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MINISTRY OF HEALTH

Concept Notes on Dapivirine Vaginal Ring Phased Implementation for HIV Prevention among High Risk Women in Cambodia

2025



National Center for HIV/AIDS, Dermatology and STD (NCHADS)

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FOREWORD

Cambodia has achieved significant success in controlling the HIV epidemic. Moving forward to reach the 95-95-95 targets by 2025 and achieve the elimination of new HIV infections by 2030, the Ministry of Health is committed to supporting a range of innovative approaches to prevent HIV transmission among key populations. With financial support from the Global Fund and the UNAIDS/DFAT grant, and under the leadership of the National Center for HIV/AIDS, Dermatology, and STD (NCHADS) and technical support from key partners, oral PrEP has already been implemented in Cambodia. Other PrEP options are coming on board as well.

The Dapivirine Vaginal Ring (DVR), recommended by the World Health Organization (WHO) in 2021 as part of combination HIV prevention for women, is a long-acting, easy-to-use, and discreet HIV prevention option. Designed specifically for women, it can be offered alongside existing HIV prevention methods, such as oral or injectable PrEP and condoms, providing women with an additional choice for HIV prevention. We are proud that Cambodia will be the first country in Asia and the Pacific region to pioneer the implementation of DVR for HIV prevention among high-risk women.

This concept note on the DVR Phased Implementation for HIV Prevention among high-risk women in Cambodia, approved by the Ministry of Health, provides a framework for integrating DVR into Cambodia's combination HIV prevention and further scaling up of DVR services as part of comprehensive HIV prevention efforts.

The Ministry of Health strongly hopes that all concerned stakeholders, led by NCHADS, will implement this innovative HIV prevention option effectively and efficiently in Cambodia.

Phnom Penh, O.G. /. O.S. /2025

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We are grateful to our many partners from KHANA, RHAC, CWPD, EWNet, FoNPAM, WNU, and AHF for their unwavering support. Thanks to the FEW outreach workers, field staff, and women representatives for their essential efforts, participation and contributions.

We appreciate the expertise and crucial support of Ms. Patricia Ongpin, Country Director of UNAIDS, and Mr. Polin UNG, Adviser for Services for All Implementation at UNAIDS, as well as Dr. Sushena Reza-Paul, Regional PrEP Consultant at UNAIDS AP, for her valuable insights, and consultant Assoc Professor Iryna Zablotska-Manos for drafting this concept note on behalf of the TWG.

We deeply appreciate everyone's contributions and look forward to continued partnership in integrating the Dapivirine Vaginal Ring into Cambodia's combination HIV prevention package.

Phnom Penh, O. 4./.. Q. &.. /2025

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Abbreviations

3TC Lamivudine (antiretroviral drug)

ARI Acute Retroviral Infection

ART Antiretroviral Treatment

ARV Antiretroviral

B-IACM Boosted-Integrated Active Case Management

CAB-LA Long-acting injectable cabotegravir

CBO Community-based Organization

DVR Dapivirine vaginal ring

FEW Female Entertainment Worker

FTC Emtricitabine (antiretroviral drug)

HBV Hepatitis B Virus

HCV Hepatitis C Virus

NCHADS National Center for HIV/AIDS, Dermatology and STD

NNRTI Non-Nucleoside Reverse Transcriptase Inhibitor

PEP Post Exposure Prophylaxis

PrEP Pre-exposure Prophylaxis

SOP Standard Operating Procedure

STI Sexually Transmitted Infection

TasP Treatment as Prevention

TDF Tenofovir Disoproxil Fumarate

TWG Technical Working Group

UNAIDS Joint United Nations Programme on HIV/AIDS

USAID United States Agency for International Development

WHO World Health Organization

1. INTRODUCTION

1.1 The HIV epidemic in Cambodia

By the end of 2023, approximately 76,000 people were living with HIV in Cambodia, including 74,000 adults aged 15 years and older, of whom 36,000 (47%) are women.¹ HIV prevalence tends to be higher in urban areas compared to rural regions. This is partly due to higher population density and greater mobility in cities, which can increase the risk of HIV transmission.

About 86% of new HIV infections are among key populations and their clients or partners. Although, prevalence in the adult general population declined to 0.5% in 2023¹, it remains about 10 or more times higher in the key populations. Some provinces have higher HIV prevalence rates due to factors like migration patterns, economic and tourism activities, and the concentration of key populations. There are still significant challenges in HIV prevention, such as addressing inequalities and ensuring that the remaining undiagnosed individuals are reached.

As to female entertainment workers (FEWs), while the nationwide HIV prevalence is 4.9%, it is higher in Preah Sihanouk (6.8%), Phnom Penh (5.9%) and Battambang (5.9%).² HIV infection among freelance FEW (working in the streets, parks, public space, using social media or communication application to solicit paying partners) is 7 times higher compared to venue-based FEW (6.9% versus 1%, respectively). Higher HIV prevalence is observed among FEW who experienced violence compared to those who did not (5.3% vs 4.8%, respectively). Only 60% had an HIV test in the past 12 months or know they are living with HIV.

According to the IBBS 2022 data² for FEWs, there is also a high prevalence of sexually transmitted infections such as syphilis (18.9%), *Chlamydia trachomatis* (CT, 22.6%) and *Neisseria gonorrhoeae* (NG, 18%). However, only 41% of FEWs had an STI test in the past 3 months.

Underlying the high rates of HIV and STI are risk and vulnerabilities that FEW encounter. FEWs participating in the IBBS 2022 reported having different types of partners - regular, multiple casual and paying partners (65%, 49% and 67%, respectively).² Condom use with these partners varies: only 55% of FEWs report using condoms at last sex with regular partners versus 85% with casual and 94% with paying partners. However, 38% of women who had paying sex partners in the last 3 months (30% on Phnom Penh) did not use condoms consistently, including 10% who used condoms only sometimes or never (8% in Phnom Penh). Overall, 18% of FEWs (10% in Phnom Penh) report avoiding health care in the past year due to fear or concern of stigma around exchanging sex for money or goods, and 1 in 10 (13% in Phnom Penh) report physical violence by a sex partner or forced sex. Overall, 7% of FEWs injected drugs (less than 6% in Phnom Penh). Three in five FEWs report having more than 5 drinks of alcohol before sexual encounter, and almost half do not use condoms when they are under the influence of alcohol or drugs. The rates of contraception use are low while abortions are common (28% and 63%, respectively).

According to the IBBS 2022 data², only 10% of FEWs knew about PrEP (13% in Phnom Penh)², despite the fact that PrEP has been officially available in Cambodia since 2019.

1.2 The HIV response in Cambodia

Cambodia is among the first countries in the world to achieve the 90-90-90 targets in 2017³ and is working towards achieving the 95-95-95 targets (95% of people living with HIV know their status; 95% of those who knew their HIV status enrolled in ART; 95% of those on treatment are virally suppressed) by 2025.

HIV prevalence in the general adult population declined from an estimated 1.3% in 2000 to 0.5% in 2023 (2024 national HIV estimates).⁴ In 2023, Cambodia has diagnosed approximately 89% of the estimated population of people living with HIV (PLHIV), placed nearly all diagnosed PLHIV on ART, and achieved 87% of all estimated PLHIV in Cambodia had suppressed viral load).¹

Cambodia scaled up combination HIV prevention and testing services to more than 90,000 people from key populations using innovative and differentiated approaches, including virtual outreach initiatives. Government- and community-led pre-exposure prophylaxis (PrEP) services were also scaled up to more than 31,000 clients by the end of December 2024.⁵

These accomplishments result from a conducive environment for the national HIV response – a combination of effective policies, strategic frameworks, a legal framework, and a broad collaboration among various partners. Furthermore, this environment has fostered an active involvement of civil society organizations (CSOs), which has been crucial in spearheading prevention efforts for key populations, offering care and support services for PLHIV, and collaborating closely with government and international partners to enhance community-led initiatives.

The National Strategic Plan for HIV and STI Prevention and Care in the Health Sector 2021-2025 provides comprehensive guidance for Cambodia's HIV response. The plan aims to reduce new HIV infections to fewer than 250 by 2025 and to increase the coverage of HIV and STI prevention services for key populations and their partners. To achieve these objectives, several strategic priorities have been outlined, particularly focusing on key populations including FEWs.

One of the primary strategies is to increase geographic coverage and expand the provision of a combination package for HIV and STI prevention. This includes: innovative approaches such as PrEP and other tailored interventions to meet the specific needs of key populations, including FEWs; improving the quality and friendliness of prevention services and enhancing community outreach, making sure that they are accessible to key populations; optimizing the use of social media and other online platforms to reach higher-risk and hard-to-reach key populations; expanding and strengthening the enabling environment and reducing barriers to accessing services (such as gender-based violence (GBV) and other social factors that contribute to the vulnerability of key populations), and expanding access to PrEP for key populations at high risk. The rollout of PrEP and diversifying the available PrEP options (including the dapivirine vaginal ring (DVR)) is a strategic priority action in Cambodia's HIV response because the latter targets the population of FEWs, provides more prevention options for them, empowers women with more control over their prevention methods, and is part of a combination prevention strategy. Focus on female-controlled DVR PrEP helps reduce stigma and should involve significant community engagement.

