MINISTRY OF HEALTH NASCOP

Pre-exposure Prophylaxis for the Prevention of HIV Infection - A Toolkit for Providers [Plus other Front Matter]

DRAFT 0

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Overview of Recommendations for Post-Exposure Prophylaxis to Prevent HIV Infection

What is PrEP?	PrEP is a form of HIV practice in which persons not infected with HIV who are at high risk of
	the disease take antiretroviral medication in an attempt to lower their chances of becoming
	infected if exposed.
Who can take	PrEP is recommended for HIV negative persons at substantial ongoing risk of HIV infection
PrEP?	such as
	 Sexual partner with HIV who has not been on effective therapy for the preceding 6 months,
	Sexual partner/s are of unknown HIV status and are at high-risk for HIV infection (has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs, from high HIV burden settings)
	Engaging in transactional sex
	Recent sexually transmitted infection
	Recurrent use of post-exposure prophylaxis
	History of sex whilst under the influence of alcohol or recreational drugs as a habit
	Inconsistent or no condom use or unable to negotiate condom use during intercourse
	with persons of unknown HIV status
	Injection drug use where injection equipment is shared
	Sero-discordant couples trying to conceive
	Requests for PrEP
Contraindications	HIV positive
to PrEP	Renal impairment - as shown by creatinine clearance < 60 ml/min
	Lack of willingness to adhere to daily PrEP and associated follow-up schedule
Initiating PrEP	PrEP is initiated only after thorough behavioural and risk assessment (to establish level of risk and willingness to use PrEP); and clinical and laboratory evaluation assessment (to exclude HIV infection and any establish safety to use PrEP). Clients should also receive
	adequate adherence counselling.
What are the	Preferred
recommended	TDF/FTC (300 mg/200 mg) as FDC once daily
PrEP medications?	Alternative
	TDF 300 mg once daily
	TDF/3TC 300 mg/300 mg as FDC once daily
	At initiation, prescribe PrEP for only 30 days to allow for follow-up visits to assess adherence,
	tolerance and commitment to continue with PrEP.
What is effective	PrEP should be offered as part of a comprehensive, individualized prevention plan following
PrEP use?	behavioural risk assessment and adherence counselling. Combination prevention includes:
	Risk reduction counselling Prevention and treatment of STIs
	• Safer sex practices • Substance abuse treatment
	Consistent & correct condom use Prevention of gender-based violence (GBV)
	VMMC (where indicated) Adherence to PrEP - efficacy of PrEP is dependent on
	adherence.
Follow-up	After starting PrEP, clients require regular follow-up (initially at 1 month) then every 3
	months thereafter (i.e months 3, 6, 9, 12, 15, 18 etc) to monitor HIV status, adherence side
	effects and risk reduction efforts.
	PrEP is not meant to be a lifelong intervention. It is a method of prevention during periods
Discounting	when a person is at greatest risk of acquiring HIV.
Discontinuation of	PrEP should be discontinued in any of the following circumstances
PrEP	HIV positive ● change in risk (low risk) ● renal adverse effect (CrCl < 60 ml/min) ● watering displaying a graph of a
	sustained non-adherence • sustained viral suppression in the HIV partner of a discordant
	couple ● client request to discontinue.

Schema for Managing Pre-Exposure Prophylaxis for HIV Prevention

Initial Visit/First Contact

- Brief behavioural risk assessment to determine if PrEP is
- Discuss effective PrEP use, clarify misinformation
- Perform initial clinical and laboratory assessment
 - o Baseline HIV test, and rule out acute HIV infection
 - Screen for STIs and risk of renal disease/hepatitis B infection
 - o In females, determine if pregnant



If HIV negative and meets eligibility criteria for PrEP

- · Offer adherence counselling
- Prescribe 30 day supply of PrEP (TDF 300 mg/FTC 200 mg OD)
- Discuss combination prevention and risk reduction
- Follow-up visit at 2 weeks to assess side effects

30 day review

- Assess for adherence and offer adherence counselling and support
- Ask about any side effects. Find out how the client is coping with the side effects. Reassure if
- Assess for STIs, (and pregnancy in women) and acute HIV infection
- Assess for risk of kidney disease, if available, obtain serum creatinine and calculate creatinine
- Discuss risk reduction and provide condoms

