

Job Aids for Long Acting Injectable Cabotegravir (CAB-LA)

As part of the NDOH National
Implementation Guidelines
for Long Acting Injectable
Cabotegravir (CAB-LA)

Job Aids for healthcare providers to support
Ring implementation and research sites

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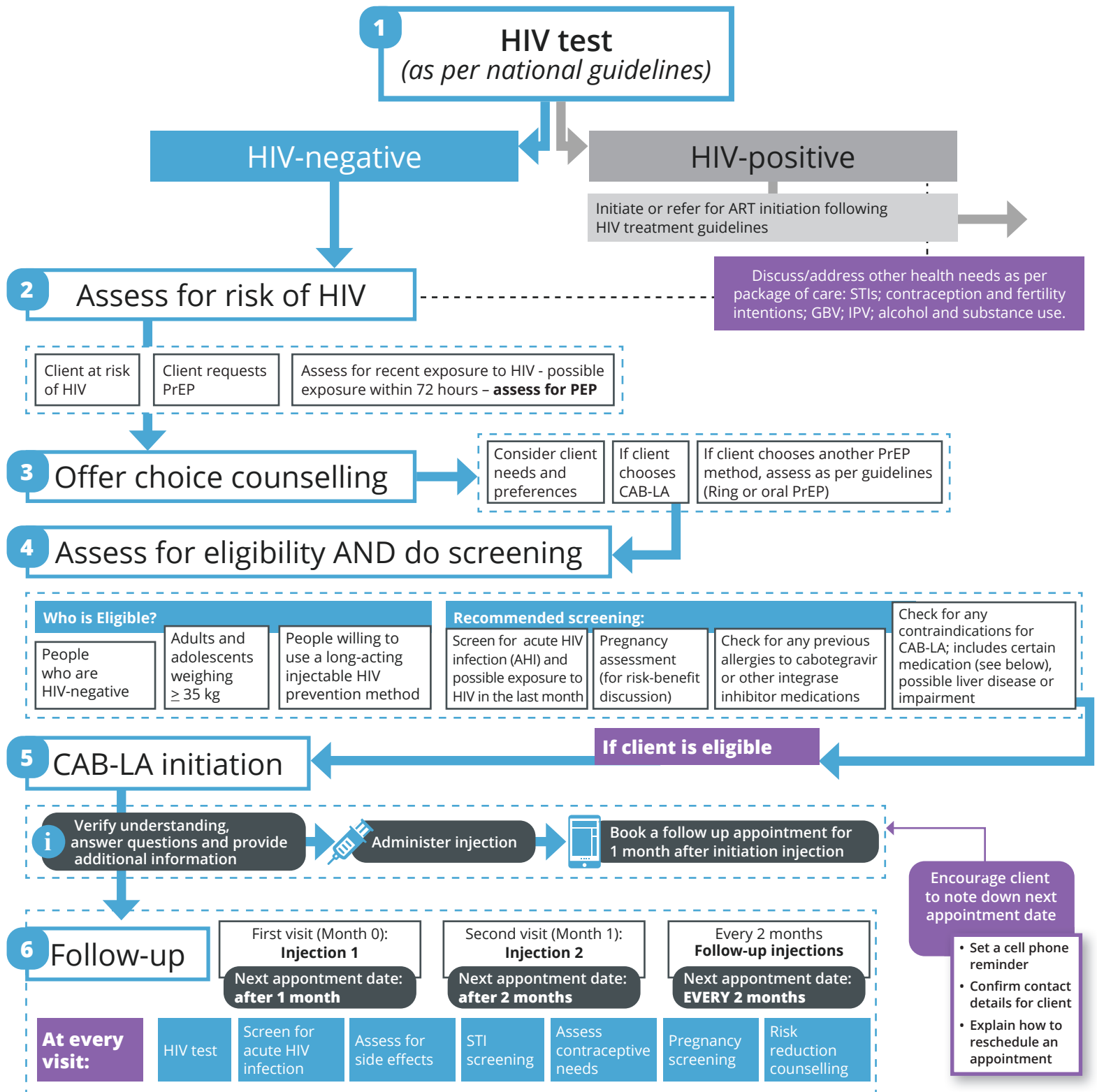
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Contraindications: CAB-LA should not be provided to the following individuals:

- An HIV-positive test result according to the national HIV testing algorithm, or unknown HIV status. This includes:
 - Potential exposure to HIV in the past 72 hours (counsel and refer client for PEP)
 - Signs of acute HIV infection together with potential exposure to HIV within the past month (Note: potential exposure to HIV important as signs of acute HIV infection may be due to other causes)
- Certain co-administered anticonvulsants or anti-tuberculosis medications. These include:
 - Certain anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, and phenytoin
 - Certain antimycobacterials: rifampicin containing tuberculosis treatment; rifapentine containing tuberculosis preventative treatment
- Allergy or hypersensitivity reaction with previous use of CAB or other integrase inhibitor medications
- Weigh less than 35 kg
- May have advanced liver disease and acute hepatitis - liver function testing be considered, where available, before starting CAB-LA, including in instances when liver impairment is suspected, e.g. clients with high alcohol use

Key counselling points to support healthcare providers when introducing their clients to CAB-LA

How often are injections given?

Explain the injection and HIV testing schedule to the client:

- Injection 1: Given immediately on initiation of CAB-LA (HIV test before injection 1)
- Injection 2: Given 4 weeks (1 month) after the first injection (HIV test before injection)
- Injection 3 and all injections thereafter- every two months (HIV test before injection)

Note: To use CAB-LA, clients must be available for injection appointments

How long does it take before the client is protected?

Inform client that it takes 7 days for the CAB-LA injection to be fully effective and to use additional HIV prevention measures during this time.

- Always using condoms, correctly
- If condoms cannot be used, it is advisable not to engage in sexual activity during this time

How safe is the injection?

Reassure client that CAB-LA is safe and well tolerated.

Are there any side effects of the injection?

- Side effects are generally mild to moderate
- Side effects may include: headache; nausea; diarrhoea; tiredness and injection site reactions (ISRs)
- Everyone's body is different, and side effects differ
- Side effects are more common in the first month, get less and mostly disappear over time
- Most side effects can be managed – encourage clients to share any concerns with their healthcare provider

How often will the client need to come to the clinic?

- Emphasise the importance of keeping to injection appointments
- Choose a set date or set time of the month that works for the client e.g the first Wed of the month, or the 5th day of the month
- Explore appropriate ways for the client to remember the date, for example – a calendar reminder on their phone, a note pinned to a place the client sees daily, an appointment card in their bag (which ever works best for the client)
- Explain to clients the process to follow if they miss their appointment or wish to reschedule their appointment
- Encourage clients to come to the clinic if they are experiencing ongoing side effects and/or any other concerns

Date of next appointment

Provide the client with a date of next appointment

- Emphasise the importance of making a note and returning for their next injection appointment
- Explain the importance of keeping the injection dates to maintain protection
- If client is not able to visit the clinic on the date of the appointment, it is important to contact the nurse/clinic/site to reschedule (always provide details of how to do this)

What if the client wants to stop using CAB-LA?

If a client wants to stop, explain the following:

- After the last injection, the client remains protected for 2 months
- After 2 months the drug level gradually decreases thereby reducing the level of HIV protection.
- It takes about a year after stopping for CAB to clear from the body.
- During this time, if a client contracts HIV after stopping CAB-LA, they run the risk of developing resistance to ARVs
- It is important to use other HIV prevention methods after stopping CAB-LA, especially if clients are possibly exposed to HIV, this includes oral PrEP, the Ring (if available), and condoms

What other services will may the client need?

- Offer sexual and reproductive health and HIV prevention services:
 - Promote condom use and ways to reduce exposure to HIV and STIs
 - Screen and manage STIs
 - Assess for contraception requirements and offer appropriate methods
 - Assess for pregnancy and manage accordingly including appropriate referrals
- Assess for GBV and appropriate support and referral

Overview:

- A complete dose of CAB-LA requires 1 injection: 600 mg (3 mL) of cabotegravir.
- CAB-LA is a suspension that does not need further dilution or reconstitution.
- CAB-LA is for gluteal intramuscular use only.

Prior to administration:

- If the pack has been stored in the refrigerator, the vial should be brought to room temperature prior to administration (not to exceed 30°C [86°F]) using the palms of your hands.
- Once CAB-LA has been drawn into the syringe, the medicine can remain in the syringe for up to 2 hours before injection. The filled syringe should not be placed in the refrigerator. If the medicine remains in the syringe for more than 2 hours, the filled syringe and needle must be discarded.

Storage information:

- Store at 2°C to 25°C (36°F to 77°F). Exposure up to 30°C (86°F) permitted.
- Do not freeze.

Injection pack contains:

CAB-LA vial

Syringe

Injection needle (23 gauge, 38mm)

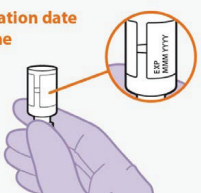
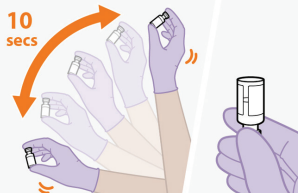
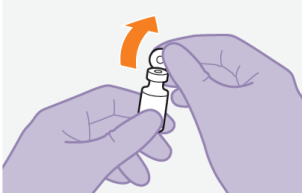
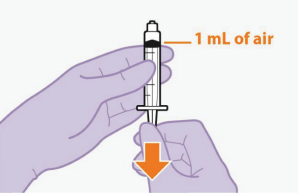
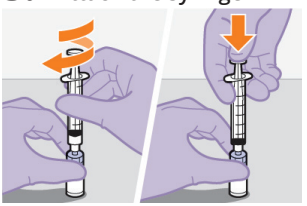

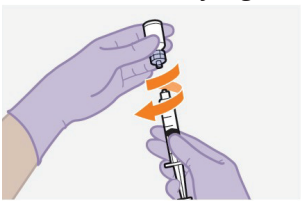
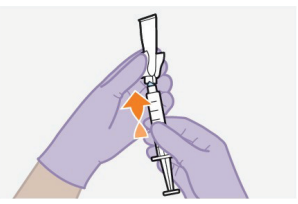
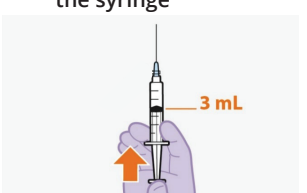

Consider the individual's build - for individuals with a BMI greater than 30, use injection needle (21 gauge, 50mm)

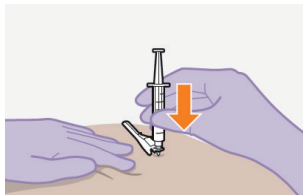
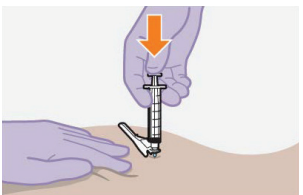


You will also need:

2 alcohol wipes

2 gauze pads

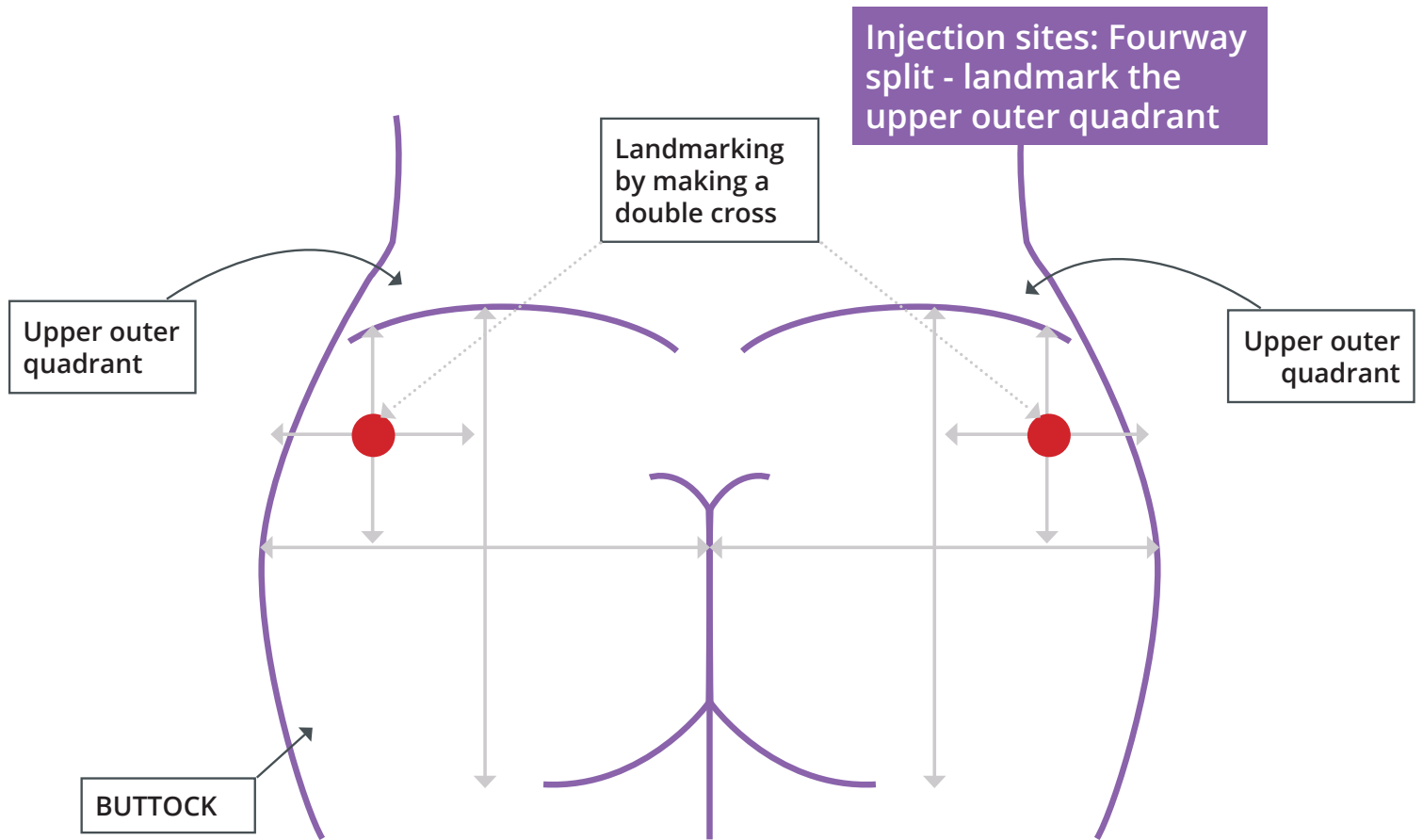
A suitable sharps container

<p>1. Inspect the vial</p> <p>Check expiration date and medicine</p> 	<p>Check that the expiration date has not passed.</p> <ul style="list-style-type: none"> • Inspect the vial immediately. If you can see foreign matter, do not use the product. • The vial has a brown tint to the glass. • Do not use if the expiration date has passed. • If the pack has been stored in the refrigerator, allow the medication to come to room temperature. 	<p>2. Shake the vial vigorously</p> <p>10 secs</p> 	<ul style="list-style-type: none"> • Hold the vial firmly, and vigorously shake for a full 10 seconds. • Invert the vial and confirm the suspension is uniform. It should look uniform. • If the suspension is not uniform, shake the vial again. • It is also normal to see small air bubbles.
<p>3. Remove the vial cap</p> 	<ul style="list-style-type: none"> • Remove the cap from the vial. • Wipe the rubber stopper with an alcohol wipe. • Do not allow anything to touch the rubber stopper after wiping it. 	<p>4. Prepare the syringe</p> <p>1 mL of air</p> 	<ul style="list-style-type: none"> • Remove the syringe from its packaging. • Draw 1 mL of air into the syringe. This will make it easier to draw up the medicine later.
<p>5. Attach the syringe</p> 	<ul style="list-style-type: none"> • Insert the needle and syringe firmly into the vial. • Press the plunger all the way down to push the air into the vial. 	<p>6. Slowly draw up the dose</p> 	<ul style="list-style-type: none"> • Invert the syringe and vial and slowly withdraw as much of the medicine as possible into the syringe. There may be more medicine than the dose amount.
<p>7. Unscrew the syringe</p> 	<ul style="list-style-type: none"> • Note: Keep the syringe upright to avoid leakage. Check that the suspension looks uniform and milky white. 	<p>8. Attach the needle</p> 	<ul style="list-style-type: none"> • Peel open the needle packaging part way to expose the needle base. • Keeping the syringe upright, firmly twist the syringe onto the needle. • Remove the needle packaging from the needle.
<p>9. Remove extra liquid from the syringe</p> <p>3 mL</p> 	<ul style="list-style-type: none"> • Hold the syringe with the needle pointing up. Press the plunger to the 3 mL dosing mark to remove extra liquid and any air bubbles. • Note: Clean the injection site with an alcohol wipe. Allow the skin to air dry before continuing. 	<p>10. Stretch the skin</p> <p>1 inch (2.5 cm)</p> 	<ul style="list-style-type: none"> • Use the z-track injection technique to minimize medicine leakage from the injection site. • Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm). • Keep it held in this position for the injection.

<p>11. Insert the needle</p> 	<ul style="list-style-type: none"> • Insert the needle to its full depth, or deep enough to reach the muscle. 	<p>12. Inject the dose of medicine</p> 	<ul style="list-style-type: none"> • Still holding the skin stretched – slowly press the plunger all the way down. • Ensure the syringe is empty. • Withdraw the needle and release the stretched skin immediately.
<p>13. Assess the injection site</p> 	<ul style="list-style-type: none"> • Apply pressure to the injection site using a gauze pad. • A small bandage may be used if bleeding occurs. • Do not massage the area. 	<p>14. Dispose safely</p> 	<ul style="list-style-type: none"> • Dispose of used needle, syringe and vial according to local health and safety laws.

Reference for images

Understanding the injection site:



Ventrogluteal vs dorsogluteal administration approach:

The ventrogluteal approach into the gluteus medius muscle is recommended because it is located away from major nerves and blood vessels. A dorsogluteal approach into the gluteus maximus muscle is acceptable, if preferred by the healthcare professional. **The injection should not be administered in any other site.**

Missed CAB-LA injection(s)

Be supportive! Your client needs you.

If client misses the injection appointment they must contact the clinic as soon as possible. If keeping to CAB-LA appointments is a problem explore other HIV prevention methods.

If keeping to the injection schedule is not working for your client, support/encourage your client to talk about switching to a different PrEP method or HIV prevention strategy.

Resuming or restarting CAB-LA after missed visit:

How much time has passed since missed injection appointment date?

Less than 1 month: continue with next injection as soon as possible.

More than 1 month: restart the 2 initiation injections, one month apart, then continue with 2-monthly injections.

If a client wants to stop, explain the following:

After the last injection, the client remains protected for 2 months.

After 2 months the drug level gradually decreases thereby reducing the level of HIV protection.

It takes about a year after stopping for CAB to clear from the body.

During this time, if a client contracts HIV after stopping CAB-LA, they run the risk of developing resistance to ARVs.

Important to use other HIV prevention methods after stopping CAB-LA, especially if clients are possibly exposed to HIV, this includes oral PrEP, the Ring, and condoms.

Switching between PrEP methods

Clients may choose to switch between PrEP methods. The process for switching between PrEP methods will depend on the method. Each method needs to be provided according to current SA guidelines – health providers should use their best clinical judgement as outlined in the table below.

Switching between the CAB-LA, Ring and oral PrEP or PEP

Ring → CAB-LA

- Remove Ring; proceed with CAB-LA initiation as soon as removed, or any time thereafter
- Note:** The Ring only provides protection locally, in the vagina, and there is no residual protection once removed

CAB-LA → Ring

The last injection provides protection for two months, so it would only be necessary to insert the Ring after two months.

Oral PrEP → CAB-LA

Complete oral PrEP regimen - taking 7 PrEP pills for 7 days after last exposure. Initiate CAB-LA on day 8 (or thereafter)

CAB-LA → oral PrEP

The last injection provides protection for two months, thereafter can initiate oral PrEP, as per guidelines

PEP → CAB-LA

- Complete 28 day course of PEP, as per guidelines
- Initiate CAB-LA after an HIV-negative test result

CAB-LA → PEP

- PEP is not required whilst the client is on the scheduled CAB-LA regimen
- PEP is only required if the person had a potential exposure to HIV 2 months after stopping CAB-LA

CAB-LA → ART

- Confirm HIV status using national testing algorithm
- HIV-positive test result

- Discontinue any further doses of CAB-LA
- Immediately link to care and initiate on ART (per national ART guidelines)



Counselling for choice for the healthcare provider

This tool can be used to assist clients to make an informed decision about choosing their biomedical HIV prevention method.

Provides the issue and opening question

Provides an explanation of why the issue/questions are important

Suggests possible questions to discuss and explore. **Note:** not every question may be relevant; only select appropriate questions

Issues to discuss with client

Explain why the question is being asked

Possible questions to ask your client

What are your chances of being exposed to HIV?

Knowing whether your partner is living with HIV or not is important for deciding about how you can protect yourself from an HIV infection.

Using a condom always does lessen the chances of you being exposed to HIV and other infections that can be spread through sexual contact.

A person living with HIV taking antiretroviral treatment (ART) regularly, has a lower concentration of the HIV virus in the body, reducing the chances of spreading the virus.

If you or your partner has had an infection affecting your private parts (STI), it can increase the chances of getting HIV. Using a condom, treatment for both sexual partners helps to stop the spread of the infection to both partners.

- Do you know whether your partner/s are living with HIV?
- Are you able to discuss HIV and HIV testing with your partner/s?
- If your partner/s have tested, do you know when was the last time they tested?

- Are you able to use condoms correctly every time you have sex?
- What are your challenges with using condoms?

- If your partner is HIV-positive, are they taking their antiretroviral medication regularly?

- If you had an STI/infection in your private parts?
 - Did you seek treatment?
 - Did you complete the treatment?
 - Did you use condoms?
- Did you tell your partner you had an STI?
- If not, what were your challenges telling your partner? Was your partner treated?

Have you used any HIV prevention methods in the past?

If you have previously tried different HIV prevention methods, it may help you to make a decision- to continue or change the method you used.

- Have you used any HIV prevention methods previously?
- How was your experience?
- Did the method you used work for you? If not, what problems did you have with using the method?
- Would you like to stay on the same method you are using or used or would you like to change it?

How important is it for your partner to be involved in choosing an HIV prevention method?

Ideally both partners should jointly agree on what method of HIV prevention to use.

This may not always happen in reality!

If you are unable to discuss HIV prevention with your partner, you may want to make this decision on your own.

- Is your partner's opinion important about choosing a method to protect you from HIV?
- Whose decision is it - can you make the decision on your own or do you need to discuss it with your partner?
- How easy is it for you to communicate with your partner about HIV prevention?
- Would you prefer to keep your choice of HIV prevention to your self?
- Are you worried about your partner finding out about your choice?

Are there other people you need to talk to about your HIV prevention choices?

For some people, discussing and getting the opinion or approval of others is important.

- Is there anyone else e.g. your parents/guardian or friends with whom you need to discuss your HIV prevention options and decision?
- Are you concerned about what they may think about you or your choices? Are you worried about them finding out? Does this matter to you?

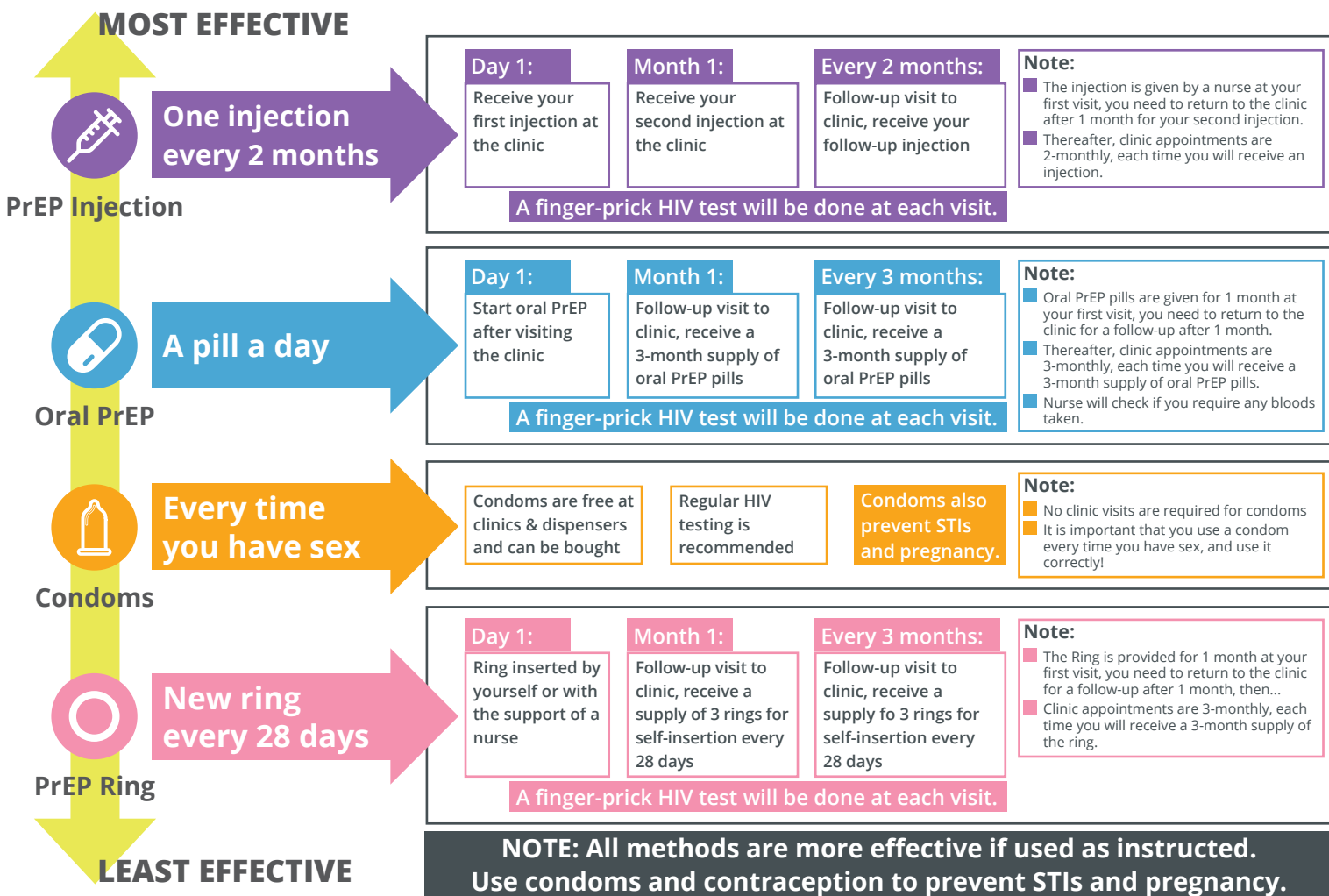
Would you like to consider methods that you can easily stop and re-start?

If you are not having sex regularly you may want to use a method that you can easily stop using or restart when you require protection again.

- Do you want a method that you can easily use, stop and re-start when sexual exposure is likely?
- Would you like a method that provides long term protection?
- Are you requiring protection for all sexual activities (all possible ways that you can get HIV (like anal and vaginal sex), or just vaginal sex)?



Find out which **HIV prevention** method will fit best into your life:



Take this quiz

To find out which PrEP method may work best for you!

Make an **X** in the white blocks next to each of the statements that is true for you... leave the white block blank, if the statement is not true for you.

Count all the **X's** in the white blocks under each method, the method with the most **X's** in the total, is the PrEP method that may work best for you!

	PrEP Pill	PrEP Ring	PrEP Injection
I can take a pill every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am comfortable with inserting anything into my vagina	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am ok with taking an injection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I want the least amount of clinic visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I don't want blood taken	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I want the best protection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I inject drugs and share needles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I want the least amount of side effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have both anal and/or vaginal sex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TOTAL number of X's			

Complete this quiz and take it with you to discuss with the healthcare provider.

Management of most common side effects and adverse events for CAB-LA

The most common side effects* for CAB-LA include:

Headache

Nausea

Diarrhea

Tiredness

Injection site reactions (ISRs)

These side effects are usually mild or moderate.

Injection site reactions are more common than other potential side effects, becoming less frequent over time as clients get used to the injection. These can include redness, pain, and swelling at the injection site.

Management of most common side effects and adverse events¹



Both oral PrEP and CAB-LA share common side effects - these include headaches, dizziness, nausea, diarrhoea, fatigue and fever



Cab-LA users may experience injection site reactions - including pain, swelling, redness, and/or bruising at the injection site.



Most side effects decrease over time

Side effects & complications management

Clients with persisting signs or symptoms may be managed as follows:

Injection site reaction management

Mild	Clients may wish to use a warm or cold compress, depending upon what works best for the symptoms they are experiencing and what is available.
Moderate	Suggest non-prescription pain medication or non-steroidal anti-inflammatory drugs (NSAIDs), which may be taken before as well as after injections to minimise pain and swelling, provided there is no contraindication to their use in the client. Note: Pregnant clients should avoid use of NSAIDs.
Severe	If severe signs/symptoms or fluctuant abscess is present and does not drain spontaneously, refer for appropriate care which may include incision and drainage and antibiotics.

Headache/Dizziness Management

Mild	Reassure the client this is common and improves with time.
Moderate	Suggest non-prescription pain medication or non-steroidal anti-inflammatory drugs (NSAIDs) to relieve symptoms, provided. Note: Pregnant clients should avoid use of NSAIDs.
Severe	Consider alternative diagnosis and refer for care.

Nausea/Diarrhea Management

Mild	Reassure the client this is common and improves with time.
Moderate	Provide symptomatic treatment (anti-emetics or anti-diarrheal).
Severe	Check liver function tests, consider alternative diagnosis, and refer for further evaluation.

Feeling fatigued or feverish

Mild	Reassure the client this is common and improves with time.
Moderate	Suggest symptomatic treatment with a non-prescription antipyretic. Note: Pregnant clients should avoid using NSAIDs.
Severe	Refer for further evaluation.

Side effects warranting urgent return for assessment

Though most side effects are mild and resolve with no or minimal intervention, client should be instructed to return to the clinic immediately if they experience any of the following severe or prolonged symptoms.



Severe generalised rash associated with blistering sores in the mouth, fever

Jaundice or persistent/severe nausea/vomiting

Shortness of breath

New onset of depression or suicidal thoughts or significant worsening of prior depression

Severe pain, swelling, discharge around the injection site that may suggest infection or fluctuant abscess

* For more detail, and less common side effects, see respective labels

1. JHPIEGO Rise Provider Training Toolkit on use of Long-acting Injectable Cabotegravir (CAB-LA) for HIV Pre-Exposure Prophylaxis (PrEP) <https://express.adobe.com/page/ktH6gpiRtwpOFY/#ongoing-clinical-management>



Management of most common side effects and adverse events for CAB-LA (continued)

Management of adverse events

Adverse events occurred in *fewer than 1%* of trial participants, and *most were not attributed to the use of CAB-LA*. The following provides an overview of the management of hypersensitivity, hepatotoxicity, and depression.

The management of hypersensitivity

Although extremely rare, hypersensitivity reactions can occur with almost any medication. Whilst serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and this could occur with CAB-LA as well.

Assessment: Clients should be questioned about signs/symptoms, including severe generalized rash, fever, blisters (in mouth or blistering skin reaction), swelling, hepatitis, angioedema, or difficulty breathing. These may be indicative of a hypersensitivity reaction.

Management: If a hypersensitivity reaction is suspected, no further doses of CAB-LA should be given. Provide client with an antihistamine and refer to doctor for further evaluation.

The management of hepatotoxicity

Hepatitis and jaundice occurred in a small number of participants in CAB-LA clinical trials. Most cases were hepatotoxicity and attributed to other causes besides CAB-LA, including alcohol, malaria, and viral hepatitis. However, clinicians should consider the possibility of CAB-LA-induced hepatotoxicity.

Assessment: Clients should be assessed for signs/symptoms including nausea, vomiting and jaundice. If there is a concern for liver dysfunction, clients should be asked about recent alcohol consumption (types and volume) as well as recent symptoms of illness and infection.

Management: If the client has jaundice or is suspected of having hepatotoxicity, CAB-LA should be temporarily stopped while the client is evaluated. Liver function testing should be done, and additional testing can be considered based on local epidemiology and clinical concern (for example, malaria, acute viral hepatitis).





The management of depression

Assessment: If clients express depressed mood or suicidal thoughts or appears to be depressed on examination, they should undergo detailed history and evaluation. Ask about a history of depressed mood or clinical depression prior to treatment with CAB-LA to determine if the symptoms are likely to be related or unrelated to CAB-LA use. Screen for other possible contributory factors, including use of alcohol or other drugs, financial or family stressors, grief or loss, and domestic violence.

Management: If the client reports new onset of depression with no prior history of depression, or significantly worsening depression since starting CAB-LA, consider temporarily stopping CAB while referring for diagnosis and treatment of depression. The risk of stopping CAB-LA must be weighed against the risk of HIV infection. If the client is at high risk of HIV infection, consider providing oral PrEP while they are being evaluated for depression.

Note: If it is not clear that the depressive symptoms are related to CAB-LA use (for example, the client has a prior history of major depressive disorder or has experienced significant stressors, such as death or financial stress that are a more likely cause), it may be appropriate to continue CAB-LA while referring for diagnosis and treatment of depression.





Summarising basic information about oral PrEP, the Ring, CAB-LA and condoms

	 Ring	 Oral PrEP	 CAB-LA	 Condoms
Active ingredients	Dapivirine	Emtricitabine and tenofovir (TDF/FTC)	Cabotegravir	No active ingredient
Description	Silicone vaginal ring	Single dose tablet	Single dose vial	Male - thin rubber (latex); Female - soft plastic (nitrile)
How is it given?	Inserted into vagina for 28 days	Tablet - taken orally daily	2 monthly injection	Male condom worn on penis (optional use of water-based lubricants if preferred); female condom inserted into vagina
How does it work?	Slowly releases dapivirine into the vagina (at the site of potential HIV infection) and prevents HIV from making copies of itself inside healthy cells around the vaginal area thereby reducing the risk of HIV infection acquired during vaginal sex Only works locally in the vaginal area	Antiretroviral drugs (TDF/FTC) prevent HIV from replicating. Oral PrEP works systemically, so the drug is absorbed throughout the body and provides protection for HIV throughout the body	An antiretroviral drug (cabotegravir) reduces the ability of HIV to replicate itself inside a healthy cell CAB-LA delivers cabotegravir systemically, so the drug is absorbed throughout the body and provides protection for HIV throughout the body	Provides a strong barrier to prevent the virus from entering the body -for anal, oral and vaginal sex Needs to be used for each sex act
Who is it for?	HIV-negative individuals assigned female at birth, and willing to use the Ring correctly as prescribed ¹ ; for protection from HIV when having vaginal sex only; (and according to guidelines ² and medical eligibility ³)	HIV-negative individuals; weighing 35kg and more; willing to use oral PrEP correctly as prescribed; for protection against all exposure to HIV; and according to guidelines and medical eligibility	HIV-negative individuals; weighing 35 kg and more; willing to return for injection appointments; for protection against all exposure to HIV; and according to guidelines and medical eligibility	Anyone wanting protection against HIV (and STIS and pregnancy)
How frequently does it need to be taken, inserted, or injected?	Monthly, and changed every 28 days	Daily pill	1 month apart for the first two injections, then every 2 months	Each and every time a person has sex
How discreet/private is this method? Can it be used without others knowing?	Ring fits snugly top part of the vagina –few males reported feeling it in studies. Extra rings are visible, but can be hidden, if needed.	Pills and pill bottles are visible, but can be hidden, if needed.	Very private. There can be a swelling on injection site after injection on buttocks, but otherwise is invisible.	Not private. Requires both partners to agree to its use
Where is this method available in South Africa?	Only at selected demonstration and implementation science/research sites	Available at many public health facilities, institutions of higher learning, and project sites	Only at selected demonstration and implementation science/research sites	Available free at all clinics, some public venues, and for sale at varied prices from shops and other outlets
How effective is it to prevent HIV if used as instructed?	35% - over 50% Low -moderate	Over 90% Highly effective	Over 96% Highly effective	Highly effective when used correctly, also protects against STIs and unintended pregnancy


1. As prescribed means as explained by the healthcare provider or package insert
2. Guidelines that are approved and adopted by Department of Health
3. Medical eligibility means that you are able to use the medication safely according to your health and taking into account any medical conditions you may have.



Summarising basic information about oral PrEP, the Ring, CAB-LA and condoms

	 Ring	 Oral PrEP	 CAB-LA	 Condoms
Starting and stopping:				
Lead in period- How long does it take when starting to provide protection for HIV?	24 hours	7 days	7 days	None for male condoms- needs to be put on just before penetration For female condoms - can be inserted up to 8 hours prior to intercourse
What happens when stopping the method?	The Ring can be removed at any time. As soon as it is removed, it is no longer protective. Because it works locally, there is no residue dapivirine left in the vagina. It is important to use other HIV prevention methods after removing the Ring	Oral PrEP needs to be used for 7 days after last sexual exposure. Thereafter, one is no longer protected, and there is no residue of PrEP in the system. It is important to use other HIV prevention when stopping oral PrEP	After last injection, CAB-LA provides protection for 2 months. Thereafter the cabotegravir decreases in the system and does not provide full protection against HIV. If one gets infected with HIV, it may result in resistance to ART. It is important to use other HIV prevention when stopping CAB-LA	No condom, no protection.
Common side effects NOTE: Most side effects can be managed by your healthcare provider, and get less over time as your body gets used to the method	Usually, mild. These include: <ul style="list-style-type: none"> • Urinary tract infections • Vaginal discharge • Vulvar itching • Pelvic and lower abdominal pain 	Most resolve within the first month: <ul style="list-style-type: none"> • Headaches • Gastrointestinal symptoms (diarrhea and nausea, decreased appetite, abdominal cramping, and flatulence) • Dizziness 	Usually mild to moderate, and gets less over time: <ul style="list-style-type: none"> • Headache/dizziness • Nausea/diarrhea • Tiredness/feverish • Injection site reactions such as redness, pain, and swelling at the injection site 	Few people are allergic to latex condoms
Does the method provide protection against STIs?	No	No	No	Yes
Does this method prevent pregnancy?	No	No	No	Yes
How discreet/private is this method? Can it be used without others knowing?	Ring fits snugly top part of the vagina –few males reported feeling it in studies. Extra rings are visible, but can be hidden, if needed.	Pills and pill bottles are visible, but can be hidden, if needed.	Very private. There can be a swelling on injection site after injection on buttocks, but otherwise is invisible.	Not private. Requires both partners to agree to its use



 health <small>Department of Health REPUBLIC OF SOUTH AFRICA</small>		PrEP Clinical form (Initiation)	
First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy	Gender:	M / F / TG
ID Number		Address	

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					PrEP method (select one):
			Weight (kg)	Pregnancy	Hepatitis B	STI Screening	Creatinine (eGFR/sCr)	
/ /	+/-	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	/ /
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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)					Outcome (RIP, LTF, TFO, Sero, DNA, Disc)	Date of Outcome
				HIV Test	Weight (kg)	STI Screen	Pregnancy	Creatinine (eGFR/sCr)		
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.

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

Seroconversion Reporting Form

Job Aid 10

 health Department of Health REPUBLIC OF SOUTH AFRICA			
First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy	Gender:	M / F / TG
ID Number		Date of visit:	dd / mm / yy
Address			
Instructions: Please use the form to document the circumstances/factors/situations pertaining to the seroconversion of the PrEP client. The available fields should be completed with the relevant information available at the time of reporting. Please complete and affix a copy of the PrEP clinical form and/or any relevant documentation.			
PrEP drugs exposure before positive HIV test			
PrEP start date:	dd / mm / yy	Date of HIV+ Test:	dd / mm / yy
Drug name (s):			
PrEP History			
1. At the time of the positive test result, is the client still on PrEP?	<input type="checkbox"/> Y Client is still on PrEP	Which PrEP method was used?	<input type="checkbox"/> Oral
	<input type="checkbox"/> N Client is still on PrEP	<input type="checkbox"/> DVR	<input type="checkbox"/> CAB LA
		(Specify date when the last PrEP dose was taken):	dd / mm / yy
2. In the last 3 months, has the client been taking/using PrEP effectively? i.e. without missing a dose or intermittent DV ring use or missed a Cab LA injection	Oral PrEP	DVR	CAB LA
	<input type="checkbox"/> 0 Never missed	<input type="checkbox"/> 0 Never missed	<input type="checkbox"/> 0 Never missed
	<input type="checkbox"/> 1 Missed 1-6 days	<input type="checkbox"/> 1 Missed 1-6 days	<input type="checkbox"/> 1 Missed 1-28 days
	<input type="checkbox"/> 2 Missed >7 Days	<input type="checkbox"/> 2 Missed >7 Days	<input type="checkbox"/> 2 Missed > 1 month
3. What is the clients partner/s HIV status?	<input type="checkbox"/> 1 Partner/s is HIV negative	<input type="checkbox"/> 3 Don't know partner/s HIV status	
	<input type="checkbox"/> 2 Partner/s is HIV positive		
4. Did client use a condom with partner/s?	<input type="checkbox"/> 1 Always	<input type="checkbox"/> 2 Sometimes	<input type="checkbox"/> 3 Never
5. Additional comments on circumstances relating to the seroconversion:	<div style="background-color: #cccccc; height: 20px;"></div>		
Resistance Testing Results			
Date	Comments:		
dd / mm / yy			
dd / mm / yy			
dd / mm / yy			
Relevant medical history			

Pregnancy Outcome Reporting Form

Job Aid 11

health Department of Health REPUBLIC OF SOUTH AFRICA		PrEP Pregnancy Outcome 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 pregnancy outcome 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 affix a copy of the PrEP clinical form and/or any relevant documentation					
PrEP drugs exposure before/during pregnancy					
PrEP start date	dd / mm / yy	Time of PrEP initiation	<input type="checkbox"/> Before pregnancy	Date of positive urine test	dd / mm / yy
PrEP stop date	dd / mm / yy		<input type="checkbox"/> During pregnancy	Estimated date of delivery	dd / mm / yy
Drug name (s): _____			Dose: Daily <input type="checkbox"/> Monthly <input type="checkbox"/> Other <input type="checkbox"/> Specify: _____		
Pregnancy outcome					
1. Did the client experience any complication during pregnancy?	<input type="checkbox"/> Y Yes. Specify: _____				
	<input type="checkbox"/> N No				
2. Did the client give birth to (a) live infant(s)?	<input type="checkbox"/> Y Yes. Date of delivery <input type="text" value="dd / mm / yy"/>				
	<input type="checkbox"/> N No. Specify reason: _____				
3. Was the infant normal at birth?	<input type="checkbox"/> Y Yes				
	<input type="checkbox"/> 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 <input type="checkbox"/> M <input type="checkbox"/>				
2	F <input type="checkbox"/> M <input type="checkbox"/>				
3	F <input type="checkbox"/> M <input type="checkbox"/>				
Relevant medical history (with focus on relevant prior gynaecological/obstetric history)					