By focusing on these strategic priorities, Cambodia aims to create a more effective and inclusive HIV prevention framework that addresses the unique needs of FEWs among other key populations.

1.3 PrEP Implementation in Cambodia

PrEP has been officially available in Cambodia since 2019.⁷ Its implementation is guided by the Ministry of Health and the National Center for HIV/AIDS, Dermatology, and STD (NCHADS). The Ministry of Health approved the PrEP Concept Note in May 2019, which outlines the benefits of PrEP and its role toward achieving the 95-95-95 target by 2025.⁷ The Standard Operating Procedure (SOP) for PrEP implementation was adopted in January 2022, providing detailed guidelines for healthcare providers.⁸ The accessibility of PrEP has significantly increased with the

involvement of community-based organisations and the introduction of same-day PrEP initiation.

NCHADS has established an ambitious national target of cumulative 10,000 PrEP clients by 2023. With the financial support from the Global Fund and UNAIDS/DFAT grant, NCHADS has scaled up PrEP services making it available at 45 sites. By the end of December 2024, 31,005 clients cumulatively enrolled on PrEP.

PrEP services in Cambodia aim to increase access to HIV prevention, particularly for key populations at higher risk of HIV infection. However, oral PrEP has been predominantly targeted to men who have sex with men and transgender women thus far, while access to PrEP for FEWs has remained low¹⁰[10].

The need for additional HIV prevention tools for FEWs in Cambodia is driven by their vulnerabilities and higher risk of infection (HIV prevalence among FEW is 10 times higher than among women in the general population²). Expanding biomedical options allows FEWs to choose the prevention tool that is suitable for them. The introduction of DVR is a significant step in this direction. NCHADS has decided on a phased introduction of DVR among FEW, which will provide important information to support scaling up.

2. DVR OVERVIEW

WHO recommends the DVR as a safe and effective option for cisgender women to prevent HIV acquisition during vaginal sex. 11-13 There is no evidence for the effectiveness of the DVR for any other transmission mode. Dapivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI), which is impregnated into a flexible silicone ring. The DVR contains 25 mg dapivirine and delivers it locally in the vagina, with a low systemic exposure (the dapivirine is delivered locally in the vagina, only a small amount of it enters the bloodstream and circulates throughout the body), and effective for preventing HIV acquisition for 28 days . Rings are individually packaged in one month or three-month packaging, with shelf-life of 5 years. The efficacy of the DVR with 25 mg dapivirine when being used is about one month (28 days). 15,16

When used correctly and consistently, the monthly DVR reduces HIV risk in women by over 50%^{17,18}, and possibly more as per some analyses.^{17,19} Because the DVR is only protective for vaginal HIV exposure and does not provide protection for anal HIV exposure or exposure to other STIs, it is recommended that condoms are offered with all PrEP, including the DVR.¹¹

Some providers may be concerned about DVR adherence and safety in adolescent girls and young women (AGYW). However, recent evidence suggests that the DVR is safe, effective and well tolerated by women aged under 18 years.²⁰⁻²³ Those AGYW who chose DVR show moderate to high adherence, similar to those who choose oral PrEP. Those AGYW who had a chance to use both methods, find both oral PrEP and DVR equally highly acceptable.

The DVR can be inserted and removed by the woman herself (which is the ultimate goal) or by the provider, depending on the woman's preference. PrEP providers should offer all DVR users their assistance for the first insertion and as long as it takes for the user to become comfortable and gain confidence to do it independently. Some women may benefit from assurance that the DVR has been inserted correctly, particularly early in use. Guidance on inserting and removing the DVR is outlined in the product information leaflet provided with the DVR. Training resources to help PrEP providers are also available.²⁴

The DVR should be worn for 24 hours before exposure to HIV. The DVR is designed to be worn continuously in the vagina for 28 days²⁵ until it is replaced with a new ring. As of note, an extended duration (three-monthly) DVR is also being evaluated; it was well-tolerated and achieved higher dapivirine concentrations in early pharmacokinetic studies compared with the monthly DVR.^{15,16}

To maintain efficacy, a new DVR should be inserted immediately after a previous ring has been removed. The DVR should not be removed prior to, during, or immediately after vaginal sex, or during menses. In the case of accidental expulsion or removal, the DVR can be rinsed in clean water and immediately reinserted if the ring has not been exposed to an unhygienic environment, or it can be replaced with a new DVR. The DVR can be safely and effectively used during menstruation. Women may choose to time the replacement of the ring with the end of their menstrual cycle. Levels of dapivirine in the vagina drop quickly and other prevention options should be used if another DVR is not inserted immediately.

Supporting effective DVR use (or adherence) is important. Effective use refers to using the DVR according to the recommended schedule of use (monthly), to reduce the risk of acquiring HIV. The DVR is unlikely to be used for life. As any PrEP product, it can be discontinued if a person is no longer at risk or decides to use an alternative PrEP product or HIV prevention method. Some groups, such as young women, may require more support or more frequent check-ins. DVR support groups may be helpful for peer-to-peer sharing.

Side-effects of the DVR are usually mild and may be experienced by up to 1 in 10 people. The most common side-effects can include urinary tract infections, inflammation of the vagina, vulva or cervix, vaginal discharge, vaginal or vulvar itching, and pelvic or lower abdominal pain. However, they are uncommon, usually happen in the first month of use and resolve by themselves without the need to remove the ring.

The DVR can be used safely with both external (also called male) and internal (also called female) condoms. Because the DVR acts locally, there is no increased risk of NNRTI-resistant HIV infection. The DVR has a favourable safety profile during pregnancy and breastfeeding. Pregnancy outcomes and contraceptive efficacy were similar between DVR and placebo in the trials. Behavioral studies showed no significant changes in sexual behavior or STI incidence. Behavioral studies showed no significant changes in sexual behavior or STI incidence. It is long-acting, discreet nature. Social harms were uncommon; only a small number of (particularly young) women (<5% of women with >1 year of use), reported the DVR destruction, physical violence, and/or relationship termination, which affected their DVR adherence. Therefore, all DVR (and any PrEP) use can be supported with IPV assessment, first line support using LIVES, trauma informed care and/or other support interventions.

The WHO Guideline Development Group believes introducing the DVR as an additional HIV prevention option could increase equity.³² The DVR provides a discrete, woman-controlled method, complementing oral PrEP to meet diverse needs. Similar to contraception, more PrEP options could lead to increased use.³⁶ Access to the DVR could also enhance sexual and reproductive health services.

WHO emphasizes integrating HIV prevention with other services like STI diagnosis, HIV testing, antiretroviral therapy, contraception, as well as counselling testing and care for partners. Women should receive comprehensive information and counseling to make informed choices.

^I LIVES is an acronym used to guide first-line support for individuals experiencing intimate partner violence (IPV). It stands for: Listen to the survivor without judgment and with empathy, Inquire: Inquire about their needs and concerns, Validate: Validate their experiences and feelings. Enhance safety: Enhance their safety by discussing a plan to protect them from further harm, and Support: Support them by connecting them to appropriate services and resources.

3. RATIONALE

The DVR is recommended by WHO for women at substantial risk for HIV.

In Cambodia, FEWs, face a significantly higher risk of HIV infection compared to women in general³⁷, driven by gender-based violence, limited ability to negotiate safe sex, and high levels of stigma and discrimination. The implementation of the DVR for this key population group in Cambodia is crucial as part of a combination HIV prevention strategy.

A recent qualitative study in Cambodia highlights the need for additional female-controlled HIV prevention options, particularly for women who may not have access to or prefer not to use condoms or other prevention options.³⁸ The study found the DVR to be an acceptable option for some women, particularly FEWs, providing a discreet, woman-controlled method that complements existing HIV prevention methods. Venue-based FEWs are more likely to use the DVR due to better sexual health education, while non-venue-based FEWs have limited access to outreach and prevention services, making the DVR a valuable option for them. Although the DVR is unlikely to replace existing methods, it can serve as an additional preventive measure. Affordability, location, and past healthcare experiences significantly influence women's choices, with a preference for NGO/CBO-led delivery due to trust and positive experiences. Ensuring privacy, confidentiality, and comfort at service venues is crucial for successful implementation. Existing health infrastructure, particularly oral PrEP channels, can support DVR provision, but adjustments such as ensuring privacy, trained health care providers and proper medical facilities are necessary.

