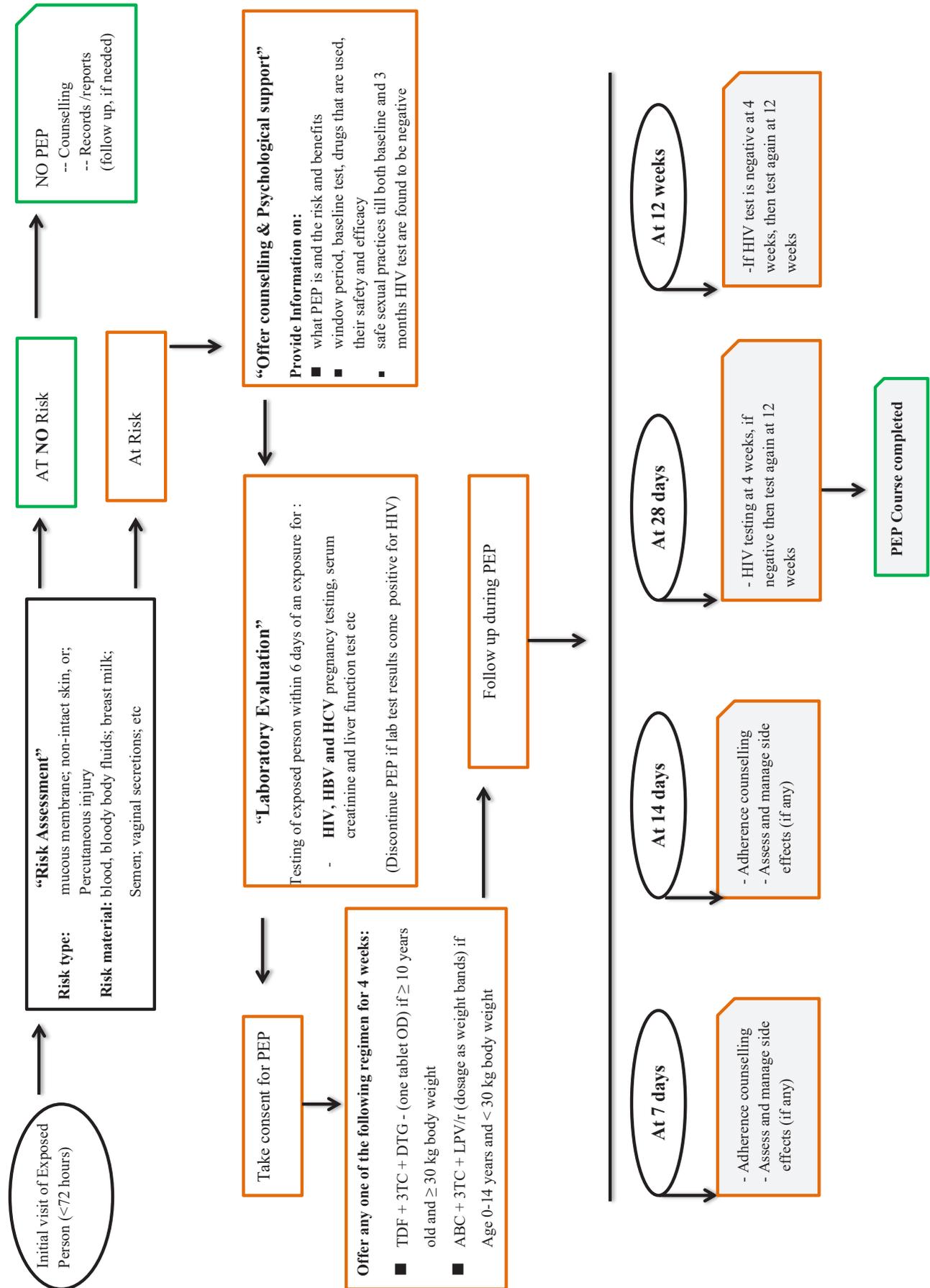
I have taken the CONSENT of the PrEP user and will be providing one of the below regimen (for 1 month during initiation) in line with the National Programme:

- Tenofovir disoproxil fumarate (TDF) 300 mg + Emtricitabine (FTC) 200 mg – 1 Tablet daily
- Tenofovir disoproxil fumarate (TDF) 300 mg + Lamivudine (3TC) 300 mg – 1 Tablet daily
- Tenofovir alafenamide (TAF) 25 mg + Emtricitabine (FTC) 200 mg - 1 tablet daily

Name and Signature of the Medical Officer

Date:

(g) PrEP Flowchart





For more details, please contact
Dr. Chinmoyee Das,
Deputy Director,
Strategic Information - Research & Evaluation,
National AIDS Control Organisation,
Ministry of Health & Family Welfare
(hod.simu@gmail.com)