Prescribe 60 days of PrEP, schedule review after 60 days

3-month review

- Assess for adherence and offer adherence counselling and support
- Ask about any side effects. Find out how the client is coping with the side effects. Reassure if
- Assess for STIs, (and pregnancy in women) and acute HIV infection
- Perform HIV test
- Discuss risk reduction and provide condoms

Prescribe 90-day refill of PrEP and 6-month return visit

6-month review

- · Assess for adherence and offer adherence counselling and support
- Ask about any side effects
- · Assess for STIs, (and pregnancy in women) and acute HIV infection
- · Perform HIV test
- · Discuss risk reduction and provide condoms

Prescribe 90-day refill of PrEP and 9-month return visit

9-month review

- · Assess for adherence and offer adherence counselling and support
- Ask about any side effects
- Assess for STIs, (and pregnancy in women) and acute HIV infection
- · Perform HIV test
- Discuss risk reduction and provide condoms. Discuss need for continued PrEP

Prescribe 90-day refill of PrEP and 12-month return visit

12-month review

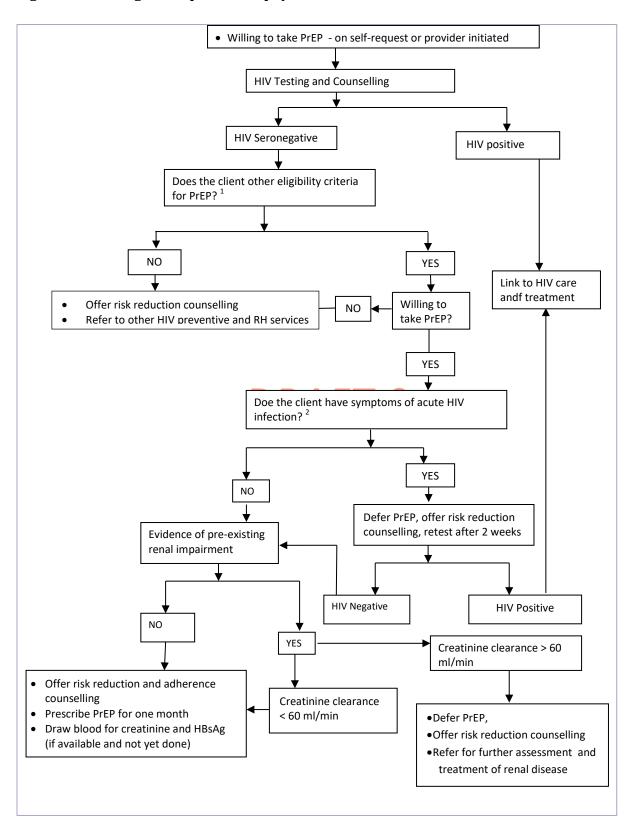
- Assess for adherence and offer adherence counselling and support
- Ask about any side effects
- Assess for STIs, (and pregnancy in women) and acute HIV infection
- Perform HIV test
- · Discuss risk reduction and provide condoms. Discuss need for continued PrEP

Prescribe 90-day refill of PrEP.



Initiating PrEP

Figure x: Initiating Pre-Exposure Prophylaxis



1. Eligibility for PrEP

Potential PrEP users must meet all of the following eligibility criteria prior to initiating PrEP

- substantial on going risk of HIV infection
- no suspicion of acute HIV infection
- documented HIV negative test result
- no contraindications to PrEP medications (TDF/FTC or TDF/3TC)
- willingness to use PrEP as prescribed, including regular visits to monitor HIV status, adherence and side effects

Establishing 'Substantial Risk' of HIV Infection

PrEP for prevention of HIV infection is only indicated for individuals at **substantial ongoing** risk of HIV infection. These include

- Sexual partner is known HIV positive and: not on ART, or on ART < 6 months, or suspected poor adherence to ART, or most recent VL is detectable
- Sexual partner/s are of unknown HIV status and are at high-risk for HIV infection (multiple sexual partners, history of STIs, transactional sex, injection drug use or from high HIV burden settings
- Engaging in transactional sex
- History of recent or current sexually transmitted infection
- Recurrent use of post-exposure prophylaxis
- · History of sex whilst under the influence of alcohol or recreational drugs as a habit
- Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status
- Injection drug use where needles and syringes are shared
- Sero-discordant couples trying to conceive

Assessing for 'substantial ongoing' risk of HIV Infection

Screening questions are used to identify (for further discussions and assessment) individuals who may be offered PrEP based on personal circumstances, risk and desire for additional HIV prevention. The questions are framed to elicit people's behaviours and vulnerabilities as opposed to specific sexual practices.