The study recommended a demonstration project, targeting both venue-based and non-venue-based FEWs in high-risk urban centers, to gather data for scaling up.

Before full implementation, a phased approach is necessary to understand acceptability, barriers, and enablers, considering the values and preferences of key populations, by enabling the collection of real-life data on demand, uptake, and other critical factors, informing the broader rollout of the DVR. It will also provide an opportunity to identify and address service delivery challenges, offer adequate training for clinicians and community-based organizations (CBOs) in DVR delivery, and generate demand within the community. These steps are essential for the successful implementation of the DVR.

By expanding the range of HIV prevention tools available, including the DVR, Cambodia can better meet the diverse HIV prevention needs of FEWs, ultimately contributing to the goal of eliminating new HIV infection among this population.

4. GOAL AND OBJECTIVES

The overall goal of the phased DVR implementation in Cambodia is to establish a comprehensive framework for the effective integration and evaluation of the DVR within existing HIV prevention services. The insights gained from early implementation in the first 12 months will inform decisions on scaling up the DVR program for a broader roll-out.

Objectives for the first phase implementation:

- 1. To provide initial guidance for DVR-PrEP introduction as part of combination HIV prevention services
- 2. To assess the real-life DVR-PrEP *demand*, *uptake* (including barriers to uptake) and *patterns of use* (including switching between prevention products and discontinuation of DVR use, with the associated reasons).
- 3. To understand the DVR-PrEP service delivery enablers, barriers and processes.
- **4.** To leverage lessons learned from DVR-PrEP introduction for developing implementation guidance for scaling up DVR in the country.

5. IMPLEMENTATION

The introduction of the Dapivirine vaginal ring for HIV prevention in Cambodia marks a significant step forward in improving access to HIV prevention for women. This concept note outlines the phased implementation of this innovative intervention, starting with Phase I. This initial phase focuses on establishing the necessary infrastructure and procedures, creating demand for DVR and engaging key stakeholders to ensure a successful and sustainable rollout.

5.1 Starting the DVR PrEP

This section outlines how to initiate women on DVR PrEP.

5.1.1 Identifying clients who can benefit from DVR PrEP: eligibility and suitability

The DVR PrEP may be a suitable and preferred HIV prevention option for many women. PrEP providers should consider a client eligible and suitable for DVR PrEP (behaviourally) if they meet the criteria listed in Box 1 below.

Box 1: DVR PrEP eligibility and suitability

Box 1: ELIGIBLE for the DVR PrEP are:

- Cisgender women who request the DVR PrEP or are identified by a PrEP provider as someone who could benefit from DVR PrEP*
- at least 15 years old (same as for oral PrEP)
- HIV-negative
- not indicated for HIV post-exposure prophylaxis or PEP (no confirmed or suspected HIV exposure in the last 72 hours)
- not suspected of acute HIV infection (AHI) with a probable HIV exposure in the previous 14 days
- not contraindicated to the DVR or not having an allergy or hypersensitivity to any ingredient in the DVR

Some women do not meet the eligibility requirements and should not be provided PrEP DVR. The reasons are provided in Box 2 below.

^{*} Suitable for the DVR PrEP include priority groups of FEWs or other women engaging in transactional sex (free-lance or massage-parlour based) and women with a partner of unknown status or living with HIV with detectable VL

Box 2: When the DVR PrEP should NOT be provided

The DVR PrEP should NOT be provided to women with:

- Unknown HIV status or living with HIV
- Symptoms of AHI (see Box 4)
- Potential exposure to HIV within the past 72 hours (in need for PEP)
- Having allergy or hypersensitivity to the active substance or other substances listed on the product info sheet.

People requesting PrEP and/or the DVR - even if they do not disclose to the provider details about their potential risk of HIV transmission - are likely to be at substantial risk³⁹⁻⁴², and to have made a choice to use the DVR based on their personal circumstances, ongoing HIV risk and prevention preferences.

A sexual history, although not required, can help identify FEWs who could benefit from PrEP, specifically DVR PrEP, among women who did not specifically come to the service for PrEP. Providers should be particularly aware that women could benefit from the DVR most if they disclose:

- inconsistent condom use or anticipating that condoms may not be used consistently
- a recent vaginal STI (identified by laboratory testing, self-report or syndromic STI screening)
- recent PEP use for a sexual exposure (one or more times in the last 12 months)
- a sexual partner(s) living with HIV who is not undetectable on ART.

5.1.2 Required procedures

Same day initiation of DVR is preferred as it may increase the uptake and minimize drop-outs.⁴³⁻

In some cases, delaying the DVR insertion may be necessary. This can include where the woman is eligible for HIV post-exposure prophylaxis (PEP) or AHI is suspected. Alternatively, women not previously familiar with the DVR and PrEP may want additional time to decide what HIV prevention option they want to use, and, if it is PrEP, then which PrEP product.

a. Testing for HIV, assessing for PEP, AHI, contraindications

PrEP providers require only a negative result of an HIV test prior to inserting the DVR. ¹³ Results of other tests conducted at the initiation visit are not required for DVR initiation (see Table 2 below). If these results come later, it is a good idea to confirm that the client can be contacted if necessary (for example, via telephone, email or SMS) for appropriate actions.

HIV testing to rule out HIV infection: HIV testing should be conducted according to the National Consolidated Guidelines on HIV Testing Services in Cambodia. ⁴⁶ See Appendix 1 for the national testing algorithm.

A non-reactive result for the first test in the national algorithm is sufficient to start the DVR PrEP. Women with indeterminate HIV test should be evaluated for early HIV infection and started on DVR (or any PrEP option) only upon receiving an HIV negative confirmatory test result.

Assessing for AHI: Providers should take an appropriate symptom and exposure history to assess for AHI. AHI is often symptomatic, with patients often reporting one or more of the symptoms such as fever, skin rash, sore throat aches and pains, swollen glands and mouth sores. However, these symptoms are not specific to AHI and most individuals will have an infection other than HIV.⁴⁷ For this reason, PrEP providers should also assess the client for possible recent exposures to HIV (for example, sex without condoms) within 14 days prior to onset of symptoms.

Given that AHI is rare and that there is low systemic exposure to dapivirine while using the ring, the risk of HIV drug resistance and delayed diagnosis is likely to be low.⁴⁸ The DVR can be offered to women who have HIV-negative test results with suspected AHI, but the provider should schedule the next follow-up visit in one month and perform follow-up HIV testing. This is generally sufficient to detect seroconversion. The provider should emphasize the importance of attending this follow-up visit.

Assessing for PEP: Women assessed for DVR may have had an exposure to HIV within the previous 72 hours (for example, condomless sex). Providers should follow the National Guidelines for Post-Exposure Prophylaxis after Non-occupational and Occupational Exposure to HIV, to assess the likelihood of exposure and determine next steps.⁴⁹

Prep providers should also discuss whether a woman who is on Pep may benefit from Prep (including the DVR and other HIV prevention options) after completing the course of Pep, for transitioning from Pep to Prep. Women can start DVR or oral Prep without a gap, immediately after completing a 28-day Pep regimen if they have a negative HIV test result and do not have any contraindications to the Prep product chosen. Immediate transition is preferable if there is repeated or ongoing exposure to HIV. Women who consent to transitioning from Pep to DVR, can be managed the same as any other women on DVR. (Note: DVR should be removed during Pep.)

b. Assessing for contraindications

Providers must assess women for DVR contraindications, including allergy or hypersensitivity to any active ingredient or other substance listed in the product information sheet. There are no systemic drug-to-drug contraindications. DVR is not advisable for a woman with vaginal trauma, severe acute ulcerative STI, or a woman who uses another intravaginal device (e.g., a contraceptive ring, diaphragm or vaginal cap). For the latter group (women using other intravaginal devices), please see advice in the next section. For advice on the acute ulcerative STIs and DVR use, see section <u>5.1.3.a</u>, STI testing and management. A woman may decide on her preferred product during the visit, so this assessment for DVR contraindications may take place before, during or after other counselling.

c. Providing information on PrEP choices and counselling in DVR use

Because PrEP awareness is lower among FEWs than among other key populations², PrEP literacy should be boosted and education about DVR should be provided to all women, even those proactively requesting PrEP.

Education about PrEP choices should start with the discussion of sexual partners and practices, use of and preferences for prevention, STIs and sexual health concerns and goals. These types of questions should not be used to ration PrEP or exclude women from PrEP services, but instead to help women make informed choices about HIV prevention. Providing details of past or current sexual behaviour or drug use is not required to access PrEP and DVR.

