2021 Updated National Implementation Guidelines

for the provision of Oral Pre-Exposure Prophylaxis (PrEP)

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FOREWORD

In 2016, the National Health Council approved the implementation of the National Policy on HIV Pre- Exposure Prophylaxis (PrEP) and Test and Treat (T&T) for selected populations at risk. The use of antiretroviral treatment as oral PrEP to prevent persons at risk from acquiring HIV, is an important milestone in our quest to reduce and curtail new HIV infections.

I am grateful to all the internal and external stakeholders who actively contributed to and made available resources for research and implementation science projects, that supported the further development and refinement of these guidelines. The development of these guidelines was a truly collaborative effort with contributions from researchers, professional bodies, donor agencies, implementing partners, international agencies, civil society, and health care users.

I want the acknowledge and extend my gratitude and appreciation to the over 300,000 HIV negative women and men from all walks of life across the country that have opted to embrace the use of antiretrovirals as protection from an HIV infection. These individuals accessed services at over 1,900 public health facilities, university campus health clinics and special clinics, that are currently offering this important intervention. Together, these PrEP users and the health facilities, have offered invaluable insights which contributed to an in-depth understanding of the delivery of oral PrEP that assisted with refining these guidelines and informed the planning for the scale-up of oral PrEP throughout the country.

It is no doubt that our nurses, doctors, counsellors, health promoters working across the board will find these guidelines invaluable in their quest to offer quality, HIV prevention services to the public.

Dr Nicholas Crisp

Acting Director General

Date: 18/10/2021

CONTENT S

ABBREVIATIONS AND ACRONYMS

AGYW	Adolescent girls and young women
ART	Antiretroviral therapy
ARV	Antiretroviral
FTC	Emtricitabine
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HIV	Human immunodeficiency virus
HTS	HIV testing services
M&E	Monitoring and evaluation
MSM	Men who have sex with men
NDoH	National Department of Health
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
SW	Sex worker
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TDF/FTC	Tenofovir disoproxil fumarate/Emtricitabine
WHO	World Health Organization

DEFINITION OF KEY TERMS

Term	Working definitions in these guidelines
AGYW	Adolescent girls and young women aged 15 to 24 years.
Adult	Person older than 19 years.
ART	Antiretroviral therapy refers to the use of a combination of three ARV drugs to achieve viral suppression in HIV positive persons and is given for life.
ARV	Antiretroviral drugs refer to the medicines active against HIV.
ANC	Antenatal care
Combination HIV prevention	A combination of behavioural, biomedical, and structural approaches to HIV prevention to achieve maximum impact on reducing HIV transmission and acquisition.
Gender affirming hormone therapy	Medicine prescribed to help a person gain the outward characteristics that match their gender identity.
Healthcare provider	Anyone who renders healthcare; includes doctors, nurses, pharmacists, trained counsellors, and community health workers.
PEP	The preventive ARV medical treatment started within 72 hours after exposure to HIV to prevent infection.
PrEP	The use of antiretroviral drugs by HIV-negative people before potential exposure to prevent the acquisition of HIV.
Serodiscordant couples	Couples in an ongoing sexual relationship in which one partner is HIV-positive and the other is HIV-negative.
Sex worker	Women, men, and transgendered people of all ages, who receive money or goods in exchange for sexual services, and who consciously define those activities as income generating even if they do not consider sex work as their occupation.
Young women	Women aged 20 to 24 years, inclusive.

Background

South Africa has the largest HIV epidemic in the world, with 7.64 million people living with HIV in 2019, representing 20% of the global HIV burden.[1] As of 2019, there were just over 4.7 million (62.7%) people in South Africa on antiretroviral treatment (ART), which is the largest ART programme in the world. Despite this accelerated progress and the introduction of *Test and Treat All* in 2018-2019, there were 121 000 new infections in women, 67 000 in men and 11 600 infections through mother-to-child-transmission (MTCT).[1]

The HIV epidemic varies significantly across and within different geographies in South Africa. Even though the epidemic is generalised, it is over-represented in some populations, including sex workers (SW) and men who have sex with men (MSM). It is also concentrated in the populations with very high vulnerability to HIV, such as adolescent girls and young women (AGYW). This contextual understanding of the HIV epidemic is critical to develop and implement effective HIV interventions. Differential vulnerability levels, social risk factors, high-risk sexual practices, and limited access to appropriate HIV interventions influence HIV incidence among these populations.[2,3,4]

WHO recommends supporting and strengthening primary HIV prevention alongside treatment, as both are needed to meet the 95-95-95 targets. In 2015, WHO recommended that all HIV positive people should be offered antiretroviral therapy (ART), regardless of their CD4 count and clinical staging, which will prevent both horizontal and vertical transmission of HIV. WHO also issued a strong recommendation that HIV negative people who are at a substantial risk of acquiring an HIV infection should be offered daily oral HIV pre-exposure prophylaxis (PrEP) as part of a combined HIV prevention strategy. This updated recommendation from WHO enables a wider range of populations and individuals to benefit from this additional prevention option and is based on individual risk assessment. According to the WHO guidance, PrEP should be an additional prevention choice in a comprehensive package of services that also includes HIV testing, risk reduction counselling, male and female condoms, lubricants, ARV treatment for partners with HIV infection, and voluntary medical male circumcision.[5]

These guidelines focus on the provision of PrEP as part of comprehensive combination prevention, drawing on implementation and research evidence and WHO recommendations.

Guiding principles

Access: Identify individuals at highest risk of HIV and ensure access to HIV prevention interventions, including PrEP.

Integration: Integrate PrEP into other HIV prevention programmes including sexual and reproductive health services.

Quality of care: Provide PrEP within broader framework of quality health service provision.

Public health and rights-based approach: PrE P can enable and empower individuals to have an informed choice of HIV prevention options, using a public health approach. This includes confidentiality, access to non-discriminatory healthcare, privacy, choice, informed decision-making, and shared responsibility.

Defining PrEP

What is PrEP?