Before starting the sexual behavioural assessment,

- Ensure adequate privacy
- Explain that this is routine practice to help provide appropriate sexual and reproductive healthcare
- Stress that that findings from the conversation will be kept confidential and only used for purposes of providing better care

General Screening Questions

In the past 6 months,

- "Have you had sex with more than one person?"
- "Have you had sex without a condom?"
- "Have you had sex with anyone whose HIV status you do not know?"
- "Are any of your partners at risk of HIV?"
- "Do you have sex with a person who has HIV?"
- "Have you received a new diagnosis of a sexually transmitted infection?"
- "Do you desire pregnancy?"
- "Have you used or wanted to use PEP or PrEP for sexual exposure to HIV?"
- Have you injected drugs that were not prescribed by healthcare provider? If yes, did you use syringes, needles or other drug preparation equipment that had already been used by another person?
- "Received money, housing, food or gifts in exchange for sex?"
- "Been forced to have sex against your will?"
- "Been physically assaulted, including assault by a sexual partner?"

If the individual answers 'yes' to any of these questions, the provider should discuss the benefits of PrEP and assess for additional vulnerabilities including:

- Unstable housing or homelessness
- Recent breakup with a sexual partner
- Recent loss of source of income
- Recent premature discontinuation of schooling or relocation from regular residence
- Habituation to psychoactive agents

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Screening Questions for People in Discordant Relationships

For the HIV negative individual in a discordant relationship, the following screening questions help to establish the need for PrEP

- "Is your partner taking ART for HIV?"
- "Has your partner been on ART for more than 6 months?"
- "At least once a month, do you discuss whether your partner is taking therapy daily?"
- "If you know, when was your partner's last HIV viral load test? What was the result?"
- "Do you desire pregnancy with your partner?"
- "Do you use condoms every time you have sex?"

2. Excluding Acute HIV Infection

Inquire about the presence of fever, fatigue, myalgia, rash, headache, sore throat, cervical adenopathy, arthralgia, night sweats, or diarrhoea; with high risk exposure to HIV infection within the past month.

Table X: Clinical Features and Symptoms of Acute HIV Infection (Ref)

Feature	Frequency (%)
Fever	75
Fatigue	68
Muscle pain	49
Skin rash	48
Headache	45
Sore throat	40
Cervical adenopathy	39
Arthralgia	30
Night sweats	28
Diarrhoea	27

Managing high risk exposure within the last 72 hrs

In HIV seronegative clients who have had a high risk exposure to HIV, provide PEP for 28 days. Obtain a rapid HIV test at 28 days, if the test result is negative, transition to PrEP immediately (if indicated, i.e. the client has substantial on going risk of HIV infection)



Table X: Initial Assessment

Complete medical	 Identify relative or absolute contraindications to PrEP such as
history and	 Past or current kidney disease
examination	 Risk of kidney disease (diabetes mellitus, uncontrolled hypertension,
	chronic NSAID use
	 Use of other nephrotoxic agents
	 Past of current liver disease
	 Current or past chronic hepatitis (B or C)
	Acute HIV infection
Establish eligibility	 Screen for substantial risk of HIV infection
to use PrEP	 Document HIV status - HIV testing using the national algorithm for HTS
	To complete a symptom checklist to exclude acute HIV infection
	Urinalysis
Baseline laboratory	To screen for renal disease in patients at risk
investigations*	Serum creatinine and creatinine clearance
	• To identify pre-existing estimated creatinine clearance less than 60 ml/min.
	Hepatitis B surface antigen
	 To identify undiagnosed current hepatitis B infection. If negative, consider
	vaccination against hepatitis B.
	Hepatitis C antibody
	• If positive, consider treatment for hepatitis C infection.
	Rapid Plasma Reagin
	To diagnose and treat syphilis infection.
	Pregnancy testing
	• To guide antenatal care, contraceptive and safer conception counselling, and
	to assess risk of mother to child transmission. Pregnancy is not a
	contraindication for PrEP use (see section below).
Screening for other	Presence of dysuria, discharge, anorectal itching or pain, rash, or ulcers. To
STIs	diagnose and treat STI (syndromic or diagnostic STI testing, depending on local
	guidelines).
Review vaccination	Depending on local guidelines, consider vaccination for hepatitis A, human
history	papilloma virus, tetanus and meningitis.
Brief counselling	 To assess whether the client is at substantial risk of HIV.
	 To discuss prevention needs and provide condoms and lubricants.
	 To discuss desire for PrEP and willingness to take PrEP.
	 To develop a plan for effective PrEP use, sexual and reproductive health.
	 To assess fertility intentions and offer contraception or safer conception counselling.
	 To assess intimate partner violence and gender-based violence.
	 To assess substance use and mental health issues.
	 If proceeding to offer PrEP, offer detailed initial adherence counselling
	(Table x)