Providing information on PrEP choices: Providers/counsellors should adapt their counselling approach to a woman's individual preferences and needs. Someone who is considering PrEP, including DVR, for the first time may require a more in-depth discussion than someone who has used PrEP previously., the discussion should be positive, focusing on achieving woman's goals for health, well-being and HIV protection.⁵⁰

Women should be informed about all available PrEP products and other HIV prevention options and empowered to make an informed decision. Offering a range of products has the potential to improve uptake, persistence and effective PrEP use as users can choose the method that suits their needs, preferences and lifestyles.³⁶

The information provided should include the potential benefits and limitations of the different PrEP products available, including effectiveness, how the products are used and potential side-effects. See Appendix 2 for the summary of information about the available PrEP products.

When selecting an HIV prevention method, discuss about their risk and consider their vulnerability to HIV, her main partner's involvement, frequency and patterns of sex, access to prevention methods, her desire for concurrent prevention of STIs and/or pregnancy, product effectiveness and side-effects, and also her personal commitment and preference for mode of use. Clients should know that PrEP including DVR is not for life and that they can switch between products. More details on the points for discussion are provided in Appendix 3.

Counseling in DVR use should be adapted to the individual needs and concerns of each woman and cover the following issues and services:

- **Follow-up during the DVR use**, including importance of regular HIV and STI testing (book a follow-up visit at a mutually convenient time and consider differentiated service delivery (DSD) options that might support the woman to stay engaged with the service.
- Strategies for effective use of DVR (product adherence and persistence)
- **Stopping and restarting the DVR use:** Women should be informed that as soon as the DVR is removed, there is no residual protection, and they should use *other available* prevention options. *Women* who stop and then decide to reinitiate *DVR use* should go through the same initiation procedures as outlined above.
- Side-effects and their management: Side-effects of the DVR are usually mild. Up to 1 in 10 women may experience urinary tract infections, inflammation of the vagina, vulva or cervix, vaginal discharge, vaginal or vulvar itching, and/or pelvic or lower abdominal pain (please refer to the product information leaflet for further information on side-effects). These side-effects are uncommon and usually occur in the first month of use. They can be managed symptomatically and will usually resolve by themselves without the need to remove the ring. Clients should contact the provider if these symptoms are severe or if they become concerned.
- **Condom use:** Both male (external) and female (internal) condoms, as well as water-based lubricants, can be used with the DVR, and their use should be encouraged. Condoms should be encouraged because the DVR does not protect from STIs and pregnancy, and for women who have anal sex, it is not protective for HIV acquisition during anal sex.
- **STIs and pregnancy:** Stress that the DVR does not protect against STI and pregnancy therefore consistent and correct condom use (male or female) and the use of reliable contraceptive methods are recommended.

If a woman has an STI at the time of initiation, it should be treated according to the last updated National Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections Case Management.⁵¹ If only mild symptoms are present, DVR can be inserted. If there is severe ulceration, pain or discharge, it is recommended to delay providing the DVR until symptoms

resolve, and a woman should be advised to use alternative HIV prevention methods. If an STI is diagnosed while the DVR is inserted, it can be treated without the DVR removal.¹³

• Switching between PrEP products: At the time of DVR implementation, injectable CAB-LA is most likely to become available as well. This gives women an opportunity to choose from and switch between three available PrEP products (oral PrEP, DVR and CAB-LA). This may happen when women's needs or preferences change. It is important that PrEP providers continue to ensure that women are aware of all PrEP options available; and support clients to choose the one that best fits their needs.

PrEP providers should use their best clinical judgement to support women to switch between PrEP products safely. There may be simultaneous use of different PrEP products as women switch between them, particularly to cover the start-up or (tail) periods and ensure no gap in protection. If switching to the DVR from oral PrEP, the DVR should be inserted on the last day that oral PrEP is taken. If switching to the oral PrEP from the DVR, the DVR should be continued for the first 7 days after starting oral PrEP.

While no serious concerns are anticipated, there are limited data on the safety of using more than one PrEP product at a time. There is no evidence to suggest that using multiple PrEP products at the same time results in any advantage in terms of reduced risk of HIV acquisition (beyond the advantages of each PrEP product individually).⁵²

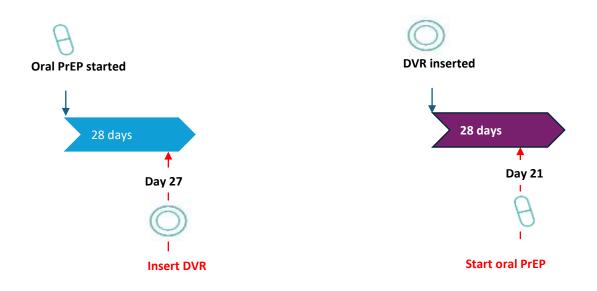
PrEP providers should support women in switching between products safely. The diagram in Bos 3 shows how and when to switch between PrEP products.

<u>Switching from oral PrEP to DVR</u>: Dapivirine reaches protective levels in vagina in 24 hours after the DVR is placed in vagina.⁵³ Therefore, the DVR should be inserted on the last day that oral PrEP is taken.

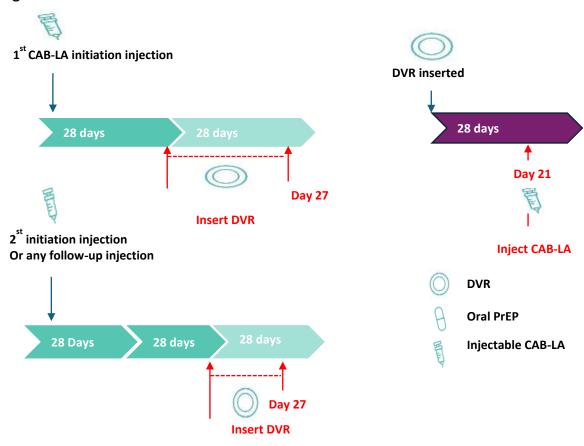
<u>Switching from CAB-LA to DVR</u>: The first injection of CAB-LA is followed by the second injection one month later.⁵⁴ The third and subsequent injections are given every two months. The levels of cabotegravir gradually decline after the respective follow-up injection is missed ("tail period"). If one month or more elapsed since the missed injection date, clients should be restarted on PrEP. If the client intends to switch from CAB-LA to DVR, this can be done during that month but not in its last 24 hours (which are needed for dapivirine to reach protective levels.

<u>Switching from DVR to oral PrEP or CAB-LA</u>: because both TDV/FTC and cabotegravir take 7 days to reach the desired levels of HIV protection^{54,55}, the client should start taking oral PrEP or receive a CAB-LA injection 7 days before the DVR is removed.

Switching from oral PrEP to DVR or from DVR to oral PrEP



Switching from CAB-LA to DVR or from DVR to CAB-LA



- *Intermittent DVR use* is not recommended. The DVR is designed to be used continuously to get optimal protection. *The* local levels of dapivirine drop quickly after the DVR is removed.
- *Cleaning the DVR:* It is not necessary to clean or remove the DVR during or after menses or sex. STIs can be diagnosed and treated without removing the DVR. ⁵⁶
- If the DVR comes out or is removed in a clean place (such as in a bed or in clothes) it should be immediately re-inserted after rinsing in clean, cool water. If this occurred in a place that is not clean, a new DVR should be inserted immediately or as soon as possible. Emphasize the importance of not removing the DVR, but if it is removed and re-inserted within the 28 days, advise condom use or abstinence for 24 hours after the DVR was re-inserted.
- other services (as appropriate), including prevention and testing for STIs, sexual and reproductive health, testing for HBV and HCV and linkage to care, mental health, and sexual and interpersonal violence (as appropriate).
- *Use of the DVR during menstruation:* The DVR should be kept in the vagina at all times, (including during menstruation), until it is replaced with a new one after 1 month. Menstrual blood may discolor the DVR but this does not affect the effectiveness. Clients should be instructed that there is no need to remove the DVR during menses. While there is some evidence that menstruation and concurrent use of tampons with DVR may result in a decrease of dapivirine levels, the clinical significance of this is not clear.⁵³
- *Use of other vaginal products*, such as contraceptive vaginal rings and menstrual cups: explain that these cannot be used with the DVR.⁵⁷ It is safe to use the DVR with tampons during menstruation, but women should be informed there may be a small risk of accidentally removing the DVR when removing a tampon. Vaginal cleaning practices, such as, douching are not advised as a healthy vagina is self-cleaning and such practices may dry out the vagina for sex and/or reduce how well the DVR works.

Healthcare providers are likely to receive many questions from women about the DVR. Please see Appendix 4 for a resource material for clinicians covering Frequently Asked Questions. Further information about PrEP counselling (including the DVR) can be found in the WHO Implementation Tool for pre-exposure prophylaxis (PrEP) of HIV infection, Module 3, Counselling. Counselling.

d. Providing the DVR

At the initial visit, the DVR can be inserted by a clinician as per client preference. However, please explain to the woman how to use the DVR, show the device and check if she understands the procedure; ask if she is happy to try removing and inserting the DVR by herself.