PrEP is defined by WHO as the use of antiretroviral drugs by HIV-negative individuals who are at substantial risk of acquiring HIV before potential exposure to HIV to prevent HIV acquisition. The current preferred regimen in South Africa is oral TDF/FTC as a fixed-dose combination.

PrEP, PEP and ART

Pre-Exposure Prophylaxis (PrEP)	Post-Exposure Prophylaxis (PEP)	Anti-retroviral treatment (ART)
ARV medication taken by HIV-negative persons before exposure to HIV to prevent HIV acquisition	ARV medication taken within 72 hours after exposure to HIV and continued for 28 days to prevent HIV acquisition	Lifelong treatment with ARV drugs for people with HIV to minimize the effect of HIV by increasing the CD4 count and reducing the viral load

Provision of PrEP

Identifying Potential Candidates for PrEP

Identifying people at greater risk of HIV infection who may benefit from PrEP and are willing to take PrEP; or who may, with assistance, be motivated to continue with PrEP is essential for programme efficiency.

Specific populations considered to be at greater risk of contracting and HIV infection include:

- Adolescent girls, boys, young women and men
- Pregnant and breastfeeding women
- Men who have sex with men
- Individuals with more than one sexual partner
- People who inject drugs
- People with a recent history of STI(s)
- Individuals who recognize their own risk and request PrEP
- Serodiscordant couples if the HIV positive partner is not virally suppressed (Box 1)
- Sex workers
- Migrant workers

Box 1: An HIV-negative individual in a serodiscordant relationship may consider PrEP if:

- The partner is not taking ART
- The partner is on ART for less than 6 months
- The partner is taking ART but is not virally suppressed
- The couple desires to have a baby

Minimum Package of Services Offered with PrEP

PrEP must be integrated into existing sexual and reproductive health services and should not be offered as a vertical programme. The PrEP screening and ART initiation algorithm is outlined in **Appendix I**. The following minimum package of services must be provided to all clients receiving PrEP services in accordance with national guidelines:

- HIV Testing Services
- Risk reduction counselling
- Voluntary male medical circumcision
- ART initiation for those diagnosed with HIV
- Syndromic STI diagnosis and treatment
- Condoms and lubricants
- Pregnancy screening
- Contraception
- Counselling for Mental Health
- TB Screening
- Voluntary partner HIV testing and treatment

Screening for PrEP

> Any person requesting PrEP, even if the healthcare worker does not perceive her/him to be at substantial risk, should be considered for PrEP.

Any person requesting PrEP, should be considered for PrEP, even if he/she may not be perceived to be at risk by the provider. To identify individuals who may benefit from PrEP, the healthcare provider should assess the following individual characteristics and/or behaviour as they increase the individual's risk for contracting HIV.

- Any individual who confirms having sex:
  - Without a condom
  - With more than one partner
  - With an HIV positive partner (see Box 1)
  - With a partner/s whose HIV status is not known
  - While under the influence of alcohol and drugs
- Any individual diagnosed with an STI often or recently
- Young women or men in age disparate relationships (e.g. with a partner older than 5 years).

HIV negative individuals who confirm any of the above should prompt a further discussion about the risks and benefits of PrEP.

Box 2: Acute HIV Infection

In acute HIV infection, the most common symptoms are fatigue, fever, sore throat, body aches, rash, headache, and swollen lymph nodes. [6, 7]

If the client has symptoms or signs of acute HIV infection, PrEP should be postponed until symptoms subside and a repeat rapid HIV test after 4 weeks remains negative.

Considerations for PrEP in Pregnant and Breastfeeding Women

HIV negative pregnant and breastfeeding women at high risk of contracting HIV, must be counselled for and offered HIV prevention interventions including PrEP together with acute HIV infection screening, adherence counselling, safety monitoring and three-monthly HIV testing and antenatal care (refer to **Appendix II**).

Any appropriately trained healthcare provider authorized to assess, diagnose, prescribe, and dispense (doctor, NIMART authorized professional nurse, and PIMART authorized pharmacist) can initiate and issue PrEP. The woman should be informed about the comprehensive HIV prevention package and care options available for her to choose, emphasizing the importance of follow up ANC visits with regular HIV testing.

Eligibility for PrEP

The following criteria will be used to offer PrEP:

- HIV-negative by routine rapid antibody test
- Absence of symptoms of acute HIV infection (see Box 2)
- Willing and able to take PrEP as prescribed
- No contraindications to TDF or FTC
- Adolescents >30kg in weight; or if <15 years in age, adolescents should be Tanner stage 3 (sexual maturity rating) or greater.

Contraindications for PrEP

The following are contraindications for PrEP use:

- HIV infection (assess the client for symptoms or signs of acute HIV infection – see **Box 2**)
- Creatinine clearance (eGFR) of:
  - less than 50 mL/min/1.73m^2 for adolescents and adults ≥16 years
  - less than 80 mL/min/1.73m^2 for children and adolescents ≥10 and <16 years
- For pregnant women: serum creatinine (sCr) greater than 85 µmol/L

Baseline Investigations

Following a negative HIV test, if the person confirms that they are interested in taking PrEP, several baseline investigations should be conducted before PrEP can be initiated (refer to **Table 1**). Please note that it is not

necessary to await the results of these baseline tests to start PrEP. If the HIV test is negative, and the individual has no symptoms suggestive of acute HIV infection, the individual can be initiated on PrEP on the same day while awaiting the results of the other baseline laboratory tests. The PrEP user can be contacted if the laboratory tests results require additional action and/or confirmation (refer to **Box 3**). If the person is not initiated on the day of the HIV test was conducted, the HIV test should be repeated on the same day that PrEP is initiated.

Table 1. Baseline Investigation performed prior to initiating a client on PrEP.

Investigation	Action to be taken
HIV test (use algorithm in National HTS guidelines)	To assess HIV infection status. If client is HIV-positive, initiate on ART If client is HIV-negative, screen for PrEP.
Hepatitis B surface antigen (HBsAg)	If $HbsAg^-$: start PrEP and vaccinate, if available If $HbsAg^+$: start PrEP and refer to a doctor for liver function monitoring and management of Hepatitis B infection. Clients with acute or chronic hepatitis B infection can be safely initiated on PrEP but require liver function monitoring. [8]
Syndromic STI screening	To diagnose and treat STI (syndromic or diagnostic STI testing).
Pregnancy screening	As per WHO guidance, PrEP may be offered to pregnant women at substantial risk of HIV. [9,10,11] If the client is not pregnant, offer contraception.

Assessing Renal Function (eGFR and sCR)			
Age/pregnancy status	**What must be measured?**	**Acceptable level for oral PrEP use**	**The Counahan Barratt formula:**
Persons ≥10 and < 16 years	eGFR using Counahan Barratt formula	>80 mL/min/1.73m^2	eGFR (mL/min/1.73 m^2) = height (cm) X 40 / Creatinine (µmol/L)
Persons ≥16 years	eGFR using MDRD equation[¥]	>50 mL/min/1.73m^2	
Pregnant*	Serum creatinine	<85 µmol/L	

Criteria and frequency of eGFR and sCr monitoring			
Age/pregnancy status	**Co-morbidity**	**Creatinine**	**Risk for low eGFR or sCr**
<30 Years	None	Not required	Not at risk
30 – 49 Years	None	Baseline	Potential risk
<49 Years	Diabetes &/or hypertension	Baseline and annually	Potential risk
50 Years and older	None	Baseline	Potential risk
50 years older	Diabetes &/or hypertension	Baseline and annually	At risk
Pregnancy	NA	Baseline, 3 and 6 months	Potential risk

* For pregnant women follow the PMTCT guidelines for initiating ART.

[¥]The Modification of Diet in Renal Disease Study (MDRD) formula is automatically calculated by the laboratory for those 18 years and older. For assistance in manually calculating the eGFR for adolescents between 16 and 18 years of age, use the calculator provided at https://www.mdcalc.com/mdrd-gfr-equation or one of numerous smartphone applications available for this purpose. Ensure that the website/application uses the correct unit of measurement (i.e. µmol/L) for the serum creatinine level.

Prescription of drugs

The recommended regimen is TDF/FTC a single tablet by mouth (PO) daily. The drugs can be taken anytime of the day, with or without food, and can be stored at room temperature.

Prescription intervals:

- At initiation – provide 1- month PrEP drug supply
- At 1 month visit: repeat HIV test and provide 3-month prescription and 3-month PrEP drug supply
- Every 3 months – repeat HIV test and if the client remains HIV negative provide 3-month prescription and 3-month PrEP drug supply

Box 3: Special considerations for eGFR testing and monitoring:

For children and adolescents (≥10 and < 16 years): If at baseline or during follow-up eGFR is less than 80 mL/min/1.73m^2, repeat the test on a separate day and if eGFR is > 80 mL/min//1.73m^2 , continue PrEP. If low eGFR is confirmed on a separate specimen and the eGFR less than 80 mL/min/1.73m^2, PrEP should be discontinued.

For adults and adolescents (≥16 years): If at baseline or during follow-up eGFR is less than 50 mL/min/1.73m^2, repeat the test on a separate day and if eGFR is > 50 mL/min/1.73m^2, continue PrEP. If low eGFR is confirmed on a separate specimen and the eGFR is less than 50 mL/min/1.73m^2, PrEP should be discontinued.

For pregnant women: If at baseline or follow-up sCr is above 85 umol/L, the test should be repeated on a separate day. If on a separate specimen the sCr is confirmed to be normal at <85 µmol/L, continue PrEP. If creatinine elevation is confirmed on a separate specimen and sCr is above 85 µmol/L, PrEP should be discontinued.

If the individual remains at risk of HIV and wants to be re-initiated on PrEP conduct the following:

- Repeat sCr/eGFR after 1-3 months:
    - If eGFR/sCr has returned to normal – restart PrEP
    - For pregnant women: if sCr is still high or higher than the previous measurement – refer for further investigation.
    - For children, adolescents and adults: If eGFR is still low or lower than the previous measurement, refer for further investigation.

For pregnant women, assess for other causes of elevated sCr if:

- Creatinine elevations are more than 3 times the baseline.
- Creatinine elevations continue after stopping PrEP.
- Creatinine elevations remain high 3 months after stopping PrEP.

PrEP Counselling

Risk reduction counselling

Client education is critical to the success of PrEP as part of a comprehensive HIV prevention plan. Providers should educate and counsel PrEP users about PrEP (refer to **Table 2**) and should provide them with other appropriate prevention options such as male and female condoms. Risk-reduction counselling should be implemented as part of HIV prevention counselling, with sexual reproductive health and contraceptive counselling at all follow-up visits for PrEP users. The main objective of risk-reduction counselling is for clients to learn how to assess their own individual HIV risk and set realistic goals for behaviour change that may reduce their risk of contracting HIV and other STIs, as well as reduce unwanted pregnancies (refer to **Appendix III**: Oral PrEP Counselling Guide).

Counselling for pregnant and breastfeeding women

The choice to start, continue or discontinue PrEP when a woman becomes pregnant should be made by the woman, following discussion of the risks and benefits with her health-care provider. All pregnant women must receive routine information and counselling provided to all HIV negative at-risk individuals (**Table 2** and **Appendix IV**: PrEP Counselling Guide for Pregnant and Breastfeeding Women).

In addition to the routine counselling a pregnant and breastfeeding woman should be advised of the safety, benefits, and side effects of taking PrEP during pregnancy and breastfeeding as outlined in **Table 3**.

The key message for risk benefit counselling for pregnant and breastfeeding women is that the benefits of taking PrEP during pregnancy and when breastfeeding for an HIV negative woman, far outweighs the risk of any possible harm to the mother and baby.

Table 2. Key counselling messages before PrEP initiation and during follow-up visits.

Topic	Key Messages
What is PrEP?	• PrEP is ARV medication that can be taken by HIV-negative persons before exposure to HIV to prevent an HIV infection. • PrEP is an additional HIV prevention option and, where possible, should be used in combination with other interventions such as condoms. • PrEP does not protect against other STIs or prevent pregnancy.
PrEP is not for life	• PrEP is taken for as long as the individual is at risk for HIV infection. • PrEP can be discontinued if the individual is no longer at risk.
PrEP works if taken	• For PrEP to be effective, it must be taken every day. • Consistent use requires that PrEP be included in the daily routine. • If a dosage is missed, the client must take the PrEP drug as soon as he or she remembers and continue to take daily as before. • PrEP can be taken with or without food and at any time of the day.
Side effects	• PrEP is safe, with no side effects in most of the users. • Some individuals may report minor side effects in the first month of PrEP use, such as diarrhea, headache, abdominal pain, and nausea. • Major side effects associated with PrEP are very rare. *

Drug interactions	• Taking alcohol will not reduce the effectiveness of PrEP. • PrEP can be taken with any kind of contraception and gender affirming hormone therapy.
Starting and stopping PrEP	• 7 consecutive days of PrEP are needed before achieving full protection from HIV infection. • PrEP should be continued for 7 days after the last potential HIV exposure in those wanting to cycle off PrEP. • The client should notify the provider if he or she decides to stop taking PrEP.
Pregnancy and breastfeeding	• WHO recommends that PrEP is safe for use in pregnant or breastfeeding women at substantial risk of HIV infection. [9,10,11]
Safer conception	• In serodiscordant relationships, PrEP can be safely used by the HIV negative partner for safe conception.
Visit schedule	• The client must return for a month one and thereafter 3-monthly for follow-up HIV testing, counselling, and safety monitoring visits.
***Major side effects are extremely rare and may include renal toxicity and metabolic complications decreased bone mineral density (which is reversible), extremely small risk of lactic acidosis and hepatic steatosis or steatohepatitis.	

Table 3: Risk-benefit counselling for pregnant and breastfeeding women eligible for PrEP.

What is the risk of contracting HIV for the mother and foetus during pregnancy?	What are the risks of taking PrEP drugs for the foetus or infant?	What are benefits of taking PrEP during pregnancy and breast feeding?
• Biological and behavioural changes during pregnancy increase the likelihood of women contracting HIV. • The likelihood of a pregnant woman contracting HIV is 2-3 times greater than in a non-pregnant woman. • Women recently infected with HIV have a much higher chance of passing on HIV to the foetus because of the high levels of the virus in the body during this time of acute (new) infection.	**We do know that:** • Very low concentrations of PrEP drugs are secreted in the breast milk. • PrEP use in HIV negative pregnant women has been shown to be safe for the mother and the foetus. • There has been an extensive use of TDF/FTC (PrEP drugs) over many years by pregnant women as part of HIV treatment, and there is no indication of any harmful effects for the foetus/infant.	• An HIV negative pregnant or breastfeeding woman taking PrEP can protect herself from HIV thus also reducing the risk of passing HIV to the foetus or breastfed infant. • PrEP is easy to take, it requires one pill a day. • PrEP can be taken by the woman without anybody else knowing if she wants to keep it to herself. • PrEP can be used by couples when one partner is positive (and is not on ART or virally suppressed) and the other is HIV negative

PrEP follow-up and monitoring

HIV testing should be repeated every 3 months to ensure that PrEP is not taken in the presence of HIV infection. Regular monitoring of kidney function when taking PrEP is recommended for individuals over 50 years and older and individuals with conditions that might lead to reduced kidney function, such as hypertension or diabetes. Less frequent monitoring is recommended for all other PrEP users. Regular monitoring also provides an opportunity to assess adherence to PrEP and to identify any adverse events and to assess whether PrEP is still needed (**Table 4**).

Table 4. Follow-Up procedures for individuals on PrEP, including pregnant women.

Activity	Following oral PrEP initiation
Confirmation of HIV-negative status*	At initiation, at 1 month, then every 3 months
Address side effects	Every visit
Adherence counselling	Every visit
Creatinine clearance/serum creatinine test	Only if indicated (Refer to **Table 1**)
STI screening and treatment	Every visit
PrEP medication issuance	1-month supply at initiation, then 3-month supply
Behavioural sexual risk reduction counselling	Every visit

*For pregnant women on PrEP, it is **not necessary** to conduct an HIV test at every BANC Plus visit, especially if the pregnant woman is adhering to the PrEP regimen. Provide PrEP adherence support and counselling at every BANC Plus visit and only conduct an HIV test if there is poor adherence to the PrEP regimen.

Discontinuation of PrEP

PrEP should be stopped if the client:

- Tests HIV-positive
- Has persistently low eGFR or high sCr levels (in pregnancy))
- Is non-adherent to PrEP
- No longer needs or wants PrEP
- If there are safety concerns where the risks of PrEP use outweigh potential benefits

For a person stopping PrEP, the PrEP medication should be continued for 7 days after the last potential HIV exposure to ensure protection.

Important to remember:
Clients initiating PrEP need 7 days of daily dosing to reach adequate levels of PrEP drugs in the body. During this period, other protective precautions should be used, e.g. abstinence or using condoms.
Clients stopping PrEP check for last potential HIV exposure in individuals wanting to stop taking PrEP. PrEP should be continued for 7 days after the last potential HIV exposure in those wanting to cycle off PrEP.

PrEP and Hepatitis B

TDF and FTC both have hepatitis B antiviral activity. Discontinuation of PrEP may cause serious liver damage resulting from reactivation of HBV. PrEP users with chronic hepatitis B should be carefully monitored when they discontinue PrEP. Some PrEP users may opt to continue using tenofovir to control their hepatitis, even if they no longer require these drugs for the indication of PrEP.

PrEP clients who test HIV-positive

Taking PrEP after contracting an HIV infection may result in the development of resistance to the drugs used in PrEP – tenofovir and emtricitabine – limiting future antiretroviral treatment options. Clients who test HIV-positive must discontinue PrEP immediately and should be initiated on ART or referred for ART as soon as possible, regardless of CD4 count. They must be linked to HIV care, treatment, and support. Where possible, their partners should be encouraged to test for HIV.

HIV seroconversion after initiating PrEP can occur and may be due to:

- **People who take PrEP drugs inconsistently** or do not take it as prescribed.
- **People who stop PrEP for a variety of reasons.**
- **PrEP failure:** People who take PrEP consistently as prescribed and become infected with HIV while taking PrEP.

PrEP Monitoring and Reporting

Routine monitoring of the PrEP programme is essential to assess uptake, effective use, and safety. The data collected will also assist with forecasting demand to ensure sufficient and an uninterrupted supply of all the required commodities.

To facilitate standardised and systematic monitoring of the programme, all PrEP service points must use the **PrEP Clinical Form** to collect client data (**Appendix V**). PrEP providers must ensure that the form is completed in detail and kept in the client file at the healthcare facility. The information contained in the clinical form must then be used for entry into TIER.Net after each clinical visit or if there is a change in the clients status as PrEP user.

The following indicators (**Table 5**) will be used for the routine monitoring of the PrEP Programme to assess uptake, safety, and continued use.

Table 5: PrEP Programme Indicators

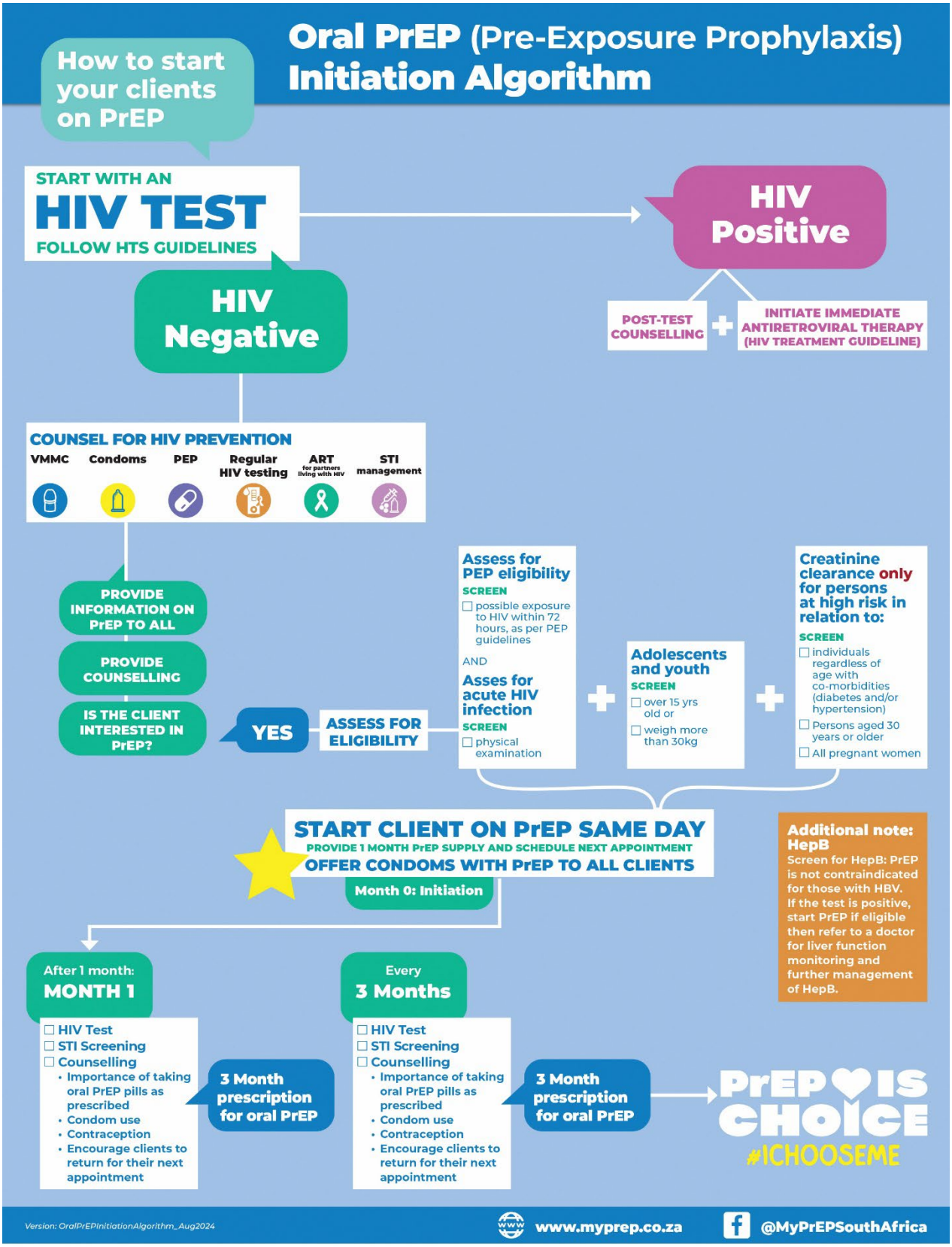
Indicator	Definition	Source document	Point of collection
PrEP Uptake	Number people who received PrEP for the first time in the reporting period.	PrEP Clinical form	At PrEP initiation
Continuation on PrEP	Number of individuals, inclusive of those newly enrolled, that received PrEP during the reporting period.	PrEP Clinical form	At monthly follow-up visit

In addition to the recording information on the PrEP Clinical Form the **PrEP Pregnancy Outcome Reporting Form** (**Appendix VI**) must be completed for each pregnant client post-delivery, to ensure that any adverse pregnancy outcomes are reported and tracked.

All persons on PrEP that have seroconverted must be reported on the **PrEP seroconversion form** (**Appendix VII**). It is important to assess the circumstances/factors/situations pertaining to the seroconversion to further inform and improve programme delivery.

APPENDICES

Appendix I: PrEP Algorithm



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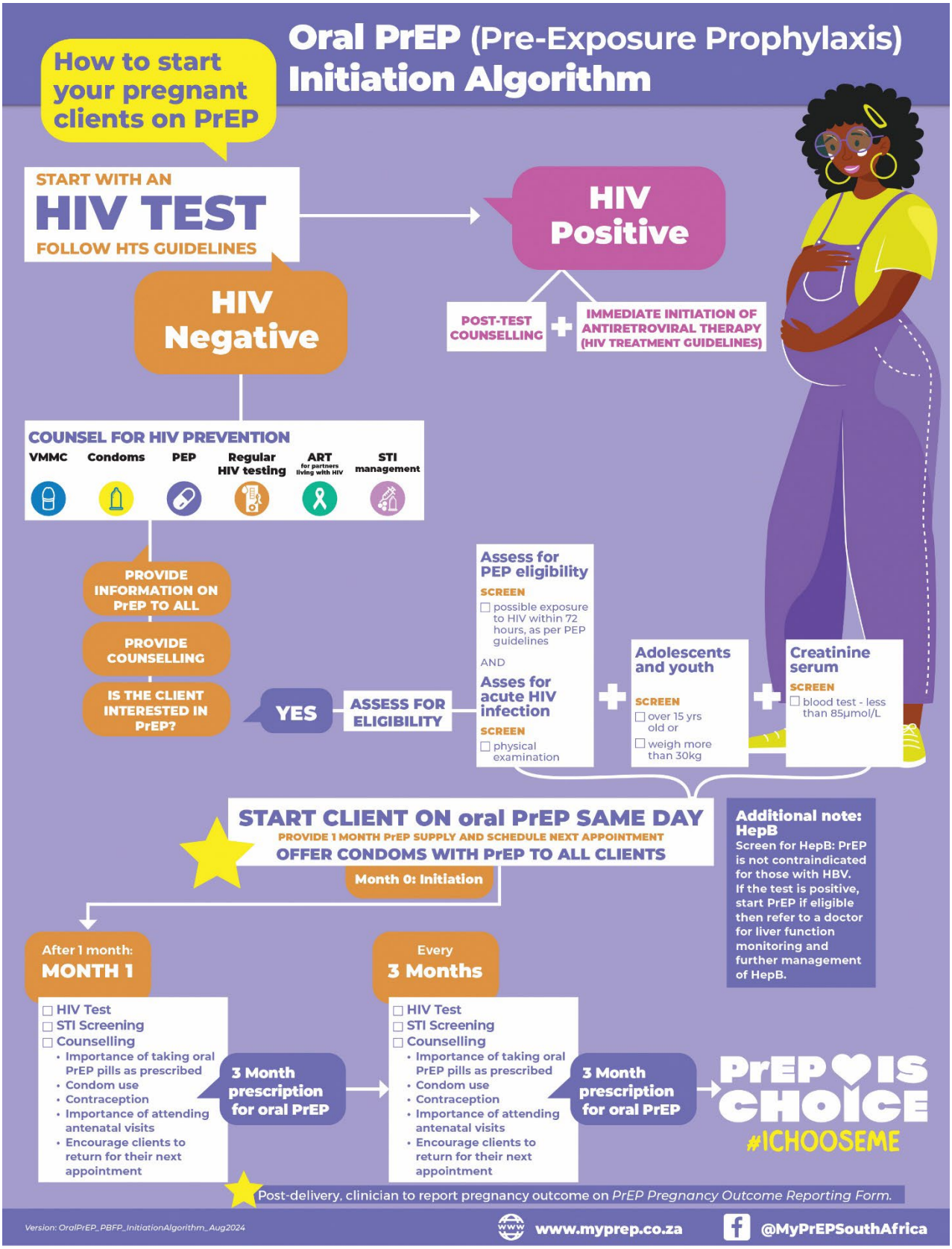
Appendix II: PrEP Algorithm Pregnant Women



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Appendix III: Oral PrEP Counselling Guide

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Step 8: If your client is interested in PrEP, inform them that the following will need to be checked by the nurse:

Adolescents
- over 15 yrs old or
- weigh more than 30kg

No signs of HIV infection
- physical examination
- HIV test

Kidneys are functioning well
- a blood test will only be done for persons:
  - who have diabetes, or high blood pressure,
  - are over 50 years in age,
  - are pregnant.

If all of these tests are OK, the client could start PrEP immediately. You do not have to wait for the blood results to start PrEP.

Step 9: Starting PrEP

Provide the correct information and education regarding PrEP:
- For the first seven days you need to use additional protection such as condoms, or abstain from sex.
- After this, you will need to take PrEP every day.
- If used correctly, PrEP prevents HIV by more than 90%.
- PrEP works best if you take the pills correctly and consistently, one pill a day, every day!
- You can stop taking PrEP if you feel you no longer need it.
- If you want to stop PrEP, continue to take the pills for 7 days after your last sexual contact.

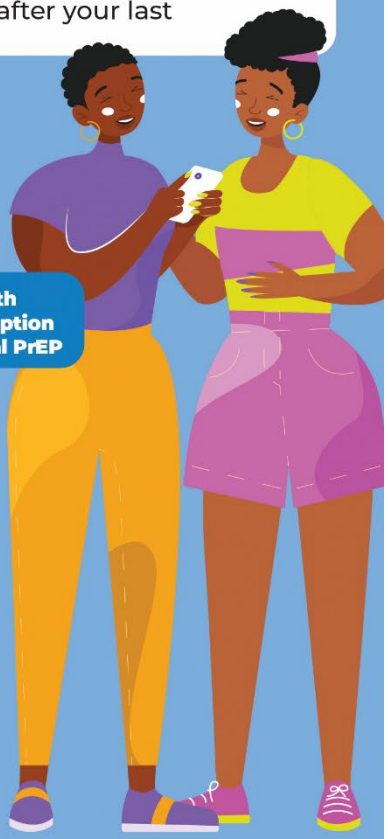
Clinic Visits:

After 1 month:
MONTH 1
- ☐ HIV Test
- ☐ STI Screening
- ☐ Counselling
  - Importance of taking oral PrEP pills as prescribed
  - Condom use
  - Contraception
  - Encourage clients to return for their next appointment

3 Month prescription for oral PrEP

Every
3 Months
- ☐ HIV Test
- ☐ STI Screening
- ☐ Counselling
  - Importance of taking oral PrEP pills as prescribed
  - Condom use
  - Contraception
  - Encourage clients to return for their next appointment

3 Month prescription for oral PrEP



Step 10: Provide support for pill-taking
- Remember to take PrEP every day.
- PrEP tablets can be taken any time of day, with food or without food.
- If you forget to take a tablet, take it as soon as you remember - if more than 2 days have passed, contact your healthcare provider for guidance.
- To help you remember to take your pill, set an alarm or link pill taking to something else that you do every day – like having your morning tea or brushing your teeth before you go to bed.
- PrEP is safe even if you are taking hormonal contraceptives, sex hormones or non-prescription drugs.
- PrEP is safe with alcohol, as long as it does not cause a person to forget to take their daily pill.

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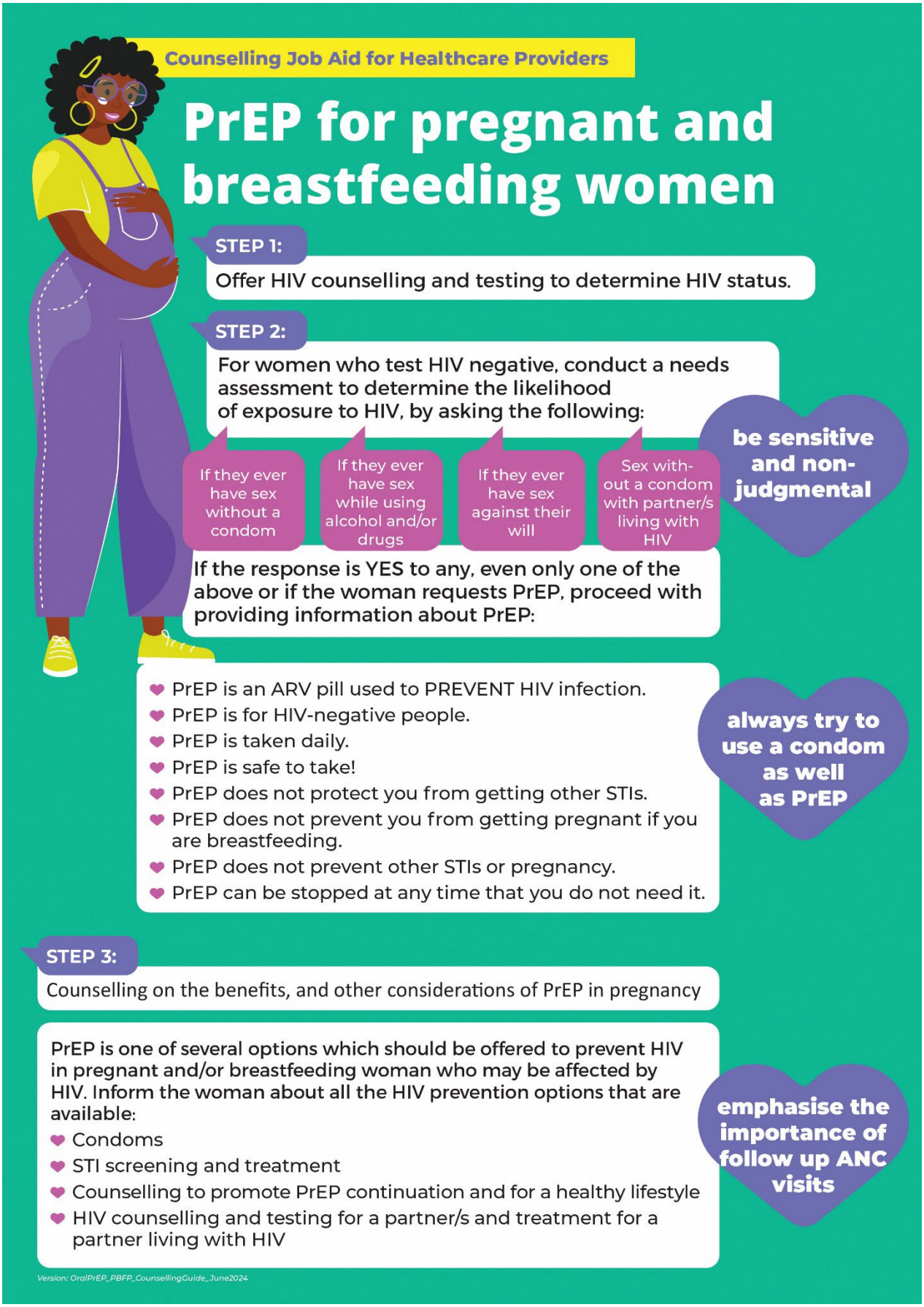
Appendix IV: Counselling Guide for Pregnant & Breastfeeding Women




The choice to start, continue or discontinue PrEP when a woman becomes pregnant should be made by the woman...
...following a discussion of the benefits and considerations of PrEP in pregnancy with her health-care provider.
Key messages and information for PrEP in pregnant and breastfeeding women:
What is the likelihood of exposure to HIV during pregnancy for mother and baby?
Biological and behavioural changes during pregnancy increase the likelihood of women contracting HIV.
The likelihood of a pregnant woman contracting HIV is 2-3 times greater than in a non-pregnant woman.
There is a greater chance of perinatal transmission among women who recently acquired HIV, this is due to high levels of the virus in the body during this time of acute (new) infection and not yet being on ARV treatment.
How could PrEP drugs affect the child?
Very low concentrations of PrEP drugs are secreted in the breast milk and will not harm the baby.
PrEP use in HIV negative pregnant women is known to be safe for the mother and child.
There has been extensive use of TDF/FTC (PrEP drugs) over many years by pregnant women as part of HIV treatment, and there is no indication of any harmful effects for the foetus or baby.
What are the benefits of taking PrEP during pregnancy and breast feeding?
A pregnant or breastfeeding woman, who tests negative for HIV, and is taking PrEP, is preventing HIV for both herself her unborn or breastfed baby.
PrEP is easy to take, it requires only one pill a day.
PrEP can be taken without anybody else knowing, it can be kept private and discreet.
PrEP can be used when a woman and her partner want to conceive safely, if she has tested negative for HIV and her partner is living with HIV.
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Ask PrEP anything on 065 869 8031
health
Department:
Health
REPUBLIC OF SOUTH AFRICA
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Appendix V: Oral PrEP Clinical Form

Clinical Forms

health Department: Health REPUBLIC OF SOUTH AFRICA

PrEP Clinical form (Initiation)

First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy **Gender:** M / F / TG	Address	
ID Number			

Instructions: Please use the below form to capture initiation, continuation, discontinuation, and re-initiation for **ALL** PrEP methods: Oral PrEP (TDF/FTC), Dapivirine ring (DVR), and Cabotegravir (CAB). If a client discontinues PrEP, continue the record with the corresponding date of discontinuation (section B). Should a client re-start or switch to another PrEP method, record with the corresponding date and PrEP method (section A), and all subsequent visits will be captured on this same form (section B). Additional clinical notes can be captured further below.

SECTION A: PrEP Initiation/Re-Initiation or Change of PrEP method

Date of Visit	HIV Test Result	PrEP Counselling Conducted?	PrEP Baseline Assessments					
			Weight (kg)	Pregnancy	Hepatitis B	STI Screening	Creatinine (eGFR/sCr)	PrEP method (*select one*):
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC: DVR: CAB

Original PrEP Initiation Date	/ /

Transfer in:
Date: / / **Clinic:**

SECTION B: PrEP continuation, monitoring and discontinuation

# of months on PrEP	Next visit date:	Actual visit date:	PrEP Method (*TDF/FTC, DVR, CAB*)	Test results (if applicable)						
				HIV Test	Weight (kg)	STI Screen	Pregnancy	Creatinine (eGFR/sCr)	Outcome (RIP, LTF, TFO, Sero, DNA, Disc)	Date of Outcome
0	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
1	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
2	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
3	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
4	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
5	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
6	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
7	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
8	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
9	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
10	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
11	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
12	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
13	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /
14	/ /	/ /	TDF/FTC: DVR: CAB	+ / -		+ / -	+ / - / NA			/ /

Notes: Medical history/reason for discontinuation or change of PrEP method etc.

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NB: Please affix any copies of additional notes or laboratory results that are necessary.

Version: Aug2024

Clinical Forms

health

PrEP Clinical form

First name	
Surname	
DOB	dd / mm / yy **Gender:** M / F / TG
ID Number	

History:

Signature: _____ Date: _____

Name: _____

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Version: Aug2024

Appendix VI: PrEP Pregnancy Outcome Reporting Form

health
Department: Health
REPUBLIC OF SOUTH AFRICA

PrEP Pregnancy Outcome Reporting Form

First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy **Gender:** M / F / TG	Address	
ID Number			

Instructions: Please use the below to capture the pregnacy outcomes of mothers exposed to PrEP drugs at any time during their pregnancy. The available fields must be completed as much as possible with the relevant information available at the time of reporting. Please complete and affix a copy of the PrEP clinical form and/or laboratory results that are necessary.

PrEP drugs exposure before/during pregnancy

PrEP start date	dd / mm / yy	**Time of PrEP initiation**	☐ **Before pregnancy**	**Date of positive urine test**	dd / mm / yy
PrEP stop date	dd / mm / yy		☐ **During pregnancy**	**Date of delivery**	dd / mm / yy

Drug name (s): _____ **Dose:** Daily ☐ Monthly ☐ Other ☐ Specify: _____

Pregnancy outcome

1. Did the client experience any complications during pregnancy?	Y	**Yes. Specify:**
	N	**No**
2. Did the client give birth to (a) live infant(s)?	Y	**Yes. Date of delivery** dd / mm / yy
	N	**No. Specify reason:**
3. Was the infant normal at birth?	Y	**Yes**
	N	**No. Specify abnormality and reason:**
4. Additional comment on pregnancy/delivery		

Infant (s) information

Infant number	Infant sex	Infant length (cm)	Infant weight (g)	APGAR score	Comment
1	F ☐ M ☐				
2	F ☐ M ☐				
3	F ☐ M ☐				
Relevant medical history (with focus on relevant prior gynaecological/obsteric history)					

Appendix VII: Oral PrEP seroconversion reporting form

PrEP Seroconversion Reporting Form

First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy **Gender:** M / F / TG	Address	
ID Number			

Instructions: Please use the form to ducment the circumstances/factors/situations pertaining to the seroconversion of the to further inform programme improvement. The available fields must be completed as much as possible with the relevant information available at the time of reporting. Please complete and affix a copy of the PrEP clinical form and/or laboratory results that are necessary.

PrEP drugs exposure before positive HIV test

PrEP start date: dd / mm / yy **Date of HIV+ Test:** dd / mm / yy **Drug name (s):**

Daily Oral PrEP History

1. At the time of the positive test result, is the client still on PrEP?	Y Client is still on PrEP N Client stopped taking PrEP (Specify date when the last PrEP dose was taken): dd / mm / yy
2. In the last 3 months, has the client been taking PrEP daily? i.e. without missing a dose	0 Never missed a dose of daily PrEP 1 Only one day of PrEP missed 2 Only two days of PrEP missed 3 Three or more days of PrEP were missed 4 7 days or more of PrEP were missed
3. Are you aware of your partner/s HIV status?	1 **My partner/s is HIV negative** 2 **My partner/s is HIV positive** 3 **I don't know my partner/s HIV status**
4. Did you use a condom with your partner/s?	1 **Always** 2 **Sometines** 3 **Never**
5. Additional comment on circumstances to the seroconversion:	

Results Resistance Testing

Date	Test Result				Comment
1	R ☐ N ☐				
2	F ☐ M ☐				
3	F ☐ M ☐				
Relevant medical history					

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