Table x: Managing Clinical and Laboratory Results on Initial and Follow-up Assessment

Screening	Action
HIV-positive at initial evaluation	Do not start PrEP, counsel and link to care and treatment
HIV-positive after initiation of PrEP	Discontinue PrEP, counsel and link to care and treatment
Positive STI Screen	Thorough genitourinary and anorectal examination, urine dipstix for urethritis, serological testing for syphilis, full STI evaluation if resources available. Refer to guidelines on syndromic management of STIs.
HBsAg-negative	Offer HBV vaccination
HBsAg-positive	This is not a contraindication to PrEP. However, will require monitoring of liver function and referral for management of liver disease.
Flu-like illness after initiating PrEP	Continue PrEP, test for HIV at first contact and after 28 days, and if negative, continue with usual follow-up.
Side effects of PrEP	GIT - nausea, vomiting, weight loss: these are often mild, self-limiting and occur during the first 1-2 months. Provide supportive counselling, offer symptomatic treatment e.g. anti-emetics like Metoclopramide 10 mg 8 hourly for 3 to 5 days. Renal - transient increase in creatinine, and rarely proteinuria and Fanconi's syndrome (presenting as polyuria, bone pain and weakness). Measure creatinine (and calculate estimated creatinine clearance) at initiation of ART, at 1 and 4 months and annually thereafter (or whenever indicated (symptom directed)). If creatinine clearance (eGFR) < 60 mL/min; do not start PrEP, recheck after 2 weeks. Refer for evaluation of underlying renal disease. If the renal function returns to normal, reassess for PrEP and initiate/continue PrEP. When restarting PrEP, optimum protection is reached after 7 doses of PrEP. PrEP should not be prescribed for individuals using nephrotoxic drugs like acyclovir, aminoglycosides, retinoids, instead, offer alternative HIV prevention options.
Pregnancy or breastfeeding	Pregnancy and breastfeeding are not contraindications to provision of PrEP. Pregnant or breastfeeding women whose sex partners are HIV positive or are at high risk of HIV infection may benefit from PrEP as part of combination prevention of HIV infection. PrEP is also indicated for HIV-negative in discordant partnerships who wish to conceive. PrEP in these situations can be prescribed during the pre-conception period and throughout pregnancy to reduce risk of sexual HIV infection.