Confidence in removing and self-inserting the DVR may take time to develop, but, after the primary DVR insertion, clinicians should pay attention to women's preferences and support their willingness to self-insert and remove the DVR. The ultimate goal is that the woman can do it herself (otherwise she would have to return to the clinic monthly).

Instructions for DVR self-insertion and removal are the same as for clinicians, except for a woman should be lying down when provider inserts or removes the DVR, while she can take different positions when doing it by herself (see Appendix 5 for instructions).

The DVR should only be inserted to past the introitus. After the insertion, ask the woman if she can feel the DVR, and if so, use an index finger to push the DVR further.

The procedure should be conducted respectfully in a designated, comfortable and confidential, clinic room.

At the DVR initiation visit, the first follow-up should be scheduled in one month.

Rates of stopping the DVR are likely to be higher in the month after starting it.^{47,60} Therefore, clinicians should stress the importance of correct DVR use and timely attendance of the follow-up visits.

5.1.3 Recommended additional procedures

Please note that only the results of an HIV test are needed to start PrEP. Waiting for other tests should not delay starting DVR as the results can be provided later.

The additional services offered should be tailored to the needs and preferences of the DVR users.

a. STI testing and management

The DVR initiation presents an opportunity to screen FEWs for STIs, but STI testing is not a prerequisite to start DVR or other PrEP. WHO recommends expanding access to etiological diagnosis of STIs for sex workers, as well as offering periodic screening for asymptomatic STIs.

Having an STI is not a contraindication for DVR initiation, unless it is a severe ulcerative STI.

If detected, STIs should be treated as per the last updated National Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections Case Management.⁵¹ If there is severe ulceration, pain or discharge, delay providing the DVR until symptom resolution, and advise to use alternative HIV prevention methods during that time.¹³

Due to a lack of data, concurrent use of the DVR and vaginally administered antimicrobial products, including vaginal metronidazole or clindamycin, should be avoided.¹³ Concurrent use of vaginally administered clotrimazole and the DVR has been reported to be safe and well tolerated⁶¹, but data remain limited, and concurrent use should be undertaken with caution. Co-administration of vaginally administered miconazole with the DVR has been studied in one trial⁶² and data are limited. Additional HIV prevention options, such as condoms, should be offered during co-administration. Consider if there are alternatives available for treatment of candida. For testing, diagnosis and treatment of STI, clinicians should follow the last updated National Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections Case Management.⁵¹ Syphilis testing can be conducted using the approved Alere HIV/Syphilis Dual test.

b. Testing for Hepatitis B (HBV) and C (HCV)

HBV and HCV testing once (at initiation or within the first 3 months of initiation) is strongly encouraged, but these are additional services which are not required to start the DVR (or other PrEP).

HBV or HCV infection is not a contraindication for oral PrEP or the DVR.

If positive for HBV or HCV, refer for further assessment and treatment respectively.

Women, who are taking tenofovir for the treatment of chronic HBV infection, would be better candidates for oral tenofovir-based PrEP than DVR.

WHO suggests that women attending PrEP services, could be a possible group for HBV catch-up vaccination, depending on the local HBV epidemiology and available resources. Therefore, if negative, discuss and refer for HBV-vaccination.

For services related to HBV and HCV, clinicians should follow Guideline of Clinical Management for Viral Hepatitis B⁶³ and Guideline of Clinical Management for Viral Hepatitis C.⁶⁴

c. Contraceptive services and pregnancy testing

Note that the DVR does not protect against pregnancy; therefore, consistent and correct condom use (male or female) and the use of reliable contraceptive methods are recommended. For management of DVR and concurrent hormonal contraception, see section 5.5.3.

If pregnancy is suspected, recommend testing and linkage to antenatal care in due time, refer if necessary. For use of DVR during pregnancy and breastfeeding see section 5.5.4.

d. Other services

Prevention commodities, including condoms (and lubes), should be offered to all FEWs at all visits.

GBV, including intimate partner violence (IPV): If indicated, assess and provide services or referral to appropriate providers.

Mental health, substance use disorders, other health issues: If warranted, this is also a good time to assess and provide services or referral for mental health and substance use disorders, as well as prevention, assessment and treatment of cervical cancer and screening and treatment of noncommunicable diseases.

5.2 DVR follow-up

This section outlines the follow-up for women using the DVR.

Follow-up visits for the DVR are typically conducted every 3 months with an additional visit at month 1.¹⁴ Follow-up visit at month 1 is an important to test for HIV and replace the DVR, but it is also an opportunity to provide support and strengthen women's confidence in DVR use, which may minimise the DVR drop-outs. As women become more confident in DVR use, the follow-up schedule can be adapted to the client's needs and preferences.⁶⁵ For example, a woman on DVR may be travelling for an extended period of time and may not be able to come at the suggested appointment time. On the other hand, some women, particularly in early stages on DVR use, may benefit from frequent visits, and indeed may request more frequent appointments (for example to change the DVR every 28 days).

At each follow-up visit, before dispensing the DVR, a medical history taking and assessment are recommended, to confirm that the DVR remains a suitable PrEP option.

All follow-up visits should include an appropriate package of services, a check-in with the client and the provision of DVR(s).

The additional services offered should be tailored to the needs and preferences of the DVR users.

5.2.1 Required procedures

a. Testing for HIV, assessment for AHI and PEP

Repeat HIV testing one months after the DVR initiation, at 3 and 6 months after initiation and every 3 months thereafter, prior to dispensing the new DVR.³² HIV testing should be conducted according to the National Consolidated Guidelines on HIV Testing Services in Cambodia⁴⁶ using the national testing algorithm shown in <u>Appendix 1</u>, Testing strategy for HIV diagnosis (National HIV testing algorithm).

HIV self-testing (HIVST) is approved by the national HIV testing guidelines for testing of key populations, including index testing.⁴⁶ It is recommended by WHO for starting, restarting or during DVR use.¹³ Discussion is ongoing about the use of HIVST in clinical or community settings (assisted or unassisted). It can replace provider-administered testing to give reassurance and confidence, and/or support effective use.⁶⁵ FEWs may prefer HIVST for convenience, privacy and

self-managed prevention. Therefore, it can be an important tool to improve FEW's access to DVR. The use of HIVST should be a woman's choice.

If AHI is suspected in the context of ineffective DVR use, providers should take a similar approach to the initial visit.

Effective DVR users will rarely require PEP. However, if DVR is not used as directed or is removed, there can be a risk of acquiring HIV. Table 1 includes information from the updated WHO PEP guidelines 2024⁶⁶ which can assist clinicians in deciding whether to initiate PEP.

Table 1: Decision-making about PEP for women initiated on DVR who did not use any other prevention method/s (such as condom or another PrEP option).

DVR placement	Route of exposure	Consider PEP?
DVR in place	Vaginal sex 24 hours or more after insertion	No, continue using the DVR
	Vaginal sex less than 24 hours after insertion	Yes
	Exposures other than vaginal sex, that is, anal sex or parenteral exposure, at any time	Yes
DVR not in place	Vaginal sex after removal	Yes

b. Assessing for side-effects

The DVR-related side effects (see Box 4) are uncommon. If they do occur, it is usually in the first month of the DVR use.

Clinicians should counsel women on possible side-effects and advise to contact them if side-effects become severe or if women become concerned. Refer to the product information leaflet for further information on side-effects.

Box 4: Side-effects of the DVR

Side-effects of the DVR (usually mild and experienced by up to 1 in 10 women):

- urinary tract infections
- inflammation of the vagina, vulva or cervix
- vaginal discharge
- vaginal or vulvar itching
- pelvic or lower abdominal pain.

For the management of side-effects see section 5.5.2.

c. Check-in discussion

Follow-up visits are an important opportunity to check-in about women's sexual health goals and concerns, as well as the DVR-specific experiences including side-effects and effective use. Women should have the opportunity to check-in with a provider, to raise any questions or concerns they might have.

In early stages of the DVR use, a check-in phone call by counsellors in between visits may be helpful to ensure women use the DVR effectively. Such a call may address any problems or questions in a timely manner.

Effective DVR use: At each visit, assess effective DVR use by discussing possible HIV exposures (including through vaginal and anal sex), DVR use (insertion or removal) and use of other HIV prevention strategies. If ineffective DVR use is identified or condomless anal sex is disclosed/reported, women should be assessed for PEP and AHI. If a woman reports challenges with effective DVR use, help her to identify a range of strategies to make effective use easier. Some options could include linking DVR replacement to menstruation for women with regular cycles, support options such as social media and support groups.

The choice of products and their availability may change over time. Therefore, information about all available PrEP options should be part of an ongoing conversation (even among FEWs who are already on DVR) should they wish to switch, as well as the discussion of alternative or additional prevention methods (see section 5.1.2.c, Providing information on PrEP choices and counselling in DVR use.) Remember that the best HIV prevention option for a woman is one that she will use effectively.

Frequency of follow-up: PrEP providers should be aware that some women, especially when they become experienced with DVR, may prefer less frequent contact and/or more streamlined visits. **Other discussion topics** may also be covered (see section 5.1.2.c, Providing information on PrEP choices and counselling in DVR use, and Appendix 3, Resource material for clinicians: Frequently Asked Questions, for more details)

Approach to counselling should be adapted to the woman's individual preferences and needs. Like the initial visit, the check-in discussion should be non-judgmental and positive, to encourage clients to discuss successes and challenges in using the DVR, intention to continue and/or switch PrEP products, and to ask new questions as needed.

d. Providing the DVR

Clinicians should pay attention to women's preferences and support their willingness to self-insert and remove the DVR.

Consideration should be given to multimonth dispensing (MMD) and providing an extra ring in case the next scheduled follow-up visit is expected to be delayed for any reason. Providers should also be aware that some FEWs may prefer to come to the clinic for every DVR change, because of the lack of confidence in self-insertion or due to difficulties storing additional rings.

When dispensing additional devices for self-replacement, inform a woman about the proper DVR storage and disposal (see Box 5 below).

Box 5: DVR storage and disposal

Shelf life	5 years	
	See expiry date on the packaging.	
Special precautions for storage	No special temperature storage conditions.	
	Store in the original package in order to protect from light.	
Packaging	Each DVR is packaged into a laminated (PET-	
	Alu/Adhesive/PP), square, heatsealed pouch.	
	Pack-sizes: one pouch or three pouches.	
Disposal	Place in an empty pouch or wrap in tissue or toilet paper	
	and dispose in the refuse bin, out of reach of children. Do	
	not dispose in the toilet.	

Source: European Medicines Agency (EMA). Product information: Dapivirine vaginal ring. Annex 1: summary of product characteristics.⁶⁷

5.2.2 Recommended procedures

Services recommended during follow-up visits include:

a. STI testing and management

Assessing or self-assessment of STI signs and symptoms at every visit is strongly encouraged, but not required to replace the DVR.¹³

Having an STI is not a contraindication for DVR initiation. If detected, STIs should be treated.⁵¹ STI management is similar to that at the initiation (see section <u>5.1.3.a</u>).

Regular syphilis testing can be conducted as part of dual HIV/syphilis testing. Periodic STI testing for gonorrhoea and chlamydia is optional but strongly encouraged. Follow-up testing at 3, 6 months and every 6 months thereafter is suggested. It may be varied according to women's needs, history of STIs and condom use.

For STI testing, treatment and/or referrals, clinicians should follow the National Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections Case Management.⁵¹

Providers should strongly encourage FEWs to use condoms for STI prevention.

Per WHO guidelines¹³, partner services, including provider-assisted referral and expedited partner therapy (EPT) of sexual partners is critical to avoid reinfection and to break the chain of transmission. If appropriate, consider EPT for gonorrhoea and chlamydia.

b. Testing for Hepatitis B (HBV) and C (HCV)

HBV testing once, at month 3 if not conducted at the DVR initiation, is strongly encouraged. HCV testing once, at month 3 if not conducted at the DVR initiation, is recommended. For services related to HBV and HCV, clinicians should follow Guideline of Clinical Management for HBV 63 and Guideline of Clinical Management for HCV. 64

c. Contraceptive services and pregnancy testing

At each visit, assess reproductive intentions and offer or refer for pregnancy testing, if appropriate. Offer reliable contraceptive options.

d. Other optional services

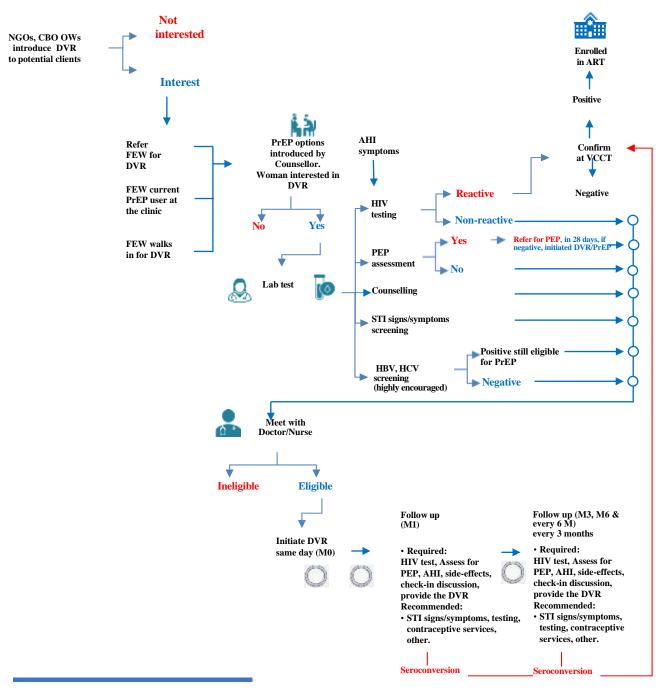
At any point during the DVR follow-up, any of the following issues may be raised: GBV, including IPV: If indicated, assess and provide services or referral to appropriate providers. Mental health, substance use disorders, and other health issues: If warranted, this is also a good time to assess and provide services or referral for mental health and substance use disorders, as well as screening and treatment of noncommunicable diseases.

5.3 Summary of procedures for starting the DVR and follow-up

See Figure 1 for DVR delivery diagram.

Required and recommended procedures are summarised in Table 2.

Figure 1: DVR delivery diagram



FEW – female entertainment worker CBO – community-based organisation OW – outreach worker NGO – non-governmental organisation HTS – health testing site SRH – sexual and reproductive health Exp. femily, alamine.

FP family planning DVR – dapivirine vaginal ring STI – sexually transmitted infection

ART – antierroviral treatment
VCCT - Voluntary Confidential Counseling and Testing
PrEP – pre-exposure prophylaxis
HBV – hepatitis B virus

HCV - hepatitis C virus

Table 2: Required and recommended procedures at DVR initiation and follow-up.

		Month	า				
Assessment	Rationale	O Initiation visit	1	3	6	9	12
Required procedures	5						
Provide information on PrEP options and DVR/ "check in" at follow-up visits	At the initiation visit, provide information about PrEP options, so that a women can make an informed choice. Provide counselling and discuss DVR use, condoms, STI, pregnancy. A regular check-in provides an opportunity to assess side- effects and effective use; discuss whether users want to continue the DVR (or switch products); discuss successes and challenges in using the DVR; and for clients to ask new questions.	х	х	х	Х	Х	х
HIV test	A negative HIV test result is required prior to initiation and regularly while using the DVR.	Х	Х	Х	Х	Х	Х
Assess for PEP	Provide PEP if the woman had a potential exposure within 72 hours ^C prior to starting PrEP, and if she reports ineffective DVR use within the previous 72 hours. Women can transition back from PEP to PrEP.	Х	х	Х	х	Х	х
Assess for signs and symptoms of AHI	The likelihood of AHI should be assessed for all women starting the DVR and those reporting ineffective use of DVR, taking into consideration both the signs and symptoms of AHI, risk of recent HIV exposure and any PrEP/condom use.	х	х	Х	Х	Х	Х
Assess for contraindications	If a woman has a contraindication to the DVR, including allergy or hypersensitivity, a different PrEP product or HIV prevention option should be offered.	х					
Provide the DVR	MMD ^{II} and self-insertion of DVR should be offered if a woman is comfortable and confident to do it on her own except in exceptional circumstances or where single-month dispensing is preferred by the user. Ensure the user has enough DVR units to cover them until the next visit.	X	х	х	Х	Х	х
Additional, recon	nmended procedures						
STI testing for syphilis, gonorrhoea, and chlamydia	It may be varied according to women's needs, history of STIs and condom use. Follow the latest National Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections Case Management. ⁵¹	х	х	Х	Х		X Every 6 month s
Screening for STI signs and symptoms	Assessment or self-assessing	Х	Х	Х	Х	Х	Х
Hepatitis B testing	Testing for HBV is optional but highly encouraged. If negative, discuss and encourage for vaccination. Follow Guideline of Clinical Management for HBV ⁶³	x (once within first3 month s)					
Hepatitis C testing	Testing for HCV is optional but highly encouraged. Follow Guideline of Clinical Management for HCV. ⁶⁴	x (once within					

-

II MMO- multi-month dispensing

		first 3 month s)					
Contraceptive services and pregnancy	Encourage condom use. Assess reproductive intentions and offer or refer for pregnancy testing, if appropriate. Offer reliable contraceptive options.	Х	Х	Х	Х	Х	Х
Other services	GBV, including IPV: If indicated, assess and provide services or referral to appropriate providers. Mental health, substance use disorders, other health issues: If warranted, assess and provide services or referral to appropriate providers; if issues raised – assess or refer for assessment and treatment of noncommunicable diseases.	Х	х	х	х	х	Х

5.4 Special considerations for specific situations

5.4.1 Management of seroconversion

HIV seroconversion can occur after starting the DVR. In most cases, this is because of a preexisting HIV infection that was undetected when starting the DVR⁵⁶, or HIV was acquired after starting PrEP due to ineffective use.

After an HIV diagnosis is made, the DVR should be removed, and women can be offered ART using first line regimens according to the National HIV clinical management guidelines for adults and adolescents in Cambodia.

5.4.2 Management of side-effects

Side-effects can be managed symptomatically and will usually resolve by themselves without the need to remove or stop the ring.

5.4.3 Management of concurrent contraception use

As there is limited systemic drug absorption from the DVR, there is no expected clinically important interaction with hormonal contraceptives, and no effect on contraceptive efficacy has been reported.⁶⁸ See comment regarding contraceptive ring in section <u>5.1.2.c</u>, Providing information on PrEP choices and counselling in DVR use.

5.4.4 DVR during pregnancy and breastfeeding

DVR has a favourable safety profile during pregnancy and breastfeeding.²⁶⁻²⁸ Therefore, during these periods, the DVR use is not contraindicated.¹³ But the DVR does not offer prevention of pregnancy.

6. MODELS OF SERVICE DELIVERY, ROLES AND RESPONSIBILITIES OF KEY PARTNERS FOR PHASED IMPLEMENTATION

6.1 Models of service delivery

The DVR, as well as oral PrEP, may be delivered via different models of service provision including health facility-based and community-based service approaches.

Differentiated service delivery (DSD) approaches can also make PrEP and DVR services acceptable and accessible, for instance by providing community- based services, and by involving communities and peers in service delivery.

DSD is person- and community-centered and adapted to the needs and preferences of the users. It may make PrEP services more acceptable and accessible and support PrEP uptake, persistence and effective use. It may also support more efficient and cost-effective use of health care resources. The key building blocks of DSD - service location ("where"), frequency ("when"), package ("what"), and provider ("who") may differ for PrEP initiation, continuation and re-initiation, as well as for various PrEP products. Examples of DSD adaptations include PrEP delivery that is community- based ("where"), multi-month dispensing (MMD) to reduce follow-up visits ("when"), integrated services to address clients' diverse health needs ("what"), and task sharing with various health worker cadres and lay providers, including key population- and community-led services ("who"). HIV self-testing can support many of these differentiated PrEP service delivery models and allow fewer in-person visits. 69,70

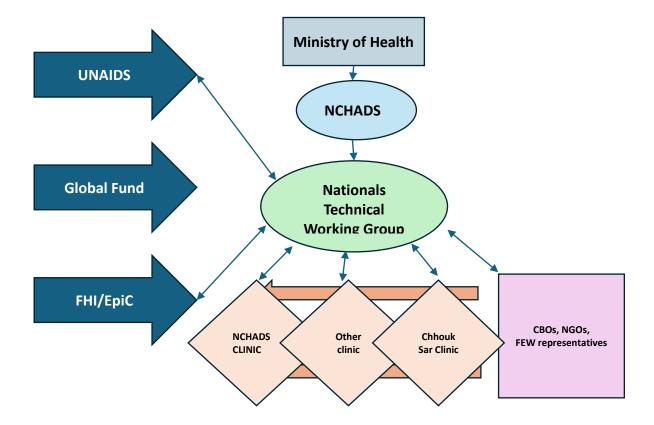
6.2 NCHADS and Boosted Continuum of Prevention to Care and Treatment TWG

The National Center for HIV/AIDS, Dermatology and STD (NCHADS) and technical advisory staff

- Technical team of NCHADS will oversee the DVR implementation at all stages of implementation.
- The NCHADS technical team will provide training to both healthcare providers and community demand creators before starting DVR delivery.
- Data Management unit will coordinate and monitor the timely submission of recording and reporting forms as well as lead a review of DVR data monthly.
- Logistics Management unit will coordinate and assist clinics in requesting DVR supply, test kits and other necessary equipment and commodities.

The DVR implementation will be conducted under the guidance of the Boosted Continuum of Prevention to Care and Treatment (BCoPCT) Technical Working Group, led by NCHADS. This group will include representatives from health care organizations providing PrEP services, community-based and non-governmental organizations (CBOs and NGOs), and technical partners organizations (supporting DVR implementation in Cambodia, such as UNAIDS and Family Health International's EpiC Project (see Figure 2). These entities are stakeholders in DVR implementation in Cambodia.

Figure 2: Leadership, governance and coordination



The TWG will:

- Oversee the overall introduction of DVR into the package of other HIV biomedical prevention strategies currently available in Cambodia (such as Treatment as Prevention and oral PrEP) or those that will become available (such as injectable CAB-LA) during the phased DVR implementation.
- Develop the DVR implementation plan and the demand generation plan for DVR implementation and play a guiding role in the monitoring and evaluation of DVR implementation.
- Assist the NCHADS in designing dissemination plans and provide direct support, as possible, for community updates on the progress and findings of DVR implementation, aligned with community sensitization efforts.
- Meet quarterly to monitor the DVR implementation progress and the relevant input from stakeholders, sites and end-user communities.
- Guide the monitoring of HIV and STI diagnoses, and safety indicators associated with DVR use among end-users.
- Ensure that stakeholder and end-user representation is considered prior to and throughout the phased DVR implementation and in the development/update of the national PrEP implementation guidelines.
- At the end of the first 12 months of implementation, the TWG will review the main results (as per specific objectives), provide input on synthesis and interpretation, and report to the NCHADS regarding the alignment of the national PrEP guidance and lessons learned from the first 12 months of DVR implementation to inform further DVR roll-out decisions and planning.

6.3 Non-governmental (NGOs) and Community-based organisations (CBOs)

NGOs and CBOs which provide outreach physically and virtually:

- Promote and generate interest in DVR among FEWs
- Provide information on DVR to FEWs, discuss its benefits and disadvantages
- Refer FEWs to a clinic providing DVRs.
- Accompany FEWs to DVR initiation and follow-up visits.
- Record the number of women who received from them information, referral or services in relation to DVR.
- Assist clinics in follow up of DVR users lost to follow-up or missing their appointment.

CBOs and NGOs that are currently providing oral PrEP will also step in to provide the DVR. The idea is to increase access to DVR and ease of its follow-up.

6.4 Medical clinics

DVR implementation will start with the health facility-based approach to DVR provision, but CBOs and NGOs may also join in delivering the DVR services. Health facility-based approach refers to PrEP service provided at a clinic. Clients come to this facility on their own (to register or undergo oral PrEP follow-up), could be referred by an outreach worker or identified amongst current PrEP users, who will be informed about all currently available PrEP options.

At the start, DVR will be offered at the NCHADS Clinic and Chhouk Sar Clinic, and at other clinics, including Tuol Kork health center, that may be considered as needed and appropriate.

As main clinical providers of DVR services, clinics will:

- Provide clinical assessment and laboratory examination for client at initiation and follow up visits
- Provide DVR, assist in its insertion
- Provide DVR counselling to interested women at initiation and follow up visits
- Collect relevant information about the DVR-related services and users and enter it into
 the national electronic medical record system. The clinics will be responsible for the
 accuracy and completeness of the information required for the coordination, monitoring
 and evaluation of the DVR implementation.
- Make a quarterly request of the DVR stock by using a standard format

7. COORDINATION, MONITORING AND EVALUATION

7.1 Coordination and technical support

Regular coordination meetings will be set up to review the implementation as well as to address any challenges that may arise during DVR implementation.

At national level,

- Monthly meetings of the NCHADS team (ACU, BCC, STI and DMU), EpiC team, UNAIDS, WHO, KHANA, CWPD and RHAC, to review the DVR data and take any necessary actions to support site implementation.
- Quarterly meeting of the HIV prevention TWG to review the implementation progress and safety indicators, identify challenges and solutions, and provide recommendations to CBOs who implement demand creation activities and healthcare providers who deliver DVR services to improve the DVR program.
- Regular 6-monthly visits to clinics by the TWG/NCHADS officials, to review and discuss implementation issues at the clinical level.

At the organisational level (clinics, NGOs, CBOs),

 Regular meetings of the DVR implementing team/s to monitor DVR-related processes and service provision, data collection and reporting and incorporate feedback from the TWG.

Joint meetings between clinics and community-based organizations,

- To facilitate open communication between clinics and community-based organizations on DVR services delivery, including demand creation, accessibility, and service delivery
- To ensure comprehensive support and resource sharing, particularly education materials, training programs and logistical support
- To increase trust and engagement between healthcare providers and CBOs, and within the community
- Provide a platform for collaborative problem-solving should any issues or barriers arise during the DVR program implementation and build the long-term sustainability of the DVR program.

UNAIDS and FHI 360/Epic will provide all necessary technical support throughout the phased DVR implementation.

7.2 Monitoring and evaluation

Table 3: DVR program monitoring indicators

Indicator	Indicator definition	Numerator (N) and Denominator (D)
Total DVR recipients	# of women who received DVR at	
	least once during the reporting	
	period	
% women who were	# of women who were dispensed	
retained/continued on	DVR past the follow-up stage out	
DVR, by follow-up	of # women due to receive DVR	
stage (M1, M3, etc)	at this stage.	
DVR, by follow-up	# women due to receive DVR at	
stage (M1, M3, etc)	this stage.	

NCHADS will monitor indicators. The TWG will meet quarterly to review indicator reports. Table 4 shows a pool of indicators that can be used for program evaluation.

Table 4: Optional indicators for the evaluation of the first 12 months of DVR implementation

Indicator	Indicator definition	Numerator (N) and Denominator (D)
Safety	Self-reported side-effects among women continuing on DVR	N: # women who self-reported side- effects, by type D: # women taking DVR
HIV positivity among women on DVR	% women who tested HIV-positive at the DVR follow-up among women who received DVR at least once in the last 12 months and had at least one follow-up HIV test	N: # women who had a positive HIV follow-up test on DVR among women who received DVR at least once in the last 12 months D: # women who received DVR at least once in the last 12 months, and who had at least one DVR follow-up HIV test
Syndromic STI diagnoses among DVR users	% women with syndromic STI diagnosis at follow-up in the last 3, 12 months % of those treated	N: # women receiving a syndromic STI diagnoses at DVR follow-up (by infection) D: # women attending the clinic for DVR follow-up
Demand	% of women who chose the DVR among those who received PrEP in the last 3 months, 12 months	N: # women who initiated DVR; D: # women assessed for PrEP
Uptake	% of eligible women who initiated DVR in the last 3 months, 12 months	N: # eligible women who initiated DVR; D: # women who were newly offered DVR
Switching from oral PrEP to DVR	# switched from oral PrEP to DVR in last 3, 12 months	% women who previously received oral PrEP and switched from oral PrEP to DVR
Switching from DVR to oral PrEP	% switched from DVR to oral PrEP	N: # women chose to switch to oral PrEP at their DVR follow-up visit, by DVR visit; D: number of women attending DVR follow-up, by visit
Self-reported adherence	% women on DVR who report adherence issues, by issue and follow-up visit	N: # women who report a DVR adherence issue at the DVR follow-up visit, by issue and follow-up visit #; D: # women attending follow-up visit
Self-reported condom use	% women reporting consistent condom use, by follow-up visit	N: # women who report consistent condom use at the DVR follow-up visit; D: # women attending a follow-up visit

Considerations should be given (if resources permit) for additional data collection using one or more of the following methods:

- A brief, online, cross-sectional survey of DVR users
- Qualitative interviews of DVR users (e.g., reasons for DVR discontinuation or switches, reasons for DVR failure among those who test HIV positive, etc.)
- Focus group discussions of the DVR users, clinicians and CBO representatives

8. COMMUNITY ENGAGEMENT AND DEMAND CREATION

The primary audience for demand generation is FEWs.

Strategies and approaches to demand generation:

Consultations with end users

- Gather insights into the needs, preferences, concerns of potential DVR users, and their preferred channels for educating the community about DVR. Use this information to tailor the program to better meet the community expectations and to increase the DVR acceptance. Consider consulting with groups who have participated in demand generation for oral PrEP among FEWs.
- Identify and address potential barriers to DVR adoption, such as cultural beliefs, misconceptions, or logistical challenges, and involve DVR users in the design of solutions to the problems.

Community Engagement and Education

- <u>Conduct widespread awareness campaigns</u> to educate women about the PrEP in general including DVR, its benefits, and how it works. Use various media channels, including social media, and community events.
- Train peer educators to share information and personal experiences with the other/potential DVR users, helping to build trust and acceptance within the community.

Healthcare Provider Training

- Provide thorough training for healthcare providers on the DVR, including its insertion, usage, and management of side-effects. This ensures they can confidently recommend and support its use.
- Establish a support system for healthcare providers to address any questions or challenges they encounter, ensuring they remain advocates for the DVR.

Integration with Existing Health Services

- Integrate DVR education and distribution into routine follow-up services for FEWs currently using PrEP, as well as in other health services for FEWs, such as family planning, HIV and STI testing services. This makes it easier for women to learn about and access the DVR.
- Work with existing health programs and initiatives to promote the DVR, leveraging their established networks and trust within the community, for example community-based HIV/STI testing and oral PrEP programs.

Tailored Messaging

- Develop culturally appropriate educational materials that resonate with the FEWs, using community appropriate language and addressing specific cultural beliefs and practices.
- Focus on specific groups of FEWs, such as free-lance and massage-parlour based FEWs, by tailoring messages to their specific needs and concerns.

Partnerships with Civil Society Organizations

- Partner with appropriate civil society organizations (CSOs such as EWNet, WNU, CWPD, RHAC, KHANA) to reach a broader audience. They can help organise community events or use community forums to disseminate information, provide support, and advocate for the DVR within the community.
- Organize joint events and workshops with CSOs to educate and engage the FEWs about the DVR.

Monitoring and Feedback Mechanisms

- Establish mechanisms to collect feedback from DVR users to understand their experiences and address any issues (for example, brief satisfaction survey, qualitative interviews or focus group discussions of DVR users) or explore adaptation of CLM to include satisfaction survey of DVR services.
- Use data collected from monitoring and evaluation activities to make informed adjustments to the demand creation strategies, ensuring they remain effective and relevant.

Advocacy and Policy Support

• Ensure continuing engagement of key stakeholders, including government officials, health authorities, and community leaders, to build support for the DVR program.

Key messages for the demand generation activities and DVR promotion materials

The key messages for demand generation and DVR promotion are primarily aimed at potential users, focusing on increasing their awareness and understanding of the method's benefits. These messages differ from the messages for training providers and educating users during service delivery, which should be more detailed and technical.

It is important that the demand generation activities and DVR promotion materials focus on:

- Safety and benefits for HIV prevention: The introduction of DVR provides women with an additional choice for HIV prevention, with a method that is safe and effective and discreet.
- It is an option for many women for whom other prevention products do not work or are not preferred.
- Ease of Use: Emphasize the convenience of using the DVR (28 days),
- <u>Empowerment</u>: Focus on how the DVR empowers women to take control of their HIV prevention
- <u>Discretion</u>: Emphasize that the DVR is designed to not be detected by partners if inserted correctly

9. CAPACITY BUILDING

Consider the following capacity building activities for the DVR implementation program: At the TWG level,

- Review and upscale, if necessary, data collection and analyses procedures to ensure robust system of monitoring of the DVR implementation indicators and end-user feedback.
- Create a roadmap that outlines milestones for specific objectives of the phased DVR implementation and capacity-building. Regularly review and update this roadmap to ensure continuous improvement.
- Capitalise on the established PrEP partnerships, coordinate the collaboration of partners
 to share resources, such as educational materials, training modules, and logistical
 support.
- Provide ongoing technical assistance to clinics, including troubleshooting, addressing challenges, and implementing quality improvement initiatives.

At the clinical level,

- Comprehensive training sessions for healthcare providers on DVR related services, to ensure they are well-prepared to provide clinical services, as well as support and educate women. This will involve inception training and continuing refreshment training as necessary.
- Ensure that clinics are equipped with the necessary tools and facilities to provide DVR services effectively (e.g., appropriate observation rooms and equipment, demonstration models, adequate storage for DVR supplies, and proper medical equipment for vaginal procedures).
- Supply clinics with educational materials, such as brochures, posters, and digital resources, to support patient education and awareness about DVR.
- Utilize technology for better data management, appointment scheduling, and follow-up tracking to enhance service delivery. Upgrade the sites if necessary.
- Develop and implement a robust monitoring and evaluation framework to track the performance of providers in DVR implementation, including patient outcomes, adherence rates, and service quality (see section 7, Coordination, Monitoring and Evaluation).
- Create channels for receiving feedback from both healthcare providers and clients, to identify areas for improvement and ensure the program meets the needs of FEWs.

At the level of community-based organisations and communities,

- Train community members as peer educators to raise awareness and provide support within FEWs communities.
- Organise workshops and informational sessions in collaboration with local organizations to educate FEWs about the DVR and its benefits.
- Conduct FEW community outreach programs physically and virtually to raise awareness about DVR and its benefits, encouraging women to visit clinics for information and services.

- Select and train FEWs to serve as peer counselors and peer navigators.
- Organise and support FEW peer support groups which can be instrumental in fostering effective DVR use.

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