PLAN 4 RING TOOLKIT

PrEP Ring Pilot Implementation Study Protocol Template

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This is part of the **PLAN 4 RING** TOOLKIT,

a suite of resources and tools designed to support planning for dapivirine ring introduction and scale-up.

The toolkit contents, listed below, can be downloaded at **www.prepwatch.org/plan4ring-toolkit**

PrEP Ring Language Considerations

PLANNING

- Introduction Framework
- Situation Analysis Template
- Guidelines Template
- Rollout Scenarios Analysis Template

DELIVERY

- Service Delivery Channel Analysis Template
- Facility Readiness Assessments
- Healthcare Provider Training Considerations
- Implementation Study Protocol Template

PROMOTION

- Demand Creation Design Guide
- Demand Creation Lessons Learned

Considerations for Monitoring and Evaluation

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PrEP Ring Pilot Implementation Study Protocol Template

Overview and how to use this tool

As new HIV pre-exposure prophylaxis (PrEP) methods become available for use, determining how best to integrate them within the existing health system will be of paramount importance. Implementation studies conducted as part of oral PrEP introduction have revealed opportunities to strengthen health system components, test new approaches to service provision, and improve provider training to optimise oral PrEP delivery and follow-up.

These lessons can inform the introduction of new PrEP methods, such as the dapivirine vaginal ring (also known as the PrEP ring and referred to as "the ring" for the remainder of the document), which may have different intended user groups, and thus may require different approaches to service provision than those currently used for oral PrEP.

This template is designed for policymakers and government technical specialists to use to apply uniform objectives, study design features, and measures across pilot implementation and other operations research studies for ring introduction, in collaboration with investigator teams. These objectives, measures, and design features are proposed across countries to facilitate the generation of a body of evidence to foster regional learning and programme refinement over time and as additional PrEP methods are introduced.

In the following text, draft pilot study guideline sections are provided for adaptation to each context, with yellow-highlighted areas indicating places for modification.

Introduction and rationale

The government of [country name], through the Ministry of Health (MOH) [or other health authority], recognises the great burden that HIV has placed on the lives and wellbeing of [nationality] families over the last four decades. The MOH [or other health authority] strives to ensure HIV prevention measures, testing, and treatment are available to and reach all citizens, including provision of oral PrEP to prevent HIV. As new PrEP methods that have the potential to expand the HIV prevention toolbox become available with sound scientific evidence of their safety and efficacy, the MOH [or other health authority] will consider whether introduction of each method in the public sector is feasible and acceptable.

The ring is a flexible silicone ring inserted into the vagina that slowly releases the antiretroviral drug dapivirine over a one month period of continuous use, after which it is replaced with a new ring. The ring protects against HIV acquisition in women only during exposure from receptive vaginal sex. This method is user-initiated and, when used in combination with other interventions to enhance HIV prevention, may present an acceptable option for clients who cannot or do not wish to take oral PrEP. Discrete choice studies (TRIO, Quatro) have been conducted in Kenya, South Africa, and Zimbabwe to determine the best way to deliver PrEP for women, with participants trying several placebo methods and documenting their preferences. The TRIO study compared oral, injectable, and ring methods and found that while injectables were most preferred, ring continuation rates were high among women willing to try the ring compared to those for other PrEP delivery methods.[1] The Quatro study compared four different vaginal methods, including the ring, and found that initial preference for ring was low but increased with trial duration and product crossover with high ring adherence.[2] **Table 1** summarises evidence regarding ring efficacy and safety from clinical trials and open-label extension studies.

TABLE 1. Summary of dapivirine ring efficacy and safety findings from multi-country trials and open-label extension studies

STUDY & STUDY DESIGN	MAIN SAFETY FINDING(S)	MAIN EFFECTIVENESS FINDING(S)	KEY LIMITATIONS REPORTED BY AUTHORS
Nel *et al.*,[3] The Ring Study; South Africa & Uganda; 1959 women ages 18–45 years			
Placebo-controlled, double-blind randomised controlled trial (RCT) (Phase III)	Serious adverse events were rare but more common in women randomised to ring (2.9% vs. 0.9%), with no detected pattern. Rates of adverse events were similar between groups, and product-related events were rare (0.4% for ring and 0.3% for placebo) and mild. No significant differences were detected in rates of non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance mutation among women with new infections.	Women receiving the ring had a 31% lower incidence of HIV infection (4.1 vs. 6.1 infections/100 person-years [p–y]); there was no significant difference in efficacy for women <21 years compared to those ≥21 years.	Limitations include the lack of standardised criteria for measuring ring use based on dapivirine concentrations.
Baeten *et al.*,[4] ASPIRE trial; Malawi, South Africa, Uganda, & Zimbabwe; 2629 women ages 18–45 years			
Placebo-controlled, double-blind RCT (Phase III)	Rates of serious adverse events, adverse events overall, and NNRTI resistance in women with new HIV seroconversions were similar between study arms.	Overall, women receiving the ring had a 27% lower HIV incidence (3.3 vs. 4.5 infections/100 p-y); women ages >21 years had significantly higher (56%) protection compared to those ≤21 years (27%), correlated to reduced adherence.	Ring use as measured by plasma levels and residual drug in used rings may not have perfectly correlated with use patterns based on variability in both measures.

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TABLE 1. Continued

STUDY & STUDY DESIGN	MAIN SAFETY FINDING(S)	MAIN EFFECTIVENESS FINDING(S)	KEY LIMITATIONS REPORTED BY AUTHORS
Nel *et al.*,[5] DREAM open-label extension (OLE) study; South Africa & Uganda; 941 women who had participated in The Ring Study			
OLE observational cohort	Serious adverse events (2.1%) and product-related adverse events (0.6%) were rare. Serious adverse events were not deemed product-related and adverse events related to product use were mild, such as vaginal itching. NNRTI resistance was detected among 29% of those seroconverting.	18 incident infections (1.8/100 p-y) were detected, with a modelled 62% lower infection rate than the simulated placebo rate.	Lack of a placebo group and the time lag between parent trial and OLE with differences in background HIV incidence rates may have affected placebo estimates. Another limitation is possible selection bias of having only participants who remained HIV-negative in the parent trial, as they were older and had lower rates of sexually transmitted infection.
Baeten *et al.*,[6] HOPE OLE; Malawi, South Africa, Uganda, & Zimbabwe; 1456 women participating in the ASPIRE trial			
OLE observational cohort	22 serious adverse events occurred, with none deemed related to product use. Two adverse events were related to product use (abdominal pain and pelvic pain with ring insertion) and were graded as mild in nature. Seven women seroconverting had NNRTI resistance mutations that differed, suggesting no distinct pattern related to dapivirine.	35 incident infections (2.7/100 p-y) were detected, with a modelled 39% lower infection rate than predicted mean incidence rate of 4.4/100 p-y from parent trial. 89% of returned rings had dapivirine levels reflecting some degree of use and drug release; 77% of participants had evidence of use across each 3-month period. Ring acceptance and use rates in the OLE were higher than in the RCT.	Limitations included lack of a placebo group, quarterly follow-up limiting precision of estimates, low inclusion of women ages 18–21 years, and greater participant experience and comfort with ring use or lack of widely available oral PrEP as an alternative, resulting in higher adherence rates.

The trials found higher HIV prevention efficacy of the ring among women who had greater drug release from their rings, reflecting more consistent use.[7] The open-label extension studies added data to support the association between consistent, correct ring use and lower HIV acquisition.[5,6] All studies noted no product-related severe adverse events. Less than 5 percent of women experienced side effects related to ring use, which were mainly urinary tract infections, pelvic pain, and vaginal discharge or itching and resolved within a few weeks.

In light of these data, the European Medicines Agency provided a positive scientific opinion in July 2020 supporting ring use for women at significant risk of HIV infection. In January 2021, the World Health Organization (WHO) recommended that the ring be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches, and the ring was included in the revised WHO Consolidated HIV Guidelines for Prevention, Treatment, Service Delivery & Monitoring released in July 2021.

The ring is currently approved for women 18 years and older because younger adolescents were not included in the original trials. The available data regarding safety in pregnant and breastfeeding women are sparse yet reassuring: among 169 trial participants who became pregnant, no congenital, maternal, or infant adverse outcomes were observed among those exposed to dapivirine.[8] Studies assessing the safety and acceptability of ring use among adolescent girls and young women ages 16–21 years (REACH), pregnant women (DELIVER), and breastfeeding women (B-PROTECTED) are ongoing, with the potential for changes in product labelling consistent with study results. Interim results from the REACH study, being conducted at four clinical research sites in Uganda, South Africa, and Zimbabwe, demonstrated that the vast majority (97 percent) of the study's 247 participants used the ring and daily oral PrEP some or all of the time. Fewer than 3 percent of participants used neither of the products, according to laboratory tests for adherence.[9]

At this time, ring use data are largely based on clinical trials rather than "real world" implementation. Moreover, discrete choice experiments measuring interest in use can inform our understanding of feasibility but not our understanding of acceptability because they do not capture user experience with the actual product. These studies also may not measure or anticipate the impact of specific barriers and facilitators to method access and use, such as partner perceptions or provider counselling and attitudes, that can be measured in implementation evaluations.

[Please add paragraph reflecting ring use or experience within the specific country. For example, ring Phase III and OLE trials were conducted in Kenya, Malawi, South Africa, Uganda, and Zimbabwe, so these countries have documented acceptability and safety data within their contexts, which should be featured in this paragraph. For countries not included in these trials or in the Quatro study (which included South Africa and Zimbabwe), here is some example text: "The ring has not been previously used or tested in [country name], and further information is needed regarding the feasibility and acceptability of this method among clients, providers, and administrators in the public sector health system. Furthermore, [MOH or health authority] administrators will require data regarding ring safety with any pilot use of the ring in [country name]. Prior to considering introduction of the ring as part of the PrEP method mix within [country name], the MOH requires evidence regarding ring acceptability among key end-user groups and health care providers, the feasibility of ring service provision in a variety of clinical and community-level settings, and anticipated barriers and facilitators to ring introduction and implementation from the perspective of health system infrastructure, cost, and community and provider-level demand."]

The MOH [or other health authority] has requested pilot ring implementation studies to address this need for data to shape ring decisions. The MOH [or other health authority] further requests that the pilot studies include a set of common features as well as conform to guidelines regarding geographic and end-user group distribution to ensure the resultant data are comparable, robust, and provide sufficient detail to guide decisions about adding the ring to the PrEP method mix and any associated policy, strategy, and guideline development.

Study objectives

1. To measure the feasibility, including cost projections, of adding the ring to available PrEP methods in [country name] among clients and service providers. [For countries that have already conducted ring feasibility assessments but desire costing analyses, please reword this objective to measure cost projections and move it to the final position in the list of objectives, as it will be informed by measures from those feasibility studies as well as from existing health systems data.]
2. To measure the acceptability of ring use among clients and service providers through PrEP method selection/uptake and continuation/use patterns (ring vs. oral PrEP).
   - **2a.** To measure product safety through described side effects and adverse events with either the ring or oral PrEP.
   - **2b.** To measure and explore responsive actions by service providers for social harms attributed to PrEP use.
3. To measure the fidelity of ring and oral PrEP service delivery against minimum service standards, including service quality, and document adaptations and the rationale for these changes.

Study design considerations

[These design considerations are illustrative; each country can adapt the considerations based on its specific priorities. For example, in countries for which feasibility and safety data already exist, health authorities and investigator groups may agree that having a single dissemination event that reports uptake, acceptability, and safety measures is preferable to the two-prong approach described below.]

The MOH [or other health authority] requests that all investigator teams include these design features in their protocols:

- Study sites should include those currently either directly providing oral PrEP or linked to oral PrEP provision (e.g., primary care sites providing family planning and sexual and reproductive health services) with representation of urban, peri-urban, rural, and remote settings, as possible. Each investigator team will complete a mapping matrix to specify the site and primary end-user group for the proposed study to maximise coverage and prevent duplication (**Annex 1**).
- The MOH [or other health authority] requests that studies include and identify clients who have used and discontinued oral PrEP as a separate arm/group from PrEP-naïve participants in the sample. The rationale for this differentiation is that users who have tried and discontinued oral PrEP (inclusive of periods of resuming use) may have different perspectives on the tolerability of side effects or product access/use, and those perspectives may influence ring continuation or switching. Because the ring is indicated predominantly for women who cannot or do not wish to use oral PrEP, it is important to capture the perspectives of experienced users who have discontinued oral PrEP as a primary client group for the ring. This number may be limited relative to new PrEP clients and can be considered an exploratory analysis.
- The MOH [or other health authority] recommends inclusion of broad community-level ring sensitisation sessions prior to and during study implementation, with qualitative assessment of planned materials to guide national adaptation. Sensitisation sessions shall feature the nature of the study (i.e., implementation assessment rather than safety/efficacy trial) and plans for inclusion of community oversight within the study's advisory committee.
- The MOH [or other health authority] recommends developing/adapting and testing draft provider training packages with minimum service delivery standards and coaching of providers on offering ring users instruction on and motivation for self-insertion at initial use and subsequent visits. Training and coaching should be provided prior to and during study implementation, with qualitative assessment of planned materials to guide national adaptation. Illustrative questions to aid in refining these packages are provided in **Tables 3 and 4**.

- For acceptability outcomes, the MOH [or other health authority] requests that all studies measure whether clients opt for either oral PrEP or the ring in addition to other HIV prevention measures (e.g., condom use) at study entry and include PrEP method discontinuation/switching and reported use of other HIV prevention methods as part of required acceptability outcome measures (please see **Table 3**). Although this differentiation may present statistical power concerns for an individual study if conducted as a pilot, we anticipate that a pooled analysis will be possible in scenarios where there are multiple studies or a multisite study, permitting greater power to detect true differences in initial and longer-term acceptability for each PrEP method.
- To contextualise acceptability outcomes, the MOH [or other health authority] requests that studies conduct qualitative interviews with a subsample of clients to explore the acceptability of ring use, including reasons for selecting or switching to the ring and reasons for continuing or discontinuing its use. These interviews should also address disclosure of ring use and discussions about ring use with partners and peers. Interviews would ideally include representatives across the age span and by group, such as sex workers. Interviews may also include key influencers, such as male partners to whom women have chosen to disclose their ring use, other family members, or community leaders. These interviews may focus on exploring communication and demand creation strategies and effective use support strategies.
- To contextualise acceptability outcomes, the MOH [or other health authority] requests that studies include qualitative interviews with a subsample of health care providers to explore ease of ring counselling and provision, including preferences for ring insertion by providers vs. teaching self-insertion at initial and follow-up visits, perceived time investment, utility of draft provider training materials/job aids, and factors motivating or dissuading providers from counselling or providing the ring. Interviews may also explore provider-targeted strategies for communication, demand creation, and effective use support. Interviews will ideally include providers representing different cadres, sexes, years in practice, and service areas (e.g., HIV service sites vs. family planning clinics vs. mobile/community/DREAMS services).
- The MOH [or other health authority] requests inclusion of measures to inform ring cost modelling across studies (**Table 5**); these measures are germane to feasibility outcomes and focus on supply side considerations.
- Study duration should be at least six months of follow-up overall with a proposed two-phase analysis of results: at one to three months (at the end of cohort recruitment) to focus on feasibility and early acceptability (e.g., uptake) and at six months to focus on acceptability outcomes.

- A member of the subnational-level health authority in the area of pilot implementation should be included in the implementation as a co-investigator with funding for routine oversight visits to the study site.
- The MOH requests the inclusion of an MOH [or other health authority]-convened advisory committee to include inputs from potential end-user groups (e.g., adolescent girls and young women, sex workers, and gender non-binary individuals) and their communities in the design (upon investigator or MOH request) and oversight of research (please see advisory committee section). Please ensure that study budgets include costs for monthly site visits by one member of the advisory committee.

Inclusion and exclusion criteria

Facility or care site features

All study sites should meet the following criteria:

- Have experience providing oral PrEP counselling and/or services
- Have links to the public sector supply chain and service quality oversight to ensure minimum service standards are met for oral PrEP
- Have authorisation from local authorities to expand service delivery to include oral PrEP provision (e.g., reproductive health care sites)

End-user participants

All studies should have the following inclusion criteria for end-user participants:

- At least 18 years of age [Can consider revising this if and when data on ring product safety among adolescents older than 15 years become available and international guidelines are adapted accordingly]
- Assigned female sex at birth — eligibility questions will need to ask potential participants about their sex assigned at birth and gender identity and to help those who are unfamiliar with these terms to answer easily
- Sexually active and wishing to prevent HIV acquisition during receptive vaginal sex
- Able to provide informed consent
- Member of priority groups for HIV prevention: sexually active adolescent girls and young women; sex workers or other women engaged in transactional sexual partnerships; clients with a partner of unknown or positive HIV status; or any client who meets other eligibility criteria and requests access to PrEP

- Using a modern contraceptive method (e.g., hormonal contraceptives, male or female condoms, intrauterine contraceptive device, standard days method) [Can consider revising this requirement if and when data on product safety during pregnancy and breastfeeding become available and international guidelines are adapted accordingly.]
- Able to return to the same health facility or care site during a six-month period

All studies should have the following exclusion criteria for end-user participants:

- Younger than 18 years [Please see above.]
- Currently pregnant or breastfeeding or planning to become pregnant or breastfeed within the next nine to 12 months — The rationale for this criterion is that data for ring safety in pregnancy and during lactation, while reassuring, are relatively sparse. Ongoing studies (DELIVER, B-PROTECTED) are investigating this issue, but these pilot studies will adhere to current ring prescribing guidelines, which stipulate that the ring should not be used by pregnant or lactating women. Women using the ring who become pregnant during the study period should be counselled based on the evidence available at that time and offered the opportunity to switch to oral PrEP. [Please see above.]
- Have documented HIV infection, signs or symptoms of acute HIV infection, or suspected HIV exposure in the last 72 hours (i.e., candidate for post-exposure prophylaxis), or have declined HIV testing
- Unable or unwilling to be contacted for follow-up appointments

Healthcare providers

[Please adapt based on current/intended PrEP service site features in your context.]
All studies should have the following inclusion criteria for health care provider participants:

- Experience with providing oral PrEP services
- Currently providing primary care services
- Able to provide informed consent
- Have participated in the draft provider ring counselling, provision, and management training course
- Have recent experience screening for and treating sexually transmitted and other reproductive tract infections
- Have recent experience providing HIV counselling and testing

All studies should have the following exclusion criteria for health care providers:

- Unwilling to provide the ring
- No experience providing HIV, PrEP, or sexual and reproductive health services

Public health sector administrators and key informants

[This participant group is optional but recommended for additional insights into feasibility, fidelity, and cost measures.]

Studies may consider inclusion of the following groups for insights into ring feasibility, fidelity of implementation and adaptations, and perceived costs:

- Provincial/county/district-level health administrators
- Government or implementing partner technical advisers for HIV service delivery
- Community leaders
- Members of HIV advocacy groups

All studies should record the number of potential participants deemed ineligible, the reason for ineligibility, and, separately, the number who are eligible but declined study participation.

Visit schedule and outcome measures and indicators

The MOH [or health authority] asks that all investigator teams include the following required measures/indicators for feasibility and acceptability analyses and safety and also proposes a number of additional indicators for inclusion for each objective. The rationale for this mandate is to ensure comparability across studies and consistent data quality to sufficiently power analyses.

We have mapped a minimum visit schedule, location, and interview type within presumed routine care visits to capture the "real world" nature of implementation studies as well as respect cost and time constraints within study operations (**Table 2**). This table is illustrative and should be adjusted based on the oral PrEP minimum service package and, where available, draft ring minimum service package schedules unique to each implementing country.

TABLE 2. Illustrative study data collection mapped to service engagement points

SERVICE DELIVERY POINT	PARTICIPANT GROUP; OUTCOME	INTERVIEW TYPE
Pre-service: Initial service site engagement following provider training	Provider; feasibility	Provider interview with quantitative questions for all; for subsample, qualitative interviews on how to improve in-service training, factors contributing to perceived service readiness, and appropriateness
Initial patient consultation with HIV testing services (HTS) and HIV prevention counselling (including PrEP)	End-user; feasibility, acceptability (service and method uptake), and fidelity (HIV prevention & PrEP counselling conducted with main points included)	Enrolment visit conducted as exit interview; for subsample, qualitative interview regarding perceived service quality and reasons for PrEP choice/non-use
	Provider; fidelity	Relevant clinical (e.g., HIV test completed) or validation (e.g., PrEP method selected and dispensed) inputs from chart review and end-user exit interview
Phone consultation at one month (or ring visit if reflective of patients preferring provider removal/insertion or service guidelines)	End-user; acceptability	We note that phone follow-up at one month may be limited to study activities but have built in this time point for monitoring use patterns.
	Provider; fidelity	For ring: to capture provider counselling, pregnancy (as indicated) testing, and offering/teaching self-insertion/removal
Quarterly PrEP follow-up visits	End-user; acceptability, fidelity, and clinical measures	Quarterly resupply visits with relevant quantitative acceptability (e.g., continuation, satisfaction, risk perception), fidelity (e.g., received ongoing counselling and adherence support), and clinical outcomes
	Provider; fidelity	Quarterly resupply visits with quantitative provider interview for fidelity (e.g., services offered with accompanying chart audit)
Ad hoc PrEP method issue management, switching, or discontinuation visit	End-user; acceptability, fidelity, and clinical measures	Quantitative interview with acceptability (including reasons for switch/discontinuing), fidelity (e.g., did provider support continuation/discontinuation decision or counsel on other options), and clinical measures (e.g., serum creatinine for oral PrEP); subsample for qualitative interviews on change in PrEP method use
	Provider; fidelity	Quantitative interview with chart audit; subsample with qualitative interviews regarding perceived reasons patients change PrEP methods and altered perspectives on how to provide different PrEP methods

Table 3 includes questions required to achieve the study objectives, along with visit type and application of information. **Table 4** provides suggested measures, with some additional entry points listed that correlate with an alternative time point for a required or suggested measure.

TABLE 3. Required study outcome measures

	REQUIRED OUTCOME MEASURES	HOW MEASURED?	WHEN MEASURED?	ROLE IN ANALYSIS?
FEASIBILITY MEASURES				
End-Users	**Interest in ring as a PrEP method**	Please see Annex 3.	Enrolment visit with questionnaire following counselling and HIV prevention method selection	Primary feasibility outcome measure for end-users
Providers	**Perceived readiness to offer the ring following training session**	Please see Annex 3 for quantitative questions. Probe service readiness in qualitative interviews for context.	Post-training interview	To inform pre/post-test as part of provider training package and help refine package
Providers	**Ring knowledge score**	Composite score for 5–7 quantitative knowledge questions with answers presented in training materials (questions and answers in Annex 3)	Questions as part of pretest and post-test for ring training package	Primary outcome for feasibility of training package; can add questions on provider's attitude about time/ability to include ring services within existing duties
ACCEPTABILITY MEASURES				
End-Users	**Uptake:** Participants initiating specific PrEP method	# consented eligible participants counselled who receive oral PrEP pills or the ring (placed by provider); enrolment interview questions (Annex 3) verified with clinic or pharmacy record	Enrolment visit (assume done as exit interview)	Primary outcome measure for specific method uptake; denominator for continuation/ acceptability measures
End-Users	**Uptake:** Reason for method selection	Please see Annex 3 for quantitative questions. In qualitative subsample, ask about why participants selected their specific method or decided not to start PrEP.	Enrolment visit (assume done as exit interview)	To provide context for method uptake and set baseline for determining acceptable features that are sustained over time

TABLE 3. Continued

	REQUIRED OUTCOME MEASURES	HOW MEASURED?	WHEN MEASURED?	ROLE IN ANALYSIS?
End-Users *(Continued)*	**Continuation:** Participants using PrEP method selected at study entry through cohort period	# participants reporting use of initial PrEP method at follow-up visits with pharmacy record verification/total # initiating that method	All follow-up visits	Primary outcome measure for acceptability; disaggregate by method, target group, prior oral PrEP use, and province
	Use patterns as part of continuation: Participants modifying PrEP use based on perceived risk or opportunity cost	Please see Annex 3 for quantitative questions. Include qualitative subset to probe reasons for intermittent use.	All follow-up visits	To characterise use patterns as part of acceptability and to inform adherence support; exploratory analyses of barriers to continuation
	Switching: Participants changing from one PrEP method to another	# participants requesting and changed from PrEP method initiated at enrolment to new method with pharmacy record verification/# total new PrEP users Please see Annex 3 for quantitative questions; probe reasons for switching in qualitative subsample.	All scheduled and ad hoc follow-up visits	Acceptability outcome; disaggregate by method, target group, and province
	Acceptability: Participant perceived acceptability, partner acceptance, and would recommend to friend	Proposed quantitative questions are in Annex 3. Please see Annex 2 for alternative question structure if you anticipate following end-users who decline PrEP use or having high discontinuation rates.	All follow-up visits	Mean/median scores; disaggregate by method, age, target group, prior oral PrEP use, and province
	Acceptability: Discontinuation and reasons for discontinuing PrEP	Please see Annex 3 for quantitative questions. Probe reasons for discontinuation in in-depth interviews among a subsample of those discontinuing PrEP and those switching methods.	Visit where discontinuation requested/ reported	Comparison by original method; self-reported length of use; disaggregate by age and target group, prior oral PrEP use, and province; reasons for discontinuing (clinical, use challenges, provider-initiated, partner-related, etc.)

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TABLE 3. Continued

	REQUIRED OUTCOME MEASURES	HOW MEASURED?	WHEN MEASURED?	ROLE IN ANALYSIS?
Providers	**Frequency offering oral PrEP and the ring**	Quantitative measure in interview [# times counselled/week; see Annex 3]; check facility pharmacy records for # new oral PrEP or ring clients receiving product in designated time period; probe in qualitative interviews to determine provider confidence vs. changes in service readiness (e.g., stock-outs)	Provider questionnaire at end of enrolment period; pharmacy record check at follow-up visits	Overall proportions; disaggregate by cadre and province
	Acceptability of counselling on the ring/oral PrEP together and offering choice	Please see Annex 3 for quantitative and qualitative questions.	After training	For quality assurance and improvement; observational checklist findings and reported qualitatively in aggregate only
ADDITIONAL CONTENT AREAS RELEVANT TO PREP EFFECTIVENESS/SAFETY MEASURABLE WITHIN PILOT STUDIES AND FOR INCLUSION IN MINIMUM SERVICE PACKAGES				
	HIV acquisition	HIV testing per national guidelines/minimum service package	1 month and quarterly/routine follow-up visits	Effectiveness outcome (though note studies are not powered for this outcome); plan aggregate across sites
	Incident pregnancy*	Pregnancy testing	1 month and quarterly/routine follow-up visits	Safety outcome; plan aggregate across sites Ring to be discontinued in event of incident pregnancy.
	Adverse drug reaction reporting per national guidelines	# of participants reporting adverse drug reactions	All follow-up and ad hoc visits	Safety outcome; relatedness to PrEP method use; plan aggregate across sites
	Social harms† reported by participant or recorded at study site	# of participants reporting social harms and sub-portion attributed to PrEP use	All follow-up and ad hoc visits	Safety outcome; relatedness to PrEP method use; plan aggregate across sites

* Change pending emerging evidence of safety in pregnancy

† Social harms should use the most appropriate national definition. A suggested definition is: "Social harms are events that cause physical, emotional, or financial but nonmedical adverse consequences due to PrEP use."

TABLE 4. Suggested outcome measures and questions for investigator consideration

	OUTCOME MEASURES	HOW MEASURED?	WHEN MEASURED?	ROLE IN ANALYSIS?
***SUGGESTED* FEASIBILITY MEASURES**				
End-Users	PrEP method planned to use at time of facility visit (enrolment)	Please see Annex 3 for suggested quantitative questions.	End-user interview following sensitisation session and before provider visit, if feasible	Comparison of client perceptions prior to and following provider counselling
	Perceived effort to access/use the ring	Please see Annex 3 for suggested quantitative questions.	Interviews following community or waiting room sensitisation sessions	Context-specific client preferences to shape demand creation and service provision
	Perceived "opportunity costs" associated with ring use	Please see Annex 3 for suggested quantitative questions.	Interviews following community or waiting room sensitisation sessions	Context-specific client preferences to shape demand creation and service provision
	Perceived effectiveness of ring compared to oral PrEP or other HIV prevention methods	Please see Annex 3 for suggested quantitative questions. Probe role of perceived effectiveness in decision-making about the two methods in qualitative interview subset.	Key informant interviews of representative end-user participants	Context-specific client preferences to shape demand creation and service provision
	Perceived self-efficacy to use ring as PrEP	Please see Annex 3 for suggested quantitative questions.	Interviews following community or waiting room sensitisation sessions	Context-specific client preferences to shape demand creation and service provision
	Perceived most reliable source for PrEP information/ recommendation	Please see Annex 3 for suggested quantitative and qualitative questions.	Interviews following community or waiting room sensitisation sessions	Context-specific client preferences to shape demand creation and service provision
	Preferred site and provider for general PrEP provision and specifically for the ring	Please see Annex 3 for suggested quantitative questions.	Interviews following community or waiting room sensitisation sessions	Context-specific client preferences to shape demand creation and service provision
	Perceived facilitators/ barriers to ring access and use	Please see Annex 3 for suggested quantitative and qualitative questions.	Interviews following community or waiting room sensitisation sessions	Context-specific client preferences to shape demand creation and service provision
Providers	**Perceived demand for ring vs. oral PrEP by clients**	Please see Annex 3 for suggested quantitative and qualitative questions.	Qualitative semi-structured in-depth interviews of subsample of providers at selected follow-up visit where providers have experience with both PrEP methods	Provider attitude inventory to determine need and content for values clarification as part of training package

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TABLE 4. Continued

	OUTCOME MEASURES	HOW MEASURED?	WHEN MEASURED?	ROLE IN ANALYSIS?
***SUGGESTED* ACCEPTABILITY MEASURES**				
End-Users	**Participants reporting ring self-insertion after initiation [ring users only]**	Please see Annex 3 for suggested quantitative questions.	First follow-up visit where self-insertion is reported	Proportions: disaggregate by age and target group, prior oral PrEP use, and subnational level
End-Users	**Participants disclosing PrEP use to at least one person**	Please see Annex 3 for suggested quantitative questions.	Enrolment visit [See partner disclosure questions in required questions for follow-up visits]	Proportions: disaggregate by type of person (e.g., male partner, family member), participant age, PrEP method and target group, prior oral PrEP use, and subnational level
Providers	**What is/is not working for providers and how can the tools/job aids/ training provided to them be improved upon to better support their role?**	Please see Annex 3 for suggested quantitative and qualitative questions.	One month and end line	Overall proportions: disaggregate by cadre and subnational level

Costing analyses content

The [MOH or national authority] also requests that the following required and suggested measures be added to permit costing analysis across studies, which will provide essential information to guide ring introduction decisions. **Table 5** provides these measures, which will be combined with health system costs in analysis. Should interest and funding be available, willingness-to-pay substudies could be considered in contexts where user fees are part of PrEP service costs.

TABLE 5. Required and suggested costing measures

OUTCOME MEASURES	HOW MEASURED?	WHEN MEASURED?	ROLE IN ANALYSIS?
REQUIRED **COSTING MEASURES**			
Patterns of PrEP visits (continuation, cycling)	For each client who initiates PrEP, collect data on dates and PrEP method use (continuation, re-initiation, discontinuation, method switching, non-refill visits for other reasons) at subsequent visits	Enrolment, scheduled follow-up, and ad hoc visits	Captured above in required acceptability measures, but repeated here because it has implications for costing
Incremental PrEP service delivery costs	Please see Annex 3 for costing data inputs needed.		Incremental cost of adding ring service delivery to existing services per visit, per client initiated, per person-year, disaggregated by type of site and type of client
SUGGESTED **COSTING MEASURES**			
Cost to clients for those seeking ring services	Include wealth quintile measures in demographic data and ask about estimated costs borne by clients to access PrEP services. Please see Annex 3.	Conducted at the pilot testing phase or during early stages of scale-up	Clarifies the cost to clients of seeking ring services and assesses the extent to which these costs represent barriers
Ratio of numbers of rings dispensed to used	Data relating numbers of rings dispensed to patterns of use (please see Annex 3).	Track ring insertion and removal via reported use across follow-up visits	Estimating costs of service delivery per person-year of protection

Study efficiency review

The MOH [*or health authority*] requests that each investigator group list specific subnational sites, type(s) of service sites, and end-user groups planned for each study prior to submission to the institutional review boards (IRBs). These selections will be reviewed to ensure coordination across investigator groups and to suggest alterations or expansion in target groups or service sites to ensure multiple data sources for key measures. A matrix will be provided to facilitate this process (Annex 1). Each investigator team should include a plan for sustained ring provision for women who participate and wish to continue ring use after the study period.

Ring implementation pilot advisory committee

The MOH [*or health authority*] will convene an advisory committee to provide ongoing guidance and input during protocol development (upon request of the MOH or the investigator team), implementation, initial results presentation (feasibility and uptake data), and final results presentation. We recommend that investigator teams avail themselves of the expertise within the advisory committee for the wording of the consents and questionnaires as well as selection of study facilities and engagement with local community-based organisations.

The committee will comprise MOH [or health authority] and stakeholder representatives, including representatives from end-user groups, who are not investigators on the pilot implementation studies (number to be determined by health authority). The committee will also include representation from advocacy groups for sexual and reproductive health and HIV prevention in [country name] and civil society organisations comprised of specific ring end-user groups. advisory committee members will be nominated by the MOH [or health or HIV authorities] and selected members of the [relevant technical working group] not affiliated with pilot implementation studies. At least one advisory committee member will be selected from the provincial health team and one from the health teams of each district where the pilot studies will be conducted.

The advisory committee will be available to review study instruments and protocols to provide contextual insights as well as suggest improvements in phrasing or supplemental questions to better achieve the study outcomes. Committee members will also assist investigator teams and the MOH in designing dissemination plans and will provide direct support, as possible, for community updates on study progress and findings, aligned with study and national community sensitisation efforts.

To ensure alignment with MOH [or health authority] guidance, investigator teams should submit the protocols, instruments, and consent documents for MOH [or health authority] review and concurrence prior to IRB submission. The MOH [or health authority] will consult the committee as needed to confirm guideline adherence. The committee will also ensure that study efficiency review (e.g., geographic and end-user representation) has been completed prior to implementation.

The advisory committee will meet quarterly to monitor study progress and input from sites and communities in the study areas. The committee may convene ad hoc meetings in the event of reported safety or social harms and ensure mitigation measures proposed by the investigators are sufficient to address the issue, potentially in collaboration with the local IRB. At study end, the investigator team will present the main results to the committee for input on synthesis and interpretation, and the committee will report to the MOH [or health authority] regarding study alignment with MOH [or health authority] guidance and lessons learned to inform product introduction decisions and planning.

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Annex 1. Proposed study subnational site and focus population matrix

Investigator Team	[Province or other sub-national level]	[District or other sub-national level]	Site (facility or civil society organisation community or DREAMS centre name)	Focus group	Sample size

Annex 2. Domain considerations for acceptability questions

Streamlined approach to assess end-user ring feasibility measures for implementation studies

[Assuming questions are asked after initial visit with an HIV prevention counsellor or after a PrEP method has been selected]:

1. Which method would you prefer to use for HIV prevention?

- **a.** Dapivirine ring
- **b.** Oral PrEP
- **c.** Male condom
- **d.** Other: _____
- **e.** None of the above

2. [If PrEP method selected as preferred method]:

What influenced your decision about your preferred method for HIV prevention?
(Select all that apply using statements in Column A.)

[If non-PrEP method selected as preferred method, or no method selected at all]:

What influenced your decision about why you prefer not to use the ring or oral PrEP?
(Select all that apply using statements in Column B.)

	COLUMN A	COLUMN B
RELEVANT DOMAIN	Reasons for preferring PrEP method (ring or oral PrEP)	Reasons for not selecting either PrEP method for HIV prevention (or selecting no prevention method at all)
Cost	It is affordable (or free).	The PrEP methods are too expensive.
Access	It is available in my community.	The PrEP methods are not currently available in my community.
Ability to access	It is available and will be easy for me to get (e.g., reasonable clinic wait times, no transportation issues).	The PrEP methods might be available, but they would not be easy to get (e.g., long clinic wait times, transportation issues).
Ease of use	It will be easy for me to use.	I do not believe the PrEP methods will be easy to use.
Side effects	I will not worry about the side effects.	I think the PrEP methods will cause side effects.
Emotional comfort/ discomfort	It will cause me to feel pleasant feelings like happiness or reassurance.	Either PrEP method would cause me to feel unpleasant feelings like sadness or anger.
Physical comfort/ discomfort	It will not cause my body discomfort to use.	Either PrEP method would cause my body discomfort.
Social comfort/ discomfort	It will not cause me worry related to the reactions of people around me.	Either PrEP method would cause me worry related to the reactions of people around me.
Effects on health and well-being more generally	It will be good for my well-being.	Either PrEP method would not be good for my well-being.
Perceived effectiveness	It will be effective for me in preventing HIV if I use it well.	Either PrEP method would not be effective for me in preventing HIV.
Support/disclosure	I will have support from someone close to me to use it well.	I will not have support for using either PrEP method from someone close to me.

→

RELEVANT DOMAIN	COLUMN A Reasons for preferring PrEP method (ring or oral PrEP)	COLUMN B Reasons for not selecting either PrEP method for HIV prevention (or selecting no prevention method at all)
Self-efficacy	I can use it correctly and consistently.	I would not be able to use either PrEP method correctly and/or consistently.
Risk perception *(only relevant for those who chose no prevention method)*	I am not at risk for getting HIV right now.	

[For each option selected, one could go on to ask a more specific question about that particular response similar to or the same as items we have already pulled out from the existing surveys.]

3. What most influenced your decision?

Response option 1: Repeat options from the questions above but have participants rank their top three reasons.

Response option 2: Think about what things are most important to you now in choosing a product that would provide HIV prevention. What is the most important to you? What is the second most important?

(Have participant free list and record responses verbatim below:)

a. (Most important): _____

b. (Second most important): _____

Annex 3. Illustrative questions for ring pilot implementation studies

Domain	Question	Responses	Skip pattern
Feasibility Measures: End Users	Which method do you prefer to use for HIV prevention?	1. Vaginal ring 2. Oral PrEP 3. Male condom 4. Other: [describe] 5. None of the above	***[Add for questions that follow regarding reason(s) for preference prior to actual use]***
Feasibility Measures: Providers	How well did your training prepare you to counsel and offer the dapirivine ring to clients?	1. Very well prepared 2. Adequately prepared 3. Not very well prepared 4. Not prepared at all	
	How comfortable do you feel about counseling clients on use of the dapirivine ring?	1. Very comfortable 2. Somewhat comfortable 3. Somewhat uncomfortable 4. Uncomfortable 8. No response	
	How confident are you that you can teach a client how to insert and remove the dapirivine ring herself?	1. Very confident, 2. Mostly confident, 3. Somewhat confident 4. Not confident 8. No response	
	If the ring is available at your facility, how likely are you to recommend the ring to your future clients?	1. Very likely 2. Somewhat likely 3. Neither likely or unlikely 4. Somewhat unlikely 5. Very unlikely	probe service readiness in qualitative interviews for context

Domain	Question	Responses	Skip pattern
Ring knowledge score ***[Composite score for the following 5–7 quantitative knowledge questions with answers present in bold, italicized font.]*** Circle all that apply.			
	The dapivirine vaginal ring ("the ring") is used:	1. To prevent mother-to-child transmission of HIV 2. To prevent HIV infection after potential exposure to HIV 3. ***By HIV-negative persons to prevent HIV acquisition*** 4. To treat HIV infection 5. Only by key populations	Primary outcome for feasibility of training package; can add questions RE provider attitude for time/ability to include ring services within existing duties
	The ring is:	1. Often felt by partners during sex 2. ***For use in combination with safer sex practices when oral PrEP is not/cannot be used or is not available*** 3. For people at substantial risk of HIV infection who want to prevent HIV acquisition during receptive anal sex 4. ***For people at substantial risk of HIV infection who want to prevent HIV acquisition during receptive vaginal sex***	
	The ring is replaced:	1. At the same time each day 2. ***Once a month*** 3. Every 3 months 4. Once per year 5. After every sexual encounter	
	Contraindications to the ring include:	1. HIV-negative status 2. ***HIV-positive status*** 3. Concurrent treatment with vaginal miconazole 4. ***Allergy to any medicine in the ring*** 5. Estimated creatinine clearance <60 cc/min	

Domain	Question	Responses	Skip pattern
	The ring should be discontinued if a client:	1. ***Has a positive HIV test*** 2. Develops renal disease (creatinine clearance <60ml/Min)* 3. Reports headaches and stomach upset 4. ***Requests to discontinue*** 5. ***Is no longer at substantial risk and wishes to discontinue***	
	Which of the following statements is/are true regarding the ring?	1. ***Adherence to drug(s) means that an individual is taking prescribed medications correctly and consistently*** 2. Effectiveness of the ring does not depend on adherence 3. The ring also provides protection against other STIs 4. The ring should be used for life 5. ***There are no food or alcohol restrictions when using the ring*** 6. ***The only diagnostic required before ring initiation is an HIV test (Note: This will be true only if studies in pregnant women document ring safety in pregnancy)***	
	The ring should be removed during menses.	1. True 2. ***False***	Indicate whether the following statements about the ring are true or false.
	The ring is most effective after it has been in place for 24 hours.	1. ***True*** 2. False	
	The ring should not be disposed in a flush toilet.	1. ***True*** 2. False	
	The ring can be used with male condoms.	1. ***True*** 2. False	
	The most commonly reported adverse reaction to the ring is urinary tract infection.	1. ***True*** 2. False	
	The ring can only be inserted by a trained medical professional to ensure proper fit.	1. True 2. ***False***	

PrEP RING PILOT IMPLEMENTATION STUDY PROTOCOL TEMPLATE

Domain	Question	Responses	Skip pattern
Acceptability Measures: End Users	Were you counseled on HIV prevention methods today?	1. Yes 2. No	If No, end interview.
Uptake/ Feasibility	Which HIV prevention methods were you counseled about?	1. Oral PrEP 2. Dapivirine ring 3. Male condoms 4. Female condoms 5. Limiting number of partners 6. STI screening and treatment 7. Other (specify): _____	
	Of these methods, which method(s) have you chosen to use? ***[Circle all that are stated]***	1. Oral PrEP 2. Dapivirine ring 3. Male condoms 4. Female condoms 5. Limiting number of partners 6. STI screening and treatment 7. 7. Other (specify): _____	If selected 1 or 2, verify in clinic notes and proceed with interview.
	Would you say you chose this product mainly because you liked the product you chose, or because you disliked the other product?	1. Liked this product 2. Disliked the other product.	
	What do you like most about the PrEP method you selected	***[Open response or populate with most frequent reasons detected during pre-testing.]***	
	What do you dislike most about the other PrEP method?	***[Open response or populate with most frequent reasons detected during pre-testing.]***	
End-User: Follow-up Acceptability	What HIV prevention method(s) are you currently using?	1. Oral PrEP 2. Dapivirine ring 3. Male condoms 4. Female condoms 5. Limiting number of partners 6. STI screening and treatment 7. Other (specify): _____	If 1 or 2 NOT included in response, confirm with prompt and, if confirmed, skip to discontinuation questions.
	Did you temporarily stop using your PrEP method at any time since the last appointment?	1. Yes 2. No	

Domain	Question	Responses	Skip pattern
	For how long did you stop using the method?	# days _____	
	Why did you stop using the method?	1. Menses 2. Broke up with partner 3. Removed before sex 4. Forgot to take pills for a day or more 5. Discussed with partner and agreed that we don't 6. need PrEP 7. Other (specify)]	
	Did you resume using your PrEP method?	1. Yes 2. No	If No, skip to questions below for discontinuation/ switching. If Yes, see below # days
	How long ago did you start using the method again?	# days _____	
	Why did you resume?	1. Menses finished 2. New partner 3. Feel personal risk for HIV has increased 4. Partner encouraged PrEP use 5. Other (specify)	
Switching: Participants changing from one PrEP method to another	Did you change your PrEP method today?	1. Yes 2. No	If no, go to method-specific acceptability questions.
	If yes, what method have you selected?	1. Oral PrEP 2. Dapivirine ring 3. Other (specify): _____	
	Why did you switch PrEP methods?	1. Side-effects 2. Not convenient to use 3. Difficult to keep private 4. Partner didn't agree 5. Clinic stock-out of first method 6. Other (specify)	

Domain	Question	Responses	Skip pattern
Acceptability: Participant perceived acceptability, partner acceptance, and would recommend to friend	Since your last visit, overall, how much do you like using the vaginal ring/oral PrEP every day?	1. Like very much 2. Like 3. Neither like nor dislike 4. Dislike 5. Dislike very much	
	Since your last visit, overall, how satisfied have you been with this method for preventing HIV?	1. Very satisfied 2. Somewhat satisfied 3. Neutral 4. Somewhat dissatisfied 5. Very dissatisfied	***[Add skip pattern based on current PrEP method; ring questions here, immediately followed by oral PrEP questions]***
Ring Users	How easy or difficult is it for you to insert the vaginal ring?	1. Very easy 2. Somewhat easy 3. Neither easy or difficult 4. Somewhat difficult 5. Very difficult	
	How easy or difficult is it for you to remove the vaginal ring?	1. Very easy 2. Somewhat easy 3. Neither easy or difficult 4. Somewhat difficult 5. Very difficult	
Oral PrEP Users	How easy or difficult is it for you to remember the pill every day?	1. Very easy 2. Somewhat easy 3. Neither easy or difficult 4. Somewhat difficult 5. Very difficult	
	How easy or difficult is it for you to swallow the pill?	1. Very easy 2. Somewhat easy 3. Neither easy or difficult 4. Somewhat difficult 5. Very difficult	
All participants	Is your primary partner	1. Supportive 2. Not supportive 3. Doesn't know about PrEP use 4. Not applicable	
	Would you use this method in the future?	1. Yes 2. No ***[Open response: Why or why not?]***	

Domain	Question	Responses	Skip pattern
	Would you recommend this method to a friend?	1. Yes 2. No ***[Open response: Why or why not?]***	
Acceptability: Discontinuation and reasons for discontinuing PrEP	Did you stop using your PrEP method at any time since the last appointment without resuming use?	1. Yes 2. No	
	Why did you stop using oral PrEP/ ring? ***[Multiple responses allowed, probe until all elicited]***	1. Side effects 2. Not at risk/ not sexually active 3. Partner objected 4. Now HIV positive 5. Fear of side-effects 6. Fear of inadvertent partner discovery 7. Discomfort with use 8. Interferes with daily activities 9. Can't remember daily use/monthly use 10. Product not available 11. Provider said not to use it 12. Other (specify)	
	What is the most important reason you stopped using oral PrEP/ the ring? ***[Select single best answer]***	1. Side effects 2. Not at risk/ not sexually active 3. Partner objected 4. Now HIV positive 5. Fear of side-effects 6. Fear of inadvertent partner discovery 7. Discomfort with use 8. Interferes with daily activities 9. Can't remember daily use/monthly use 10. Product not available 11. Provider said not to use it 12. Other (specify)	
	When did you stop using oral PrEP/ the ring?	[# days ago] _____]	

PrEP RING PILOT IMPLEMENTATION STUDY PROTOCOL TEMPLATE

Domain	Question	Responses	Skip pattern
	With whom did you discuss stopping using the ring/ oral PrEP?	1. No one 2. Regular partner 3. Parent 4. Friend/neighbor 5. Provider at health facility 6. Community health worker 7. Other (specify) _____	
	What have you been using to prevent HIV since stopping?	1. Nothing, not at risk/sexually active 2. Nothing, partner won't use condoms 3. Male condoms 4. Female condoms 5. VMMC 6. Oral PrEP 7. Ring 8. Other	
	Are you still using this/these methods today?	1. Yes 2. No	
	Did your partner/husband know you were using PrEP?	1. Yes 2. No	***[If no, skip next question.]***
	If yes, does your partner/ husband know you stopped using PrEP?	1. Yes 2. No	
	Was the decision to stop using PrEP made mainly by you, mainly by your partner, or you made the decision together?	1. Mainly your decision 2. Mainly partner's decision 3. Joint decision 4. Partner was not aware of PrEP use	
Acceptability Measures: Provider	About how many clients have you counseled this week about PrEP method use?	[_____ clients]	Check facility pharmacy record for new PrEP starts during the relevant time interval.
	About how much time does it take to counsel clients on PrEP methods, including discussion of side effects and need for follow-up	[_____ minutes]	

Domain	Question	Responses	Skip pattern
	About how much additional time does it take to counsel clients on the ring, including discussion of side effects and insertion/ removal?	[_____ minutes]	
	How important is it for a provider to insert the ring for the first time? ***[Read options and select option provider agrees with]***	1. Essential 2. Prudent but not necessary 3. Unnecessary but clients like it 4. Not important)	
Qualitative questions:	How does offering the ring affect service delivery? (probe for negative and positive impacts)		
	How does offering the ring affect your workload?		
	How do you determine whether or not to discuss oral PrEP with a client? What about the ring?		
	This question should be a short response in a quantitative tool as well as probed in qualitative interviews.	Who needs to be counseled on all PrEP methods? (what are some client characteristics)	
	This question should be a short response in a quantitative tool as well as probed in qualitative interviews.	Who needs to be counseled on using oral PrEP? (what are some client characteristics)	
	This question should be a short response in a quantitative tool as well as probed in qualitative interviews.	Who needs to be counseled on using the ring? (what are some client characteristics)	
PrEP Safety, Fidelity, & Effectiveness Measures ***[These measures should be abstracted from the end-user record and reviewed with the provider following end-user follow-up interview]***	Did the client receive HIV counseling and testing at this visit?	1. Yes 2. No	[Enrollment & follow-up visits per Minimum Service Package schedule]

Domain	Question	Responses	Skip pattern
	What was the result of the HIV test?	1. Reactive (Positive) 2. Non-reactive (Negative) 3. HIV test not performed [Query provider after client interview completed – stated reason: _____]	Go to next if Reactive test. If non-reactive, skip to pregnancy testing question for ring users; skip to adverse drug reaction question for oral PrEP users. If test not performed, query and add stated reason.
	For clients with reactive HIV test, was the client referred and seen for rapid ART counseling and start?	1. Yes 2. No	
[Ring users only]	Did the client receive a urine pregnancy test?	1. Yes 2. No	[Enrollment & follow-up visits per Minimum Service Package schedule]
	What was the result of the pregnancy test?	1. Reactive (Positive) 2. Non-reactive (Negative) 3. Pregnancy test not performed [Query provider after client interview completed – stated reason: _____]	
[Chart and provider query]	Was a side-effect or adverse reaction reported and attributed to PrEP use?	1. Yes 2. No	Skip to social harms questions.
	If yes, please describe.	1. [Short answer]	
[Chart and provider query]	Did the client report any social harms related to PrEP use?	1. Yes 2. No	If no, skip to next series of questions, per investigator team preferences.
	If yes, what type of issue was reported?	1. Inadvertent PrEP use disclosure/ discovery 2. Intimate partner violence 3. Family shunning/disapproval 4. Community shunning/disapproval 5. Other (specify): _____	
	What type of services or referral was provided?	[Short answer]	

PrEP RING PILOT IMPLEMENTATION STUDY PROTOCOL TEMPLATE

Domain	Question	Responses	Skip pattern
Required Costing Measures			
Incremental PrEP service delivery costs [calculate for each PrEP method]	Record aggregate data during the study period at each involved facility for the following: ▪ Additional staff time per PrEP visit by different types of visits and record staff cadre [use MOH HRH scale for salaries & benefits] ▪ Numbers of different types of visits by site/population served (annually and by month) ▪ Numbers of rings or month supply of oral PrEP dispensed (total dispensed per visit during study implementation) ▪ Numbers and prices of additional lab tests and HIV tests conducted for PrEP users (including rates of confirmatory and tiebreaker HIV tests – annually and by month) ▪ Numbers of clients tested for HIV who choose to initiate ring ▪ Numbers and prices of other additional commodities used for ring (gloves, test tubes, stationery, etc.) [Use MOH commodity unit cost data] Estimate of other PrEP method-specific costs, e.g. equipment, disposal, training costs, ring-specific demand creation, mass media, and community outreach costs		
Suggested Measures: These questions correspond to Table 2 in the guide			
Suggested Feasibility Measures: End Users	Which method do you intend to use for HIV prevention?	1. Oral PrEP 2. Ring 3. Condoms 4. Other (specify) 1. Haven't decided	
	Would you be willing to use the oral PrEP for HIV prevention?	1. Yes 2. No	
	Would you be willing to use the ring for HIV prevention?	1. Yes 2. No	
Perceived effort to access/use the ring	If you were interested to use the ring to prevent getting HIV, and it was available for free at local clinics, please rate how likely you would be to use the product on a scale of 1–5	1. Definitely would NOT use it 2. Probably would NOT use it 3. Not sure 4. Maybe would use it 5. Definitely would use it	
Perceived opportunity costs related to PrEP use [Divide into two questions each by specific PrEP method]	In general, how worried are you about the effect of the ring/oral PrEP on your own health	1. Very worried 2. A little worried 3. Not worried at all.	

Domain	Question	Responses	Skip pattern
	Do you think using the ring/oral PrEP would cause emotional discomfort? By this we mean the product causes you to feel unpleasant feelings like sadness or anger	1. A little bit 2. A lot 3. Not at all	
	Do you think using the ring/ oral PrEP would cause physical discomfort? By this we mean the PrEP method takes your body feel uncomfortable.:	1. A little bit 2. A lot 3. Not at all	
	Do you think the ring/oral PrEP would cause sexual discomfort	1. A little bit 2. A lot 3. Not at all	
	Do you think the ring/oral PrEP would cause social discomfort? By this we mean discomfort or worry related to the reactions of people around you.	1. A little bit 2. A lot 3. Not at all	
	Some women may have worries about the effect of ring on their own health or wellbeing. Are you worried the ring could…?: a. Cause infections or cancer? b. Make you gain weight? c. Affect your future fertility? d. Result in people thinking you are HIV positive? e. Anything else related to the ring? ***[specify]*** f. Anything else related to oral PrEP? ***[specify]***	a – d: 1. Yes 2. No e. [Open response] f. [Open response]	
	Would you mind wearing the vaginal ring…: a. During sex? b. When not sexually active? c. During menses? d. During daily activities?	1. Yes 2. No 3. Not applicable ***[Response series for each component a–d of this question.]***	

Domain	Question	Responses	Skip pattern
Perceived effectiveness of ring compared to oral PrEP or other HIV prevention methods	How effective do you think the vaginal ring is at preventing HIV?	1. Not at all effective 2. Somewhat effective 3. Very effective 4. Don't know	
	How effective do you think oral PrEP is at preventing HIV?	1. Not at all effective 2. Somewhat effective 3. Very effective 4. Don't know	
	Which method do you think would be most effective for you at preventing HIV?	1. Vaginal ring 2. Oral PrEP 3. Neither 4. Don't know	
	The ring is about 50% effective at preventing HIV if used correctly and consistently. Would you use the ring if you think you could use it well?	1. Yes, the ring provides enough protection to make me want to use it 2. Yes, I don't think I can use the ring better than I can take oral PrEP 3. No, the ring is not effective enough. I prefer oral PrEP	
End-user feasibility: Perceived self-efficacy to use ring as PrEP	How comfortable do you think you will be wearing the vaginal ring every day?:	1. Usually/mostly comfortable 2. Sometimes uncomfortable, 3. Usually/mostly uncomfortable.	
Perceived most reliable source for PrEP information/ recommendation	Who do you look to help guide your decision making about PrEP use?	1. Your primary partner 2. Your mother 3. Another family member, specify 4. A friend 5. Your doctor or clinician 6. Traditional healer [insert local term] 7. A religious leader [insert local term] 8. Other, specify	
Qualitative questions:	Where would you go and who would you talk to for answers to questions you might have about oral PrEP? What about for the ring?		

PrEP RING PILOT IMPLEMENTATION STUDY PROTOCOL TEMPLATE

Domain	Question	Responses	Skip pattern
Preferred site and visit frequency	How acceptable would it be to get PrEP methods like oral PrEP or the ring from: a. An STI clinic b. Family planning clinic c. ART clinic d. Pharmacy	1. Very unacceptable 2. Somewhat unacceptable 3. No opinion 4. Somewhat acceptable 5. Very acceptable	
	How acceptable would it be to you if you had to go to the clinic every ___ months to get new rings and be tested for HIV: a. Every month b. Every 3 months c. Every 6 months	1. Very unacceptable 2. Somewhat unacceptable 3. No opinion 4. Somewhat acceptable 5. Very acceptable	
Perceived facilitators/barriers to ring access and use	Indicate which barriers/ challenges you have to ring use or access: Mark all that apply or "None could be identified"	1. Barriers to return to clinic for resupply (e.g., money or time) 2. Disruption in routine (for example, travel away from home) 3. Forgetting/no dose available 4. Job commitments 5. Lack of privacy 6. Medication side effects 7. Negative reactions (family, friends, partner) 8. Partying/ drugs/alcohol 9. School Commitments (classes or exams) 10. Side effects 11. Stigma/ fear of stigma 12. Other (Specify:_____) 13. None could be identified	
	Did you require any help from the clinician to insert the ring?	1. Yes 2. No	
Qualitative questions:	What are some things that can make it easier to use the ring throughout the month?		
	Is there anyone who supports/helps you use your ring throughout the month?		
	Some people have problems with using a monthly ring. Tell me of a specific time when you had a challenge with the ring.		

Domain	Question	Responses	Skip pattern
Provider Feasibility: Perceived demand for ring vs. oral PrEP by clients	What do you see as the benefits of the ring?" [select all that are named spontaneously;	1. Woman-controlled method 2. Easy to use 3. No problems remembering to use 4. Protects against HIV 5. Helps women who can't use oral PrEP 6. Other (specify): _____	
	What about the ring makes it hard for women to consider using it	1. Ideas that it promotes promiscuity 2. Fears that the ring causes cancer or other illness 3. Not enough research 4. Less effective for HIV prevention 5. Need to replace every month 6. Other (specify): _____	
	What about the ring makes it hard for women to continue using it after they start?	1. Partner disagreement 2. Fears that the partner will feel it during sex or find it 3. Side-effects like itching 4. Less effective for HIV prevention 5. Concerns about supply stock-outs 6. Need to replace every month 7. Other (specify): _____	
Qualitative questions:	In your experience, which clients prefer the ring to oral PrEP?		
	What are some of the concerns clients might have about the ring? What do you do to address these concerns?		
	In your experience, what concerns do you have about providing oral PrEP to clients? What about the ring?		***[Probe effectiveness, safety, correct use, sustained supply]***
Suggested Acceptability Measures: End-Users			
Ring users only:	Right after being trained to insert the ring, how did you feel about inserting the ring yourself for the first time (at the health facility)? Would you say very at ease, at ease, somewhat nervous or very nervous?	1. Very at ease 2. At ease 3. Somewhat nervous 4. Very nervous 5. No response	

Domain	Question	Responses	Skip pattern
	How confident were you to insert the ring that very first time? Would you say very confident, somewhat confident, or not very confident?	1. Very confident, 2. Somewhat confident 3. Not very confident 4. No response	
Participants disclosing PrEP use to at least one person ***[All PrEP users]***	Do you plan to tell your husband or main partner about your PrEP use?	1. No, I do not plan to tell him 2. Yes, I plan to tell him 3. Don't know 4. No response	
	Do you plan to tell any other adult you live with about your PrEP use?	1. . No, I do not plan to tell them 2. Yes, I plan to tell them 3. Don't know 4. No response	
Suggested acceptability measures: Providers			
	On a scale of 1 to 10 where 1 is not at all prepared and 10 is very well prepared, how well did the ring training prepare you to counsel and provide the ring?	_____ (scale number)	
	Are you aware of the ***[insert name of job aid]***?	1. Yes 2. No 3. Don't know	If No or Don't Know, skip to next section.
	On a scale of 1 to 10 where 1 is not at all useful and 10 is very useful, how useful is this job aid?	_____ (scale number)	
	Were you trained on the use of this job aid?	1. . Yes 2. No 3. Don't remember 4. No response	
Qualitative questions	What about the ring provider training worked well?		
	What would you like to change or improve about this training package?		
	How do you feel about the level of training you received on ***[specific name]*** job aid?		

Domain	Question	Responses	Skip pattern
Suggested Cost Measures:			
Cost to clients for those seeking ring services	Qualitative interviews with current or potential PrEP clients to assess the impact of transport, opportunity and other costs to clients by wealth quintile. ***Include wealth quintile measures in demographic data*** and ask about estimated costs borne by clients to access PrEP services.		
Ratio of numbers of rings or month oral PrEP supply dispensed to used	Aggregate data relating numbers of rings or oral PrEP supply dispensed.	Quantify patterns of use (obtained from required end-user acceptability measures) and compare to quantity dispensed.	

Question Resource Appendix

Document with optional questions for consideration by ring pilot implementation studies

Domain	Question	Responses	Skip pattern
Costing Measures			
Incremental PrEP service delivery costs ***[calculate for each PrEP method]***	Record aggregate data during the study period at each involved facility for the following: ▪ Additional staff time per PrEP visit by different types of visits and staff cadre [use MOH human resources for health scale for salaries & benefits] ▪ Numbers of different types of visits by site/population served (annually and by month) ▪ Numbers of rings or monthly supply of oral PrEP dispensed (total dispensed per visit during study implementation) ▪ Numbers and prices of additional lab tests and HIV tests conducted for PrEP users (including rates of confirmatory and tiebreaker HIV tests, annually and by month) ▪ Numbers of clients tested for HIV who choose to initiate the ring ▪ Numbers and prices of additional commodities used for the ring (gloves, test tubes, stationery, etc.) [Use MOH commodity unit cost data.] Estimate other PrEP method-specific costs, e.g., equipment, disposal, training, ring-specific demand creation, mass media, and community outreach costs.		
Suggested Measures			
Suggested Feasibility Measures: End-Users	Which method do you intend to use for HIV prevention?	1. Oral PrEP 2. Ring 3. Condoms 4. Other (specify) 5. Have not decided	
Perceived effort to access/use the ring	Would you be willing to use oral PrEP for HIV prevention?	1. Yes 2. No	
	Would you be willing to use the ring for HIV prevention?	1. Yes 2. No	
	If you were interested in using the ring to prevent getting HIV and it was available for free at local clinics, please rate how likely you would be to use the product on a scale of 1–5.	1. Definitely would NOT use it 2. Probably would NOT use it 3. Not sure 4. Maybe would use it 5. Definitely would use it	

Perceived opportunity costs related to PrEP use ***[Divide into two questions each by specific PrEP method]***	In general, how worried are you about the effect of the ring/oral PrEP on your own health?	1. Very worried 2. A little worried 3. Not worried at all	Proceed with skip pattern based on selected PrEP method.
	Do you think using the ring/oral PrEP would cause emotional discomfort? By this we mean the product causes you to feel unpleasant feelings like sadness or anger.	1. A little bit 2. A lot 3. Not at all	
	Do you think using the ring/ oral PrEP would cause physical discomfort? By this we mean the PrEP method makes your body feel uncomfortable.	1. A little bit 2. A lot 3. Not at all	
	Do you think the ring/oral PrEP would cause sexual discomfort?	1. A little bit 2. A lot 3. Not at all	
	Do you think the ring/oral PrEP would cause social discomfort? By this we mean discomfort or worry related to the reactions of people around you.	1. A little bit 2. A lot 3. Not at all	
	Some women may have worries about the effect of ring on their own health or wellbeing. Are you worried the ring could…?: a. Cause infections or cancer b. Make you gain weight c. Affect your future fertility? d. Result in people thinking you are HIV positive e. Anything else related to the ring? (specify) f. Anything else related to oral PrEP? (specify)	a – d: 1. Yes 2. No e. [Open response] f. [Open response]	

	Would you mind wearing the dapivirine ring…?: a. During sex b. When not sexually active c. During menses d. During daily activities	1. Yes 2. No 3. Not applicable *[Response series for each component **a–d** of this question.]*
Perceived effectiveness of ring compared to oral PrEP or other HIV prevention methods	How effective do you think the ring is at preventing HIV?	1. Not at all effective 2. Somewhat effective 3. Very effective 4. Do not know
	How effective do you think oral PrEP is at preventing HIV?	1. Not at all effective 2. Somewhat effective 3. Very effective 4. Do not know
	Which method do you think would be most effective at preventing HIV for you?	1. Dapivirine ring 2. Oral PrEP 3. Neither 4. Do not know
	The ring is about 50% effective at preventing HIV if used correctly and consistently. Would you use the ring if you think you could use it well?	1. Yes, the ring provides enough protection to make me want to use it. 2. Yes, I think I can use the ring better than I can take oral PrEP. 3. No, the ring is not effective enough. I prefer oral PrEP.
Perceived self-efficacy to use ring as PrEP	How comfortable do you think you will be wearing the dapivirine ring every day?	1. Usually/mostly comfortable 2. Sometimes uncomfortable 3. Usually/mostly uncomfortable
Perceived most reliable source for PrEP information/ recommendation	To whom do you look to help guide your decision making about PrEP use?	1. Your primary partner 2. Your mother 3. Another family member (specify) 4. A friend
Qualitative question	Where would you go and who would you talk to for answers to questions you might have about oral PrEP? What about for the ring?	

Preferred site and visit frequency	How acceptable would it be to get PrEP methods like oral PrEP or the ring from…?: a. An STI clinic b. Family planning clinic c. ART clinic d. Pharmacy e. Drop-in centre	1. Very unacceptable 2. Somewhat unacceptable 3. No opinion 4. Somewhat acceptable 5. Very acceptable	
	How acceptable would it be to you if you had to go to the clinic every #___ months to get new rings and be tested for HIV? a. Every month b. Every 3 months c. Every 6 months	1. Very unacceptable 2. Somewhat unacceptable 3. No opinion 4. Somewhat acceptable 5. Very acceptable	
Perceived facilitators/barriers to ring access and use	Indicate which barriers/ challenges you have to ring use or access. Mark all that apply or "None could be identified."	1. Barriers to return to clinic for resupply (e.g., money or time) 2. Disruption in routine (for example, travel away from home) 3. Forgetting/no dose available 4. Job commitments 5. Lack of privacy 6. Medication side effects 7. Negative reactions (family, friends, partner) 8. Partying/drugs/alcohol 9. School commitments (classes or exams) 10. Side effects 11. Stigma/fear of stigma 12. Other (specify: _____) 13. None could be identified	
	Did you require any help from the clinician to insert the ring?	1. Yes 2. No	
Qualitative questions:	What are some things that can make it easier to use the ring throughout the month?		
	Is there anyone who supports/helps you use your ring throughout the month?		
	Some people have problems with using a monthly ring. Tell me about a specific time when you had a challenge with the ring.		

Suggested Feasibility Measures: Providers Perceived demand for the ring vs. oral PrEP by clients	What do you see as the benefits of the ring? ***[Select all that are named spontaneously.]***	1. User-controlled method 2. Easy to use 3. No problems remembering to use 4. Protects against HIV 5. Helps clients who cannot use oral PrEP 6. Other (specify): _____	
	What about the ring makes it hard for clients to consider using it?	1. Ideas that it promotes promiscuity 2. Fears that the ring causes cancer or other illness 3. Not enough research 4. Less effective for HIV prevention 5. Need to replace every month 6. Other (specify): _____	
	What about the ring makes it hard for women to continue using it after they start?	1. Partner disagreement 2. Fears that the partner will feel it during sex or find it 3. Side effects like itching 4. Less effective for HIV prevention 5. Concerns about supply stock-outs 6. Need to replace every month 7. Other (specify): _____	
Qualitative questions:	In your experience, which clients prefer the ring to oral PrEP?		
	What are some of the concerns clients might have about the ring? What do you do to address these concerns?		
	In your experience, what concerns do you have about providing oral PrEP to clients? What about the ring?		Probe effectiveness, safety, correct use, sustained supply.
Suggested Acceptability Measures: End-Users			
Ring users only:	Right after being trained to insert the ring, how did you feel about inserting the ring yourself for the first time (at the health facility)? Would you say you were…?	1. Very at ease 2. At ease 3. Somewhat nervous 4. Very nervous 5. No response	
	How confident were you about inserting the ring that very first time? Would you say you were…?	1. Very confident, 2. Somewhat confident 3. Not very confident 4. No response	

Participants disclosing PrEP use to at least one person [All types of PrEP]	Do you plan to tell your husband or main partner about your PrEP use?	1. No, I do not plan to tell him. 2. Yes, I plan to tell him. 3. Do not know 4. No response	
	Do you plan to tell any other adult you live with about your PrEP use?	1. No, I do not plan to tell them. 2. Yes, I plan to tell them. 3. Do not know 4. No response	
Suggested acceptability measures: Providers	On a scale of 1 to 10, where 1 is not at all prepared and 10 is very well prepared, how well did the ring training prepare you to counsel and provide the ring?	_____ (scale number)	
	Are you aware of the ***[insert name of job aid]***?	1. Yes 2. No 3. Do not know	If No or Do not Know, skip to next section.
	On a scale of 1 to 10, where 1 is not at all useful and 10 is very useful, how useful is this job aid?	_____ (scale number)	
	Were you trained on the use of this job aid?	1. Yes 2. No 3. Do not remember 4. No response	
Qualitative questions	What about the ring provider training worked well?		
	What would you like to change or improve about this training package?		
	How do you feel about the level of training you received on *[specific name]* job aid?		

Suggested Cost Measures:

Cost to clients for those seeking ring services	Qualitative interviews with current or potential PrEP clients to assess the impact of transport, opportunity, and other costs to clients by wealth quintile. ***Include wealth quintile measures in demographic data*** and ask about estimated costs borne by clients to access PrEP services.		
Ratio of numbers of rings or monthly oral PrEP supply dispensed to used	Aggregate data relating numbers of rings or oral PrEP used to supply dispensed.	Quantify patterns of use (obtained from required end-user acceptability measures) and compare to quantity dispensed.	