Table X: Initial adherence preparation and counselling

Theme	Adherence Message/action
Setting the stage	Introduce yourself to the client, giving your name and role; ensure adequate privacy and
	reassure about confidentiality
What is PrEP?	PrEP involves HIV-negative people using ARV medications to prevent themselves from
	becoming infected with HIV. PrEP is provided as part of combination prevention,
	including efforts at ongoing risk reduction
Does PrEP work?	Evidence from scientific studies involving HIV negative people at risk of HIV infection has
(Effectiveness)	shown that PrEP is highly effective if you take it as prescribed.
How is PrEP used?	PrEP is provided as tablets. You should take one tablet daily (at any most convenient)
	time of day).To ensure you do not forget take PrEP each day:
	Make it a daily habit linked to an activity you do daily like brushing teeth, taking a
	meal etc
	 Disclose PrEP use to a partner or trusted person
	Use reminder devices like a cell phone alarm
	 Discuss with your provider how you can enrol onto an SMS reminder system
	If you forget to take a tablet, take it as soon as you remember. Occasionally, you
	may take 2 tablets in a day, but you should never exceed more than 2 tablets per
	day.
	PrEP tablets can be taken any time of day, with or without food.
	PrEP use is a personal, responsible choice to protect yourself and your sexual
	partners from HIV. Discussing PrEP use with trusted friends or other PrEP users may
	be helpful.
	PrEP can be used safely with family planning pills or injections.
Starting PrEP	You will need a HIV test before starting or re-starting (if you had stopped) PrEP. This
	is to ensure that you do not already have HIV infection before starting PrEP because
	PrEP is not effective in treating existing HIV infection.
	• It takes up to 7 days of daily used of PrEP tablets to achieve maximum protection.
	During this period, and as much as possible, you are encouraged to practice safer sex
S: 1 2 52	practices especially consistent, correct used of male or female condoms.
Stopping PrEP	Discuss stopping PrEP with your provider. You can stop using PrEP 28 days after your last
	possible HIV exposure. People can stop PrEP if they are no longer at substantial risk of
	acquiring HIV infection. Ways to lower risk include: adopting safer sexual practices, such
	as not having no sexual contact, or using condoms for all sexual contacts; following an effective course of ART for more than 6 months if a serodiscordant couple; leaving sex
	work; ceasing injection drug use or the sharing injection drug use equipment
Protection from other	PrEP does not offer protection from other STIs such as gonorrhoea, syphilis, herpes etc.
STIs	Discuss with your provider if you suspect that you have an STI (genital sores or
3113	discharge). Using a condom each time you have sex will provide additional protection
	from HIV and other STIs
Prevention of	PrEP does not prevent pregnancy. Use effective contraception unless you want
pregnancy	pregnancy. If you want to become pregnant, discuss with your provider about safer ways
	to conceive. PrEP can be used in pregnancy and during breast feeding.
PrEP safety	PrEP use is safe. A few people may experience minor side effects like diarrhoea, nausea,
	decreased appetite, abdominal cramping or flatulence; dizziness or headaches. Such
	side-effects are usually mild and resolve without stopping PrEP. Typically, these
	symptoms start in the first few days or weeks of PrEP use and last a few days and almost
	always less than 1 month. Discuss with your provider if these side effects are severe or
	they persist for longer than one month.
	A few people may not be able to use PrEP due to kidney-related side effects
PrEP during pregnancy	PrEP can be used safely during pregnancy and breastfeeding. The risk of HIV infection is
and breastfeeding	higher during pregnancy and breastfeeding. It is also easier to pass HIV to the unborn or
	breastfeeding baby if HIV infection occurs during pregnancy or breastfeeding.
Client concerns	Clarify misconceptions, address any client concerns

Table x: Pre-Initiation Education Check-list

Item	Item
How PrEP works as part of combination prevention	Explain the need for baseline and follow-up tests including HIV testing.
 Limitations of PrEP Link efficacy to adherence PrEP reduces but does not eliminate the risk of acquiring HIV PrEP does not prevent pregnancies and STIs PrEP use The medications used (show the client the pills) How the medications are used (daily) Number of daily doses required to achieve efficacy (7) What to do when doses are missed? Discontinuation of PrEP (need to continue for 28 days from last potential exposure to HIV) Side effects and what to do in case these are experienced. 	What to do in case of client experiences symptoms of seroconversion (acute HV infection)
Long-term use and safety of PrEP DRA	 Risk reduction counselling and Support Education (risk and safer sex practices) Managing mental health needs Couple counselling Access to, and consistent use of condoms and lubricants Access to and need for frequent HIV testing Early access to ART VMMC STI screening and treatment Harm reduction for PWID

Table X: Pre-Initiation Assessment Check-list

Item	Y/N	Item	Y/N
HIV testing and counselling, HIV-negative		STI screening and treatment	
Symptoms of acute viral infection in last 6		For Women	
weeks		Pregnancy test	
		Pregnancy and pregnancy intention	
		• Is the client currently using any contraception?	
		 If not, is she interested in using long- term hormonal contraception in addition to condoms? 	
		Is the client trying to conceive?	
		• Is the client pregnant or breastfeeding?	
Behaviour risk assessment		Plans for accessing PrEP	
Substance use and mental health screening		Serum creatinine and creatinine clearance >60 mL/min	
Partner information		HBsAg	
Pre-initiation education and understanding of PrEP		HCV serology	
Readiness and willingness to adhere to prescribed PrEP and follow-up schedule		Medication history	



Table X: Adherence support during follow-up visits

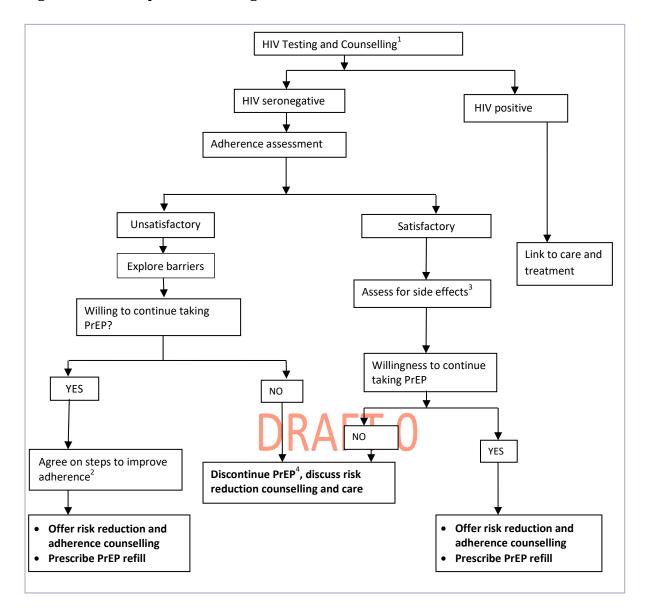
Theme	Adherence message/action
Setting the	Introduce yourself to the client, giving your name and role, ensure adequate privacy and
stage	reassure in confidentiality
Assess	Understanding and experience with adherence: dosage and timing
	Experience with possible side effects
	Risk reduction efforts since last visit
	Challenges to adherence and risk reduction
	Possible acute seroconversion illness ¹
Advice	In case of problems with adherence, explore approaches to improving adherence
	Emphasize need for adherence and ongoing risk reduction including consistent use of
	condoms to prevent STIs and pregnancy
	Remind clients circumstances under which PrEP can be discontinued
Agree	Adherence and risk reduction goals based on degree of the client's desire to meet
	these goals
Assist	Provide client with any reading material, and if available access to telephone
	consultation
Arrange	Schedule next counselling/refill appointment date

Managing suspected acute seroconversion illness

Continue PrEP, test for HIV at first contact and after 28 days, and if negative, continue with usual follow-up.



Figure X: Follow-up after initiating PrEP



1. HIV Testing

Offer HTC as per the national HTS Guidelines. HIV sero-status should be established and documented at the initiation of PreP, at 1 month and every 3 months thereafter.

2. Improving adherence to PrEP

Approaches to improve adherence include:

- a. Encouraging the client to make it a daily habit linked to an activity done daily such as brushing teeth, taking a meal etc
- b. Disclosure of PrEP use to a partner or trusted person
- c. Use of reminder devices like a cell phone alarm
- d. SMS reminders

3. Assessing for medication side effects

- a. *Minor side effects* few people may experience minor side effects like diarrhoea, nausea, decreased appetite, abdominal cramping or flatulence; dizziness or headaches. Such side-effects are usually mild and resolve without stopping PrEP.
- Elevated creatinine where available, serum creatinine should be estimated at baseline and 6-monthly while using PrEP. Self-limiting mild creatinine elevation occurs in a few individuals. Risk factors for significant creatinine elevation include:
 - co-morbid conditions such as diabetes mellitus and uncontrolled hypertension.
 - Age> 45 years of age
 - Reduced CrCl (< 90 ml/min) at baseline
 - Concurrent use of nephrotoxic agents such as NSAIDs
 - o If the creatinine clearance (CrCl) is < 60 ml/min, discontinue PrEP immediately, repeat creatinine after 2-4 weeks.
 - If the CrCl > 60 ml/min, PrEP may be restarted and creatinine re-assessed after 1 month.
 Exclude treatable/preventable causes of elevated creatinine such as dehydration, herbal remedies and supplements, NSAID use/abuse, other medications, uncontrolled blood pressure etc.

Cockcroft–Gault equation:

Estimated Cr Clearance = Sex * ((140 - Age) / (SerumCreat)) * (Weight / 72)
Notes:

- For "sex", use 1 for a male, 0.85 for a female
- Give "age" in years
- Provide "serum creatinine" in mg/dl_
- Give "weight" in kilograms (should be lean body weight)

4. Discontinuing PrEP

Indications for discontinuing PrEP include;

- The client becoming HIV positive
- Change in risk status (low risk)
- o Renal dysfunction with sustained creatinine clearance below 60mL/min
- Client request to stop
- Sustained non-adherence
- Sustained viral suppression of the HIV positive partner in a discordant relationship.
 However, advise the couple to continue using condoms consistently.

PrEP use can be discontinued at least 28 days from the last high risk exposure to HIV, if the exposure was in the last 7 days. Clients discontinuing PrEP for reasons other than a HIV positive test or renal intolerance should receive counselling on risk reduction strategies and education in safely restarting PrEP should they feel ready to do so.

5. Managing sus

Special Considerations

Chronic HBV infection: TDF and FTC (as used for PrEP) are also effective in the treatment of HBV infection. HIV infection is not a contraindication to PrEP use. However, due to the risk of hepatitis flare-

up in the next 1-3 months, exercise caution when discontinuing TDF/FTC. Consider referring such clients to physicians experienced in managing HBV infection (such as MOPC in the public sector).

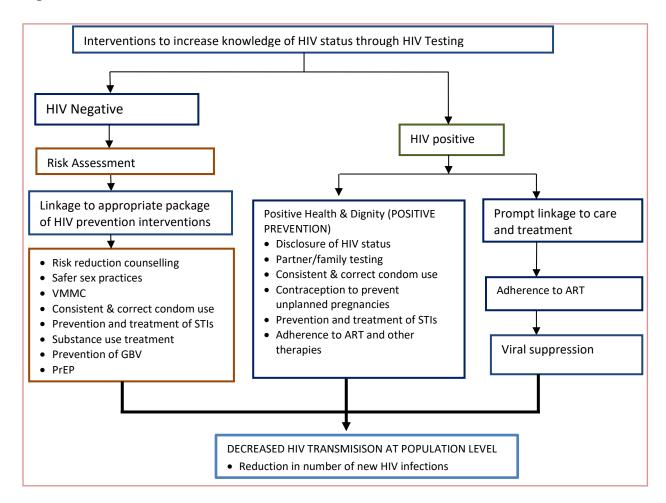
Pregnancy/Breastfeeding: Pregnancy and breastfeeding are not contraindications to PrEP. Risk reduction counselling should be intensified for an uninfected individual who becomes pregnant while taking PrEP. PrEP should be continued due to the increased risk of HIV infection during pregnancy. The client should receive standard antenatal care and be followed up monthly and after cessation of breastfeeding.

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Combination Prevention of HIV Infection

PrEP should not be offered in isolation, but instead as part of a package of evidence-informed combination prevention suited to individual client risk profile and preferences, local disease HIV transmission dynamics and cultural practices and attitudes.

Figure x: Combination Prevention of HIV Infection



Appendices

Appendix x: Pre-Exposure Prophylaxis Client's Assessment and Follow up Form

PRE-EXPOSURE PROPHYLAXIS CLIENT'S ASSESSMENT AND FOLLOW UP FORM

CLIENT PROFILE			PRE-EXPOSURE PROPHYLAXIS (PrEP)
Client Name:			Risk factors assessment (If yes in any, within 6 m	onths)
Unique ID: Height:	Height: (Cm) Age: (Years) Weight: (Kgs) Tel Contact: History of sex under influence of alcohol or drugs		" Yes " No	
Date of Birth: Age:	((Years)	Sexual partner unknown HIV status	" Yes " No
Site Name: Weight: Safe	((Kgs)	Engaging in transactional sex (money or gifts/food)	" Yes " No " Yes "
Space: Tel Contact	:	_	History of recent STI	No
Date of enrolment: (DD/MM/YYYY)		_	Recurrent use of PEP	" Yes " No
Ward:				" Yes " No
MEDICAL HISTORY			History of sex under influence of alcohol or drugs	7
History of any of the following			Inconsistent or no condom use	" Yes " No
(Indicate YES or NO against each of the following)			Injection drug use where needled and syringes are shared	" Yes " No
Liver disease	" Yes " No		Sero-discordant couples planning to conceive	" Yes " No
Renal disease	" Yes " No		sero discordant couples planning to conceive	_
Pregnant	" Yes " No		Having multiple sex partners	" Yes " No
Breastfeeding	" Yes " No		Ongoing GBV/IPV	" Yes " No
Any malignancy expected to require further treatment	" Yes " No		CRITERIA FOR PrEP INITIATION-If Yes to all	
Any malignancy expected to require further treatment	" Yes " No		Confirmed HIV negative	" Yes " No
Uncontrolled hypertension or Diabetes	" Yes "		Does not have a current or recent illness consistent	" Yes " No

	No			with acute HI\	/ infection				
Currently receiving any of the therapies below? (Indicate YES or NO against each of the following)									
Drugs that decrease renal function	" Yes " No			Willing to take	e prep and att	tend follow-up			
Anti-retroviral therapy (including HIV post- exposure prophylaxis (PEP)	" Yes " No		Willing to take prep and attend follow-up evaluations "Yes "No						0
BASELINE LABORATORY INVESTIGATIONS (Insert results in the space provided)				No contraindi	cation for use	of TDF +/-FTC,	/зтс	" Yes " No	
Creatinine clearance		(ml/min)		Consent	" Yes " No				
Hepatitis B (HBsAg) " Negative	" Positive							-	
Other Tests (please specify)				Eligible for PrEP		" Yes " No			
Comments:				Enroled for PrEP		" Yes " No		Date:	<u></u>
		UN	AL	U	•	<u> </u>	•	Versior	n: August 2016

Appendix x: Follow-up Form for PrEP Clients

		CONTIN	UATION FOR	M FOR Pri	EP CLIENT	S				
Date of enrolment: (DD/MM/YYYY)				Unique	ID					
Data Element	Individual Client Visitation Details									
Date of visit (DD/MM/YY)	Month 1	Month 2	Month 3	Month 6	Month 9	Month 12	Month 15	Month 18	Month 21	Month 24
	11	11	11	//	//	//	11	//	//	//
Weight (Kg)										
Blood pressure										
Received adherance counseling (Y/N)										
Is the client adherent? (Y/N)										
If no, what is the reason for non- adherence? (Use provided codes below)										
Does the client have symptoms of adverse drug reaction (ADR)? (Y/N)				\						
If yes, what details of ADR (Use codes/Write the details)										
Symptoms of sexually transmitted infection (Y/N)										
If yes to above question, insert name of the STI (Use Codes below)										
Treatment for STI issued (Y/N)										
Is the client Pregnant? (Y/N)										
If yes, what is the expected date of delivery?										
Is the client Breast feeding? (Y/N)										
Is the client at risk of HIV infection? (Y/N)										

If yes, insert the reason for HIV risk					
HTS Result (Negative/Positive)					
Received information on condom use? (Y/N)					
Received Condom? (Y/N)					
Does the client want to continue taking PrEP? (Y/N)					
Conclusion: Continue or Discontinue?					
If Discontinue, state the reason (Use codes below)					
Date of return:					
Clinician Initials					

Codes:

Reasons for Non-Adherence/Discontinuation: Non-adherence (NA), Client is no longer at Risk (NR), Client's Choice not to take PrEP (CC), Adverse Drug Reaction (ADR), Stigma (S), Client on Other Medication (OM), Intimate Partner Violence (IPV), Transfer Out (TO), Others (O)

Adverse Drug Reaction (ADR): Lactic Acidosis (LA), Severe Hepatomegaly (SH), Acute Exercerbation of HBV infection (HBV), Acute Renal Failure (ARF), Lipodistrophy (L)

STI Diagnosis: Genital Ulcer Disease (GUD), Vaginitis and/or Vaginal Discharge (VG), Cervicitis and/or Cervical Discharge (CD), Pelvic Inflammatory Disease (PID), Urethral Discharge (UD), Anal Discharge (AD), Others (O)

Appendix x

PrEP SUMMARY REPORTING TOOL County: Site Name: Ward:				
Reporting Month:		1		
Indicator	A 15-19 years	ge 20-24 years	Total	
Number Eligible for PrEP	13-13 years	20-24 years		
Number Enrolled for PrEP				
Number Refilled with PrEP drugs				
Number Stopped PrEP				
Number Restart on PrEP				
Number Tested for HIV				
Number Tested Negative		DACT	\cap	
Number Tested Positive Number Screened for STI		JNAFI	U	
Number Pregnant				
Number Breastfeeding				
Number received Adherence Assessment				
Number of condoms Dispensed				
Remarks:				
Name of person reporting:	Date:			