## **CAB PrEP Situation Analysis Tool**

## **Interview Question Bank**

*This interview question bank is designed to help you identify the questions you will ask stakeholders in interviews to inform a situation analysis for CAB PrEP.*

**Introduction and Context (I)**

**I1.** Please briefly describe your experience and role with oral pre-exposure prophylaxis (PrEP) introduction and implementation.

**I2.** Have you already learned about the cabotegravir long-acting pre-exposure prophylaxis (CAB PrEP) injection? Do you have any question about the product before we begin?

*Note: This question is not necessary for stakeholders who are highly involved in HIV prevention and PrEP (e.g., Ministry of Health officials).*

**I3.** Thinking back to the rollout and scale-up of oral PrEP, what do you think worked well? What has been challenging? What should be done differently for future HIV prevention methods?

**I4.** How do you feel CAB PrEP could complement other HIV prevention options currently available (e.g., oral PrEP, voluntary medical male circumcision, condoms)?

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**G. Diverse Service Delivery Channels (G)**

**G1a.** Through which channels is PrEP currently provided? Is PrEP provided through any channels that are HIV adjacent, such as outpatient departments or sexually transmitted infection (STI) or antiretroviral therapy (ART) clinics?

**G1b.** CAB PrEP may be an appropriate addition to sexual and reproductive health (SRH), family planning (FP), or maternal and child health (MCH) services in addition to HIV services. Are HIV STI and SRH/FP/MCH services currently integrated? What has worked well and what has been more challenging? What would need to happen to support inclusion of new PrEP methods in SRH/FP/MCH services?

**G1c.** Are there existing programs for populations that are disproportionately affected by HIV, such as adolescent- and youth-friendly services or DREAMS, that could be leveraged to increase access to new PrEP methods?

**G1d.** How are adolescent girls and young women (AGYW) and other priority populations who are not already attending health care facilities reached? How could this be improved?

**Interview Questions for Data Collection**

**The following questions are organized along the PrEP Introduction Framework:**

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**Planning and Budgeting (P)**

P1: Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working group.**

**P1a.** How should the discussions about these new PrEP methods start in your country? How do you imagine introducing new PrEP methods in your country (e.g., a pilot or demonstration project, a phased rollout, immediate introduction)?

**P1b.** Is there a task force or technical working group (TWG) leading the introduction of biomedical HIV prevention methods (e.g., for oral PrEP, the PrEP ring, or CAB PrEP)? Who is in this working group, and does it include relevant stakeholders from priority populations or for integration in SRH/FP/MCH services? Are there any upcoming milestones for introducing CAB PrEP? What is the expected timeline for decisions?

Responses should include details on:

* Plans for a task force or TWG to lead CAB PrEP introduction
* Timelines and/or milestones for key decisions
* Plans for participation of stakeholders from other relevant areas (e.g., FP, MCH)

P2. Identify **focus** **populations and set targets** for PrEP methods.

**P2a.** With the introduction of oral PrEP, some countries identified focus populations for oral PrEP use. Sometimes these are key populations, such as men who have sex with men, people who inject drugs, transgender people, and sex workers. In other cases, they are country-specific priority populations, such as AGYW, truck drivers, and people engaged in commercial fishing. Were focus populations identified for oral PrEP? If so, how? How will this exercise be similar or different for CAB PrEP introduction?

**P2b.** For oral PrEP, some countries identified focus geographies where oral PrEP would be introduced before scaling up the program across the country. Were focus geographies identified for oral PrEP? If so, how were these areas selected? How will this exercise be similar or different for CAB PrEP introduction?

Responses should include details on:

* Plans for end-user populations for CAB PrEP (e.g., population groups, targets set)

P3. Engage **community stakeholders** to inform planning for PrEP rollout.

**P3a.** How were community stakeholder groups engaged throughout the planning and implementation process for oral PrEP? What worked well? What did not work well? Have key and priority populations been engaged in planning for oral PrEP?

**P3b.** In what ways can community stakeholder and key population engagement improve when planning for the introduction of new PrEP methods?

Responses should include details on:

* Key lessons on community engagement from oral PrEP rollout (e.g., effective ways to authentically engage community members and hear their perspectives)
* Plans for engaging community stakeholders on CAB PrEP introduction

P4. Develop impact, cost, and/or cost-effectiveness **analyses** to inform PrEP planning.

**P4a.** When oral PrEP was introduced, were any impact, cost, or cost-effectiveness analyses conducted or discussions held? What analyses have already been conducted or will be conducted to inform planning for the introduction of new PrEP methods? Which delivery channels will the analyses focus on (e.g., existing HIV services, FP, MCH)?

Responses should include details on:

* Existing analyses for oral PrEP and/or HIV prevention
* Plans for cost-effectiveness analyses for CAB PrEP rollout

P5. Include CAB PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, FP).

**P5a.** Thinking back to oral PrEP planning and rollout, what policies or plans needed to change to support introduction of oral PrEP (e.g., national HIV strategies, standard treatment guidelines)? What would now need to change to include CAB PrEP? What is the timeline for these policy or guidelines changes?

**P5b.** How can PrEP methods be integrated with broader SRH and other programming, especially for women and AGYW? What would need to happen at the policy or guidance level to support inclusion of the PrEP methods in SRH/FP/MCH services that already deliver HIV services? What would need to happen at the policy or guidance level to support inclusion of the PrEP methods in SRH/FP/MCH services that do not currently deliver any HIV services? Do you anticipate that some PrEP methods will be easier to integrate with SRH/FP/MCH services?

Responses should include details on:

* Key HIV prevention strategies/plans that will need to incorporate CAB PrEP; how these strategies/plans currently incorporate oral PrEP
* Other strategies/plans that could include CAB PrEP (e.g., plans for SRH, adolescent health, or private sector delivery)

P6. Issue standard **clinical guidelines** for delivery and use of PrEP methods.

**P6a.** How were clinical guidelines for the delivery and use of oral PrEP developed and disseminated? Do you think this process would be the same for the introduction of new PrEP methods? When do you expect this process to begin/finish? How often are guidelines typically reviewed for revisions?

*Note for interviewer: You can ask interviewee additional question about the status of guideline decisions for product specifications once World Health Organization and/or regulatory authorities’ decisions are established.*

**P6b.** Who will issue clinical guidelines for public and private health care workers? Who influences these decisions?

Responses should include details on:

* Current state of and lessons learned from clinical guidelines for oral PrEP
* Plans/timelines for clinical guidelines for CAB PrEP

P7. Develop an **implementation plan and budget** to guide PrEP introduction and scale-up.

**P7a.** Was a national implementation plan created for oral PrEP (at the national/subnational level)? If so, what was the process for developing it? What worked well? What did not work well? Would this process be the same for new PrEP methods? What might be done differently for the integration of new PrEP methods in national implementation plans?

**P7b**. Was a budget created for oral PrEP (at the national/subnational level)? Where does the budget for oral PrEP come from, and who would be expected to provide the budget for new PrEP methods?

**P7b.** To what extent has a timeline and plan for introduction and scale-up of CAB PrEP already been developed? Will this be easily integrated into the plans for oral PrEP? Is budgeting for new PrEP methods expected to fall within the budget for oral PrEP or other HIV prevention methods?

Responses should include details on:

* Plans/timelines for introduction and scale-up of CAB PrEP
* Integration of CAB PrEP in HIV prevention budgets and donor requests
* Source of financial resources to support CAB PrEP procurement and introduction activities

**Supply Chain Management (S)**

**S1. Register** CAB PrEP products and include them on the national essential medicines list, if needed.

**S1a.** What is the process to register new products in **[country]?** Do new PrEP products need to be on the national essential medicines list? If so, what is the process for including them?

**S1b.** What is the current situation and timeline for the regulatory approval of CAB PrEP? Is regulatory approval necessary to begin demonstration studies or pilot implementation projects?

Responses should include details on:

* Current situation/timeline for regulatory approval of CAB PrEP
* Considerations for inclusion of CAB PrEP on national essential medicines lists and other key procurement and supply chain systems
* Considerations on how scheduling and/or classification of CAB PrEP upon approval may enable or inhibit delivery of CAB PrEP through nonclinical channels (e.g., pharmacies, community-based settings)

S2. Update **supply chain guidelines and logistics systems** to include CAB PrEP.

**S2a.** Across many countries, procurement of oral PrEP was relatively simple because the underlying drugs (e.g., Truvada) were already being procured for HIV treatment. However, CAB PrEP is a new product. What will need to be considered to ensure these products are included in supply chain guidelines and logistic systems? Are there any specifications for the new injectable product form?

**S2b**. Do we anticipate any potential challenges? What is needed to include PrEP products in supply chain systems for other delivery channels (e.g., FP, MCH, private sector)?

Responses should include details on:

* Existing systems, processes, and lessons learned from oral PrEP introduction
* Expected differences for CAB PrEP, as a new product form that may not have been previously procured in HIV prevention supply chain systems
* What is needed to include CAB PrEP in supply chain systems for other delivery channels (e.g., FP, MCH, private sector)

S3. Conduct **forecasting and/or quantification** to inform procurement of CAB PrEP.

**S3a.** How is forecasting and/or quantification done for oral PrEP? Do you anticipate any challenges related to forecasting and quantification if CAB PrEP were adopted? Who oversees these processes?

**S3b**. How is forecasting and/or quantification done for the HIV tests or other commodities needed for oral PrEP? Would this process be the same for CAB PrEP?

Responses should include details on:

* Plans for CAB PrEP demand forecasting and quantification
* Key stakeholders engaged in demand forecasting and quantification
* Expected challenges and/or unknowns

S4. Establish **procurement, commodity monitoring, and distribution** for CAB PrEP and associated materials.

**S4a.** To what extent will procurement, commodity monitoring, and distribution systems for new PrEP products differ from those used for oral PrEP? How? Who oversees these systems?

**S4b.** Can you anticipate any potential barriers and/or challenges to distributing CAB PrEP to non-HIV channels?

**S4c.** Due to the product specