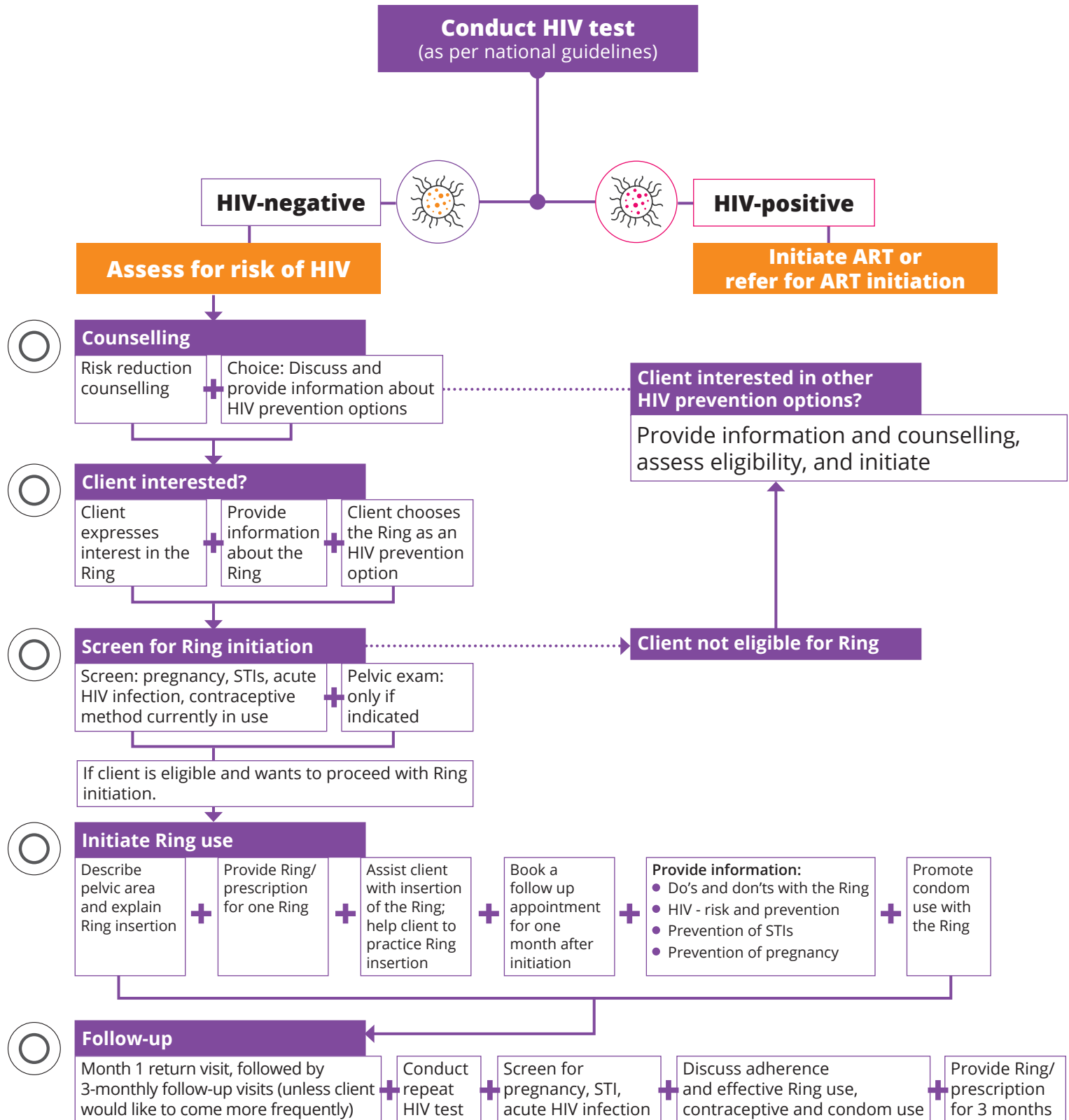


Dapivirine Vaginal Ring

referred to as the Ring

initiation algorithm



Dapivirine Vaginal Ring

referred to
as the Ring

assessment & initiation

As with oral PrEP, the Ring can be initiated on the same day for most clients. Initiation visit steps for clients beginning use of the Ring are outlined in the table below:

STEP 1:

HIV test (per national HIV testing guidelines)

Same-day HIV testing is suggested.

- If HIV-positive, client must not be initiated on PrEP and should be immediately initiated/referred for ART
- If inconclusive, defer use of PrEP and follow the national algorithm until a definitive HIV test result has been obtained
- Provide counseling on how to prevent/reduce exposure to HIV

STEP 2:

Assessment for recent exposure to HIV

Signs and symptoms of acute HIV infection (AHI):

- Fever
- Swollen lymph glands
- Skin rash
- Headache
- Sore throat
- Aches and pains
- Mouth sores

Clients exposed to HIV in the past 72 hours:

If a client reports an exposure to HIV in the past 72 hours, screen for possible eligibility for PEP instead of Ring:

- Educate clients on the difference between PEP, PrEP and ART
- After 28 days of PEP, client may be transitioned from PEP to PrEP without a gap, if eligible

Clients with possible acute HIV infection

If client presents with signs and symptoms of HIV infection and possible exposure to HIV in the previous two weeks:

- Defer use of PrEP
- Repeat HIV testing after four weeks. If HIV-negative, initiate use of PrEP if eligible

STEP 3:

Counseling for choice

Encourage informed decision-making and choice, discuss with the client:

- Challenges and successes in preventing/reducing risk
- Desire and motivation for PrEP prevention methods
- Willingness and preference for oral PrEP or the Ring, explore choices (*see Job Aid 5*)
- What are their potential exposures to HIV? For example, vaginal and/or anal sex; sharing needles with drug use; occupational exposure - emphasise that the Ring only provides protection for receptive vaginal sex
- Previous experience with HIV prevention, and oral PrEP
- Willingness and ability to use either method effectively
- Provide condoms and water-based lubricants

STEP 4:

Assess for eligibility

- Assess for eligibility and any contraindications to influence clients choice:
 - HIV-negative (as per step 1 and 2)
 - Willing and able to use the Ring
 - Aged 18 or older
 - Not currently pregnant or breastfeeding

Contraindications for the Ring:

- The Ring does not require blood tests
- There are no systemic drug to drug contraindications
- The Ring should not be provided to people with:
 - HIV-positive test result using the national HIV testing algorithm
 - Known exposure to HIV in the past 72 hours (defer PrEP and consider PEP counselling/initiation for clients, even in the absence of symptoms of AHI)
 - Signs of AHI (Box 4*) AND potential exposure within the past 2 weeks
 - Inability to commit to effectively using the Ring and attend scheduled follow-up visits
 - Allergy or hypersensitivity to active substance or other substances listed in the product information sheet
 - Recent pregnancy and delivery (within 6 weeks post-partum)

STEP 5:

Initiate Ring

- Discuss any remaining education and counseling messages about the Ring (*see Job Aid 8 & 9*)
- Explain Ring insertion and removal (*see Job Aid 7*)
- Provide one Ring for first month and provide a date for their return visit

Seek opportunities to discuss and provide SRH services:

- Explore options for preventing/reducing exposure to HIV, and the prevention of STIs and unintended pregnancy
- STI screening and management
- Provision and education about condoms use and lubricants, contraceptive services
- Mental health and GBV and IPV assessment and response.

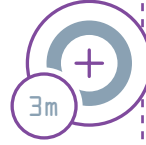
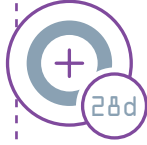
For more information: Refer to the NDOH National Dapivirine Vaginal Ring Implementation Guidelines, 2022.

Dapivirine Vaginal Ring

referred to
as the Ring

follow-up visits

Clients using the Ring will be encouraged to return after one month to have an HIV test, receive support, address side effects, discuss any difficulties with Ring adherence, and where required, get assistance removing and inserting the new Ring



After their one month visit, clients can begin a 3 monthly visit schedule (with 3 Rings provided). This can be flexible and aligned with other regular visits (e.g 2 monthly if they are on the 2-monthly contraceptive injectable)

When possible, follow-up visits should be coordinated with visits for other services to reduce the number times a client must return to receive services

Follow up visits to include:

HIV testing and possible exposure

Pregnancy testing/screening, when indicated

Support for Ring use

An integrated HIV and SRH service package

Action

- If there is possible recent exposure within 72 hours, recommend PEP
- Assess for acute HIV infection for persons who had possible exposure within the last 2 weeks (*see Box 4**)
- HIV testing: It is recommended that HIV testing should be done after one month and two-three months (depending on their return visit schedule) thereafter. Recommend more frequently where the Ring has not been used consistently.
- HIV testing is provided as per NDOH policy and guidelines
- Discuss Ring and condom use and ways to prevent/reduce potential exposure to HIV

- Currently Ring is not recommended for use by pregnant or breast feeding women
- Discuss contraception or plans to get pregnant
- Pregnancy test or screening at visits
- If pregnant, counsel on alternative prevention options and refer for antenatal care

Discuss and counsel on the following:

- Whether Ring has been in place and the importance of Ring adherence
- Challenges with Ring use
- Side effect management
- How to reduce or minimise potential exposure to HIV
- Use of additional prevention options, including condoms
- Choice and options: desire to stop or switch to another HIV prevention method e.g oral PrEP

- Follow-up services to include the integrated service package.
- STI screening and management (*see section 10.3 in guidelines*, and Job Aid 4: A note on STI management and the Ring*)
- Provision and education about condoms use and lubricants
- Contraceptive services
- Mental health and GBV and IPV assessment and response

*For more information: Refer to the NDOH National Dapivirine Vaginal Ring Implementation Guidelines, 2022.

Dapivirine Vaginal Ring

referred to
as the Ring

issues to consider with Ring use

A note on menstruation and use of tampons and the Ring

- The Ring is most effective when left in place for 28 days, and does not need to be removed during menstruation

Menstruation and the use of tampons have both been shown to possibly compromise the efficacy of the Ring – use of additional prevention is recommended

The use of menstrual cups is not recommended

A note on STI management and the Ring

This is outlined in the National Dapivirine Guidelines (see section 10.3*) as summarised below:

- Clients initiating the Ring should receive screening, testing and treatment for STIs per national guidelines.
- If testing is not possible, manage as per STI standard treatment guidelines (syndromic management) in South Africa.
 - If only mild symptoms offer the Ring.
 - If severe ulceration, pain or discharge delay providing the Ring until symptom resolution and advise condom use.
- STIs can be diagnosed and treated without removing the Ring during follow up visits.
- Early detection and treatment (as per STI guidelines) during Ring use is recommended.
- The simultaneous use of vaginally administered antimicrobial products to treat STIs has not yet been studied, and therefore is not recommended.
- When using the Ring in someone with vaginal candidiasis, preference is to use an oral anti-fungal like a stat dose of fluconazole. If a cream or pessary is to be used, such as clotrimazole and miconazole, reinforce safer sex practices until symptoms have subsided and treatment completed. Return to clinic if symptoms do not resolve within a week.

A note on pregnancy and the Ring

- Regular pregnancy testing is recommended, where indicated, for clients using the Ring
- The Ring is not currently recommended for pregnant and breast feeding women (*No safety concerns to date but limited data available*)

If pregnant, explore alternative HIV prevention options such as oral PrEP and condoms, link to antenatal care, pregnancy options counseling

A note on contraception and the Ring

- Check if client is using the contraceptive vaginal Ring (NuvaRing); and explore alternative methods if in use

All other methods can be used with the Ring, including male and female condoms

A note on GBV/IPV and the Ring

- Assess client's experience of GBV, including IPV. Provide appropriate GBV/IPV response, including first-line support and referral where necessary, and support clients to identify ways to effectively initiate and continue with Ring use.
- Although the Ring may be an option for clients concerned about IPV due to its discreet nature, clients who wish to keep their Ring use private from their sexual partner should be counseled on the possibility that a partner may feel the Ring during sex and assisted with a plan to implement should this occur.

Clients experiencing GBV or IPV should not be prohibited from receiving the Ring if they can effectively use it.

For more information: Refer to the NDOH National Dapivirine Vaginal Ring Implementation Guidelines, 2022.

Dapivirine Vaginal Ring

referred to
as the Ring

informed decision-making and choice

The Ring may be offered as an option for individuals who wish to prevent HIV acquisition through receptive vaginal intercourse, *in combination with other HIV prevention practices*

There are several factors an individual needs to consider when deciding. These tools are provided to assist the health provider encourage and support the client to understand options, and guided by information, decide on their preferred method

Job Aid 5.1 Summarising oral PrEP, the Ring and condoms

	Ring	Oral PrEP	Condoms
Active ingredients	Dapivirine	Emtricitabine and tenofovir (TDF/FTC)	Latex; Female: rubber; soft plastic nitrile
Frequency need to take it	Monthly vaginal Ring	Daily pill	Each and every time have sex
Lead in period	24 hours	7 days (for cis-gender women only)	None; needs to be put on prior to penetration. The female condom can be inserted up to 8 hours prior to intercourse.
Who is for?	Individual assigned female at birth, for protection with vaginal sex	All at risk according to guidelines and medical eligibility	All
Approval status in South Africa	Approved by SAHPRA	Approved by SAHPRA	Approved
Availability in South Africa	Selected demonstration and implementation science sites	Roll out at public health facilities, institutions of higher learning, AGYW and other key population project sites	Available at all facilities, public venues, private retail outlets etc
Efficacy in terms of prevention of HIV	35% (Note: Studies have shown that correct and consistent use of the Ring increases efficacy to over 50%)	Over 90%	98% if used consistently and correctly
STI prevention	No	No	Yes, if used consistently and correctly
Pregnancy prevention	No	No	Yes, if used consistently and correctly
Use when pregnant, breastfeeding	Not sufficient evidence	Yes, with the guidance of a health provider	Yes
Privacy: from others and sexual partner	Discreet - not visible to partner or others; partner may feel although not obvious (sits close to cervix)	Pills can be hidden - not visible to partner or others	Requires partner cooperation, visible
Mode of application	Requires insertion into vagina by a provider or self-insertion	Requires daily pill taking	Requires partner to place on penis, or self-insertion for female condom

Note: It is highly recommended that condoms are used together with oral PrEP or the Ring. However, the simultaneous use of oral PrEP and the Ring is not recommended, there is insufficient evidence to support this.

Job Aid 5.1 provides a useful summary of the key features of the Ring, oral PrEP and condoms, to assist the client in making an informed decision.

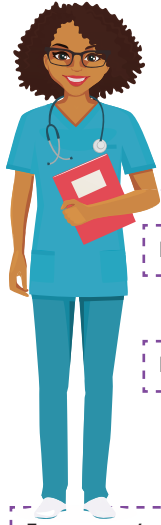
Job Aid 5.2 provides a range of considerations to reflect on when choosing a suitable HIV prevention method.

Dapivirine Vaginal Ring

referred to
as the Ring

informed decision-making and choice

Job Aid 5.2: Considerations when selecting an HIV prevention method



Issues to assist with decision-making

Potential exposures to HIV

- Vulnerability to HIV – partners HIV status? Are condoms used consistently and correctly, each and every time? If partner is HIV-positive, are they taking their ART regularly?

Partner involvement

- Is their partners opinion about their choice of HIV prevention method important?
- Whose decision is it - can the client make the decision on their own or do they need it to be a mutual decision?
- Is the client fearful of their partner finding out?

Frequency/patterns of sex

- Frequency of sex – e.g Regularly? Unpredictable and unplanned? Limited to a specific time (e.g. holidays; a sexual partner visiting for a period of time)?
- Anal/vaginal sex?

Availability and access

- What prevention methods are available and easy to access?
- What are the possible costs e.g is the product free? Money for transport to get to the place providing the method?
- Frequency to come to the service?
- Is the client able to use the service in terms of times available, transport, distance, waiting times because of queues, and how comfortable the client feels about utilising this service.

HIV, STI and pregnancy protection

- Most HIV prevention products such as oral PrEP and the Ring do not protect against STIs and pregnancy.
- Is the client able to use condoms consistently and correctly each and every time they have sex?
- Are they using contraception, and if not what are the options?
- Have they been assessed for STIs?
- Can the HIV prevention method be used together with condoms?

Effectiveness

- No HIV prevention method is 100% effective in preventing HIV, effectiveness varies.
- How effective are the methods the client is interested in? And how important is this to the client?
- How can the client get maximum protection? Are there any other issues which may affect the effectiveness of a method?

Personal commitment and preference for mode of use

- How does the client feel about how to use the method – e.g. daily pill, vaginal insertion, condom use, etc
- Is the client able to remember to take a daily pill? Does the client understand how to use the methods to ensure maximum protection, and are they willing to try? For oral PrEP, taking a daily pill, cycling on and off; complying with the lead in time of 7 days, and use for 7 days after stopping; for the Ring -how does the client feel about inserting a Ring into their vagina and having a Ring in place for 28 days?
- How easy is it to use condoms each and every time the client has sex?

Side effects

- Is this an important factor? Does the client have prior experience with side effects?

Pregnancy and breastfeeding

- How does the client best protect against HIV when pregnant or breastfeeding?
- Is the method registered for use by pregnant and breast feeding women?



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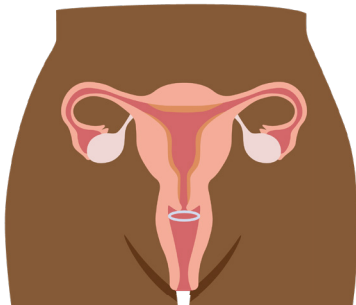
Personal preference: In the end, the client may just have a preference, because it suits them at this point in time, or they have tried a method before, and want to try something different. Its their decision, as long as they are eligible.

Dapivirine Vaginal Ring

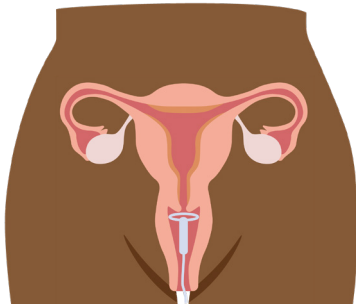
referred to
as the Ring

pelvic area

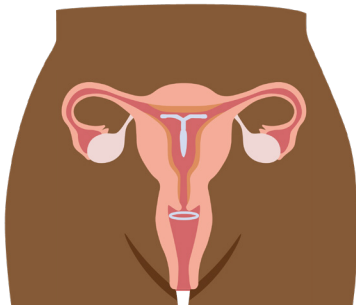
Understanding the pelvic area and where the Ring is inserted is important for clients wanting to use the Ring and learning how to use it.



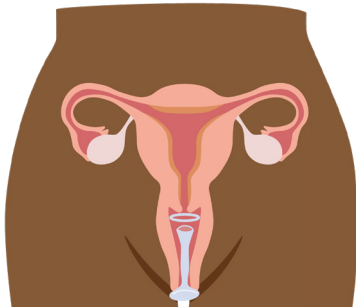
Picture of the Ring in place on its own



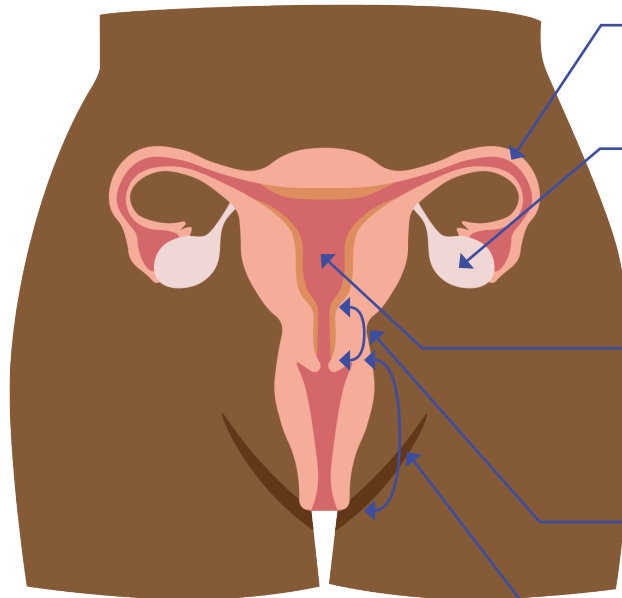
Picture of the Ring in place with a tampon



Picture of the Ring in place with an IUD



Picture of the Ring in place with a female condom



Fallopian tubes

Tubes that connect each ovary to the uterus and provide a pathway for the egg to be released for fertilization by the sperm.

Ovaries

Oblong organs about the size of your thumbnail, where your eggs are stored. You have two of them, and they are attached to the uterus by the fallopian tubes. You are born with thousands of eggs in your ovaries and will not produce any more during your lifetime.

Uterus

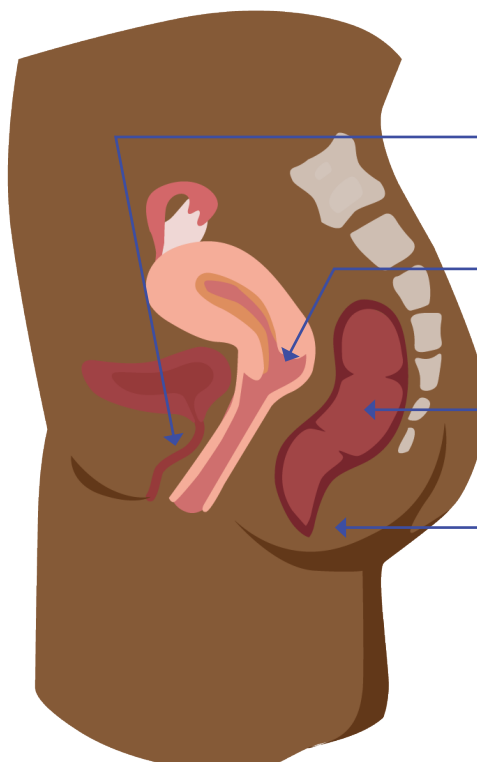
A pear-shaped organ in the middle of the pelvis, above the vagina. Sometimes called the womb because the foetus grows here during pregnancy. The uterus is where tissue and blood build up before menses.

Cervix

A muscular gateway where the uterus opens into the vagina. Your cervix separates your vagina from the rest of your body, so things like tampons or the vaginal Ring can't get "lost" inside of you.

Vagina

A tube that connects your vulva with your cervix and uterus. Babies and menstrual blood leave the body through the vagina. Some people put penises, fingers, sex toys, menstrual cups, and/or tampons here, and it is where the vaginal Ring sits.



Urethra

Cervix

Rectum

Anus

Opening to the rectum, where the butt creases start behind the vulva. Stool/poop passes through the anus when you defecate (poo) and this is where the penis enters during anal sex.

April 2023



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Dapivirine Vaginal Ring

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ring insertion and removal

Inserting the PrEP Ring

Clients may need initial guidance and support to learn how to use the Ring and, once confident, can continue to use the Ring on their own. Some clients are comfortable using the Ring on their own with minimal support from their first use. However, for clients who prefer support, a healthcare provider can help insert the Ring or confirm placement. The Ring is inserted by hand; there is no need to use a speculum or other tools to insert the Ring. Clear visual instructions should be offered with the Ring.

Ring insertion steps for clients:

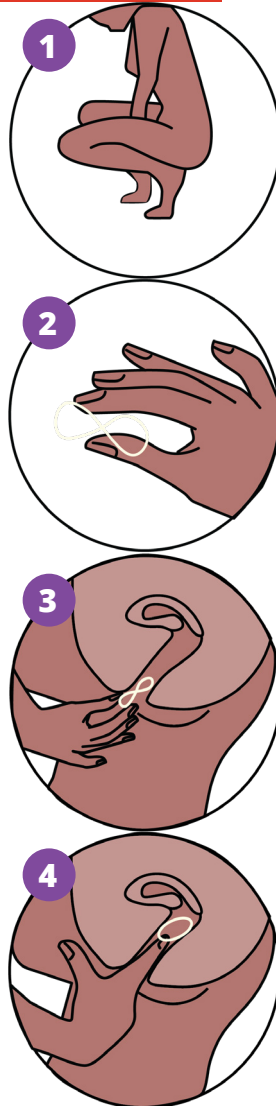
**Ring insertion should be painless. If you have any bleeding or discomfort upon insertion, contact your healthcare provider.*

Get into a position that is comfortable for inserting the Ring, such as squatting, one leg lifted, or lying down. If a healthcare provider is assisting you, you should be in a reclining position.

With clean hands, squeeze the Ring between the thumb and forefinger, pressing both sides of the Ring together so that the Ring forms a "figure 8" shape. Use the other hand to open the folds of skin around the vagina.

Place the tip of the Ring into the vaginal opening and use your fingers to push the folded Ring gently up into the vagina.

Push the Ring as far toward the lower back as possible. If the Ring feels uncomfortable, it is probably not inserted far enough into the vagina. Use a finger to push it as far up into the vagina as is comfortable.



Removing the PrEP Ring

Clients can remove the Ring without the help of a healthcare provider. However, for clients who prefer support, a healthcare care provider can help remove the Ring. The Ring is removed by hand; there is no need to use a speculum or other tools. If a client is being assisted by a healthcare provider, they should be in a reclining position during removal.

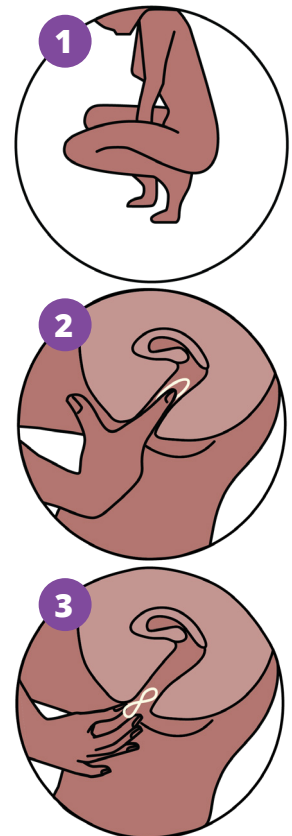
Ring removal steps for clients:

**Ring removal should be painless. If you have any bleeding or discomfort upon removal, contact your healthcare provider.*

Get into a position that is comfortable for removing the Ring, such as squatting, one leg lifted, or lying down.

With clean hands, insert one finger into the vagina and hook it around the edge of the Ring.

Gently pull the Ring out of the vagina.



Please also refer to free IPM demonstration video link at <https://vimeo.com/707699170>

Source: Mosaic Template Guidelines for Oral Pre-Exposure Prophylaxis (PrEP), PrEP Ring, and CAB PrEP unpublished Nov 2022

Dapivirine Vaginal Ring

referred to
as the Ring

key messages

Difference between PrEP, PEP and ART

Pre-exposure prophylaxis (PrEP):

- Use of antiretroviral drugs by HIV-negative individuals before potential exposure to HIV to prevent HIV acquisition.
- Current PrEP options in South Africa include oral PrEP (oral TDF/FTC as a fixed-dose combination) and the Ring.
- Other methods in the pipeline, including the two monthly long-acting injectable cabotegravir (CAB-LA)

Post exposure prophylaxis:

- Use of antiretroviral drugs by HIV-negative individuals, taken within 72 hours after exposure to HIV and continued for 28 days to prevent HIV acquisition.

Antiretroviral Treatment (ART):

- Lifelong treatment with a combination of antiretroviral drugs for HIV-positive individuals
- Prevention of mother to child transmission (PMTCT) effectively reduces transmission from a pregnant women to her infant.
- Proper use of ART for HIV-positive persons effectively reduces HIV transmission.

Effective use of the Ring

- The Ring should remain in place for 28 days without removal and should be replaced with a new Ring at the end of the 28 days.
- The Ring must be in place for at least 24 hours before it is considered maximally effective. During this time, safer sex practices should be used, for example, abstinence, condoms/lubricants.
- The Ring only prevents HIV acquisition through receptive vaginal intercourse.
- Use the Ring as long as you think you may be at risk: Some people only need to use the Ring during certain times in their lives, while others may have an ongoing need. Continue using the Ring as long as you feel you have increased likelihood of acquiring HIV or until other methods for HIV prevention work for you and your life.

Sharing the Ring

The Ring should not be shared with others. If other people are interested in using the Ring, encourage them to come to this service.

Ring use during sex

- The Ring does not interfere with sexual intercourse and should be worn during sex.
- It can be used with condoms (male and female).
- Although it is unlikely, it is possible that your partner may feel the Ring during sex. If this happens, you may need to confirm Ring placement, as it may mean that the Ring should be pushed further into the vagina.
- The Ring does not cause harm to your partner, but it does not prevent your partner from acquiring HIV.

Ring use with contraceptives

- The Ring does not prevent pregnancy, so it is important that you use a reliable method of contraception as well. Almost all methods can be used with the Ring (hormonal contraceptives pills, injectables, implants, IUDs, and barrier methods, including condoms (male and female). However, use with the contraceptive vaginal Ring (NuvaRing), diaphragm and cervical cap is not recommended.
- The Ring can be used with male or female condoms

Ring use during pregnancy and breastfeeding

There is limited information about the safety of using the Ring during pregnancy or when breastfeeding (and it is not yet recommended in South African guidelines). If you are pregnant or breastfeeding or intend to be, discuss with your health provider.

Side effects

There is a possibility of side effects with Ring use, such as urinary tract infections, vaginal discharge, vaginal and vulvar itching, and pelvic and lower abdominal pain. These side effects usually resolve without the need to remove the Ring. Urinary or reproductive tract changes may be signs of a urinary tract infection or a sexually transmitted infection, and you should seek medical advice as soon as possible.

The Ring and alcohol or other recreational drugs

Using the Ring while you are using alcohol or other recreational drugs will not hurt you. If you have concerns about this, discuss with your health provider.

Dapivirine Vaginal Ring

referred to
as the Ring

key messages

The Ring and STI prevention

The Ring does not prevent any STIs other than HIV. When possible, use a condom correctly whenever you have sex to prevent other STIs. The Ring can be used with male or female condoms.

The Ring and menses

- The Ring should be worn for 28 days, including during menses, to be most effective. The Ring does not cover the cervix and does not interrupt the flow of menstrual fluids.
- The Ring should not be removed when menstruating.
- The Ring should not be used with menstrual cups, but sanitary pads and tampons can be used.
- If using a tampon, be careful not to accidentally remove the Ring when removing the tampon. Although it is unlikely, it is possible that the Ring may fall out. If this happens in a clean location, the Ring should be rinsed in clean water and reinserted. If the Ring falls out in a dirty location, the Ring should be replaced with a new Ring.

NOTE: There is evidence that menstruation and use of tampons may result in a decrease of dapivirine levels and therefore women should be advised to use additional HIV preventive measures during menses such as condoms.

Condoms should be used when using the Ring to add additional protection, but this is especially important when menstruating.

Other ways to lower chances of getting HIV

To lower your chances of getting HIV:

- Use oral PrEP
- Adopt safer sexual practices, including consistent condom and lubricant use
- Engage in non-penetrative sex, including mutual masturbation
- Receive screening, diagnosis, and treatment for other STIs
- Ensure an HIV-positive partner in a serodifferent partnership has been on effective ART for at least six months, has an undetectable viral load, and remains adherent to ART
- Partner HIV testing
- Voluntary medical male circumcision
- Reduce number of sexual partners
- Access drug harm reduction and treatment services

Cleaning the Ring

The Ring does not need to be removed and cleaned for any reason. However, if desired, it is acceptable to remove the Ring, rinse it in clean water only, and then reinsert it immediately.

The Ring and douching

It is possible that flushing the vagina with water to clean it (or any form of douching) may dilute the concentration of dapivirine in the vagina. Douching is not recommended at any time, including while using the Ring, because it may have a negative impact on the health of the vagina.

Ring reinsertion

Although it is unlikely, it is possible that the Ring may fall out. If this happens, the Ring should be rinsed in clean water and reinserted. If the Ring falls out in a dirty location, the Ring should be replaced with a new Ring.

Ring storage

Store Rings in their original packaging in a cool, dry place, away from children and direct sunlight, and secured from any pets or animals. The Ring does not need to be refrigerated and can be safely stored at or around 30°C within 5 years from the manufacturing date on the package.

Ring disposal

Used Rings can be placed inside the original wrapper provided with the Ring or wrapped in tissue or toilet paper and disposed of in the trash bin out of reach of children. You can return your used Ring to your healthcare provider/service provision point if you prefer.

Switching between HIV prevention options

It is okay to start the Ring and decide later that you want to use another option to prevent HIV infection, like oral PrEP. Many people switch between methods as their needs change. Discuss this with your health provider.

Dapivirine Vaginal Ring

referred to
as the Ring

frequently asked questions

What if a woman wants to stop using the Ring?

The Ring is simply removed when a woman wants to stop using it. Once the Ring is removed, she is no longer protected. She can discuss prevention options with her health provider.

Can a woman use contraception with a Ring?

The Ring can be used with the following: male and female condoms, oral contraception, and hormonal injections, IUD, and implants. The Ring should not be used with contraceptive vaginal Rings, cervical caps and diaphragms.

What do I do during menstruation?

- The Ring can be used during menstruation and should not be removed.
- Tampons can be used, but caution should be exercised not to dislodge the Ring when removing.
- Menstrual cups should not be used when using the Ring.
- Menstruation and tampon use may reduce the level of dapivirine, and therefore Ring users are especially recommended to use additional prevention measures during menstruation – such as condoms.

What happens if the Ring comes out accidentally?

If the Ring comes out accidentally, or if removed, the following applies:

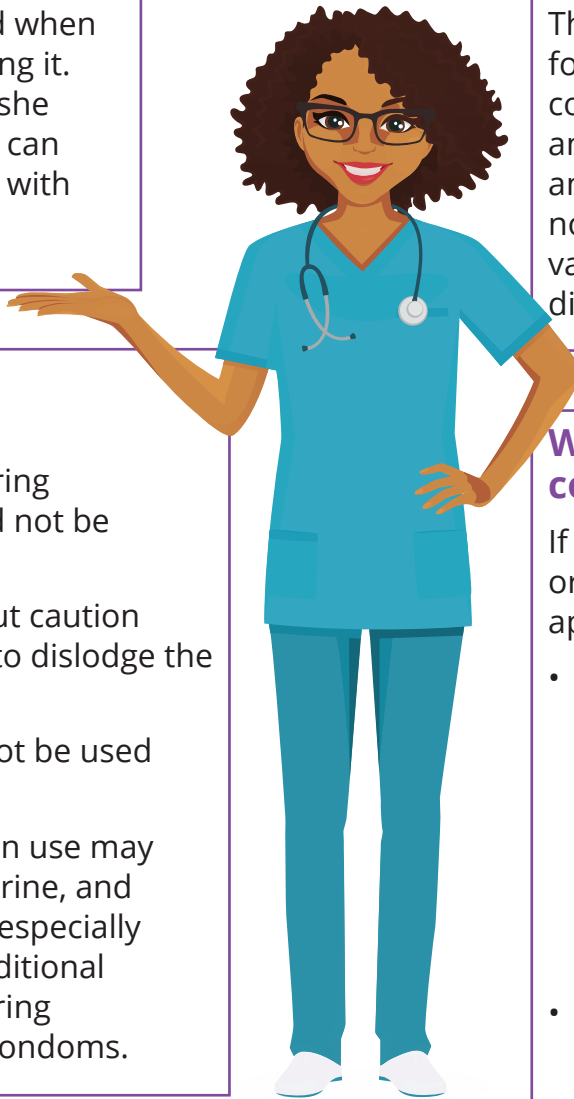
- If this happens in a clean environment and the Ring does not touch anything unhygienic (e.g. the toilet), then the Ring can be rinsed with clean water and re-inserted for the remaining time (until it has been used for the 28 days).
- If it touches something unhygienic, or if the woman is not sure, then rather discard, and re-insert a new Ring as per instructions.
- Remember that once the Ring is removed, and is re-inserted, or a new Ring is inserted, additional prevention methods should be used for 24 hours to build up the right level of protection.

Can condoms be used when using the Ring?

Yes, male and female condoms can both be used. Water-based lubricants can also be used with male condoms.

Does the Ring come in different sizes?

There is only one size: one-size-fits-all.



Dapivirine Vaginal Ring

referred to
as the Ring

frequently asked questions

Does the Ring provide protection against HIV when having anal or oral sex?

The Ring only provides protection when having receptive vaginal, it works locally. It does not provide protection when having anal or oral sex. It is designed specifically for vaginal intercourse and should never be inserted rectally. Best to use oral PrEP and/or condoms (and lubrication (water-based)) when having anal sex.

Does the Ring impact on a woman's fertility?

The Ring has no effect on a women's fertility. It does not contain hormones, nor does it impact on hormonal levels or menstrual cycle. However, women are at risk of pregnancy when using the Ring and should use contraception to prevent pregnancy.

How is the Ring disposed of when finished?

The Ring has a bag in which it can be wrapped and placed in the bin. Alternatively wrap in toilet paper or tissue and dispose in a bin, kept away from children, the same way as condoms need to be disposed of.

Is the woman still protected against HIV after removing the Ring? Does the dapivirine (ARV) build up in the system and if so, for how long does it provide protection after removal?

The Ring contains 25 mg of the ARV drug dapivirine which it releases slowly and evenly throughout the 28 days. It protects the vaginal area from HIV with very little absorption elsewhere. Once the Ring is removed it is no longer effective.

What happens if a woman gets pregnant while using the Ring? Can the Ring be used by women who are breast feeding?

There are limited data on the Ring's safety among pregnant and breastfeeding women. There are several ongoing studies researching the Ring's safety and use among pregnant and breast feeding women (Deliver and B-Protected studies). Currently, in South Africa, the Ring is not approved for use in pregnant and breast feeding women.

Does the Ring cause discomfort during sex? Can a sexual partner feel the Ring during sex?

Most participants in studies reported that they did not experience changes for themselves or their partners during sex, nor does it impact on sexual pleasure.

Does the Ring provide protection for people who inject drugs?

The Ring only provides protection when having receptive vaginal sex. If individuals who injects drugs wants HIV protection, then they need to use oral PrEP or other strategies to reduce the likelihood of HIV acquisition when injecting drugs such as clean needle exchange services.

Dapivirine Vaginal Ring

referred to
as the Ring

PrEP clinical form

health Department of 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		
/ /	+/-	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.										

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



PrEP clinical form



health
Department
of Health
REPUBLIC OF SOUTH AFRICA

PrEP Clinical form

First name

Surname

DOB

ID Number

dd / mm / yy

Gender: M / F / TG

History:

Signature:

Date:


Name:



Dapivirine Vaginal Ring

referred to
as the Ring

PrEP sero conversion form

 health Department: 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"/> DVR <input type="checkbox"/> CAB LA <input type="checkbox"/> N Client is still on PrEP (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 <input type="checkbox"/> 0 Never missed <input type="checkbox"/> 1 Missed 1-6 days <input type="checkbox"/> 2 Missed >7 Days	DVR <input type="checkbox"/> 0 Never missed <input type="checkbox"/> 1 Missed 1-6 days <input type="checkbox"/> 2 Missed >7 Days	CAB LA <input type="checkbox"/> 0 Never missed <input type="checkbox"/> 1 Missed 1-28 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:	_____		
Resistance Testing Results			
Date	Comments:		
dd / mm / yy			
dd / mm / yy			
dd / mm / yy			
Relevant medical history	_____		

April 2023


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health

 Department:
 Health
 REPUBLIC OF SOUTH AFRICA

Dapivirine Vaginal Ring

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as the Ring

Ring provision – The basics: What do services need?

Ring readiness - The essentials

- ☐ Supply of commodities (the Ring, HIV tests and all commodities to support integrated HIV and SRH services)
- ☐ Appropriate storage
- ☐ Stock control systems in place
- ☐ Reporting and M&E systems in place
- ☐ Information materials
- ☐ Infection control measures/universal precaution, including COVID-19
- ☐ Availability of other HIV prevention options (oral PrEP, PEP, condoms (male and female), lubricant)

Staff training:

- ☐ Adapted according to the scope of work of selected staff – defined by regulatory provision, clinical and non-clinical positions, etc.
- ☐ Training to include: Understanding the Ring, Ring safety and efficacy, providing the Ring, meeting HIV prevention needs of diverse user groups, raising awareness and communicating about the Ring, clinical management of clients on the Ring, counseling and supporting effective Ring use

The Ring should be integrated into the following clinical services (*with operational and accessible referrals where necessary*):

- ☐ HIV testing and counselling - HIV prevention counselling, discussion, and information: risk, HIV prevention options
- ☐ Pregnancy test or screening
- ☐ Pregnancy counselling, referral to ANC, ToP, and/or social services
- ☐ Oral PrEP
- ☐ PEP
- ☐ ART
- ☐ Contraception
- ☐ STI screening
- ☐ GBV/IPV/sexual assault services
- ☐ TB screening
- ☐ Covid screening

Provision of the Ring:

- ☐ Consultation: privacy, bed (if available, but can do insertion standing up), clean linen, screens, infection control measures

Toolkit/resources to support Ring use:

- ☐ **For providers:** Rings for demo; Q&A; pictures, model, and ability to demonstrate. Video a nice to have.
- ☐ **For clients:** Pictures and info to take home, Q&A, IEC material to share with others. Reminders: calendar, diary, phone app, reminder for 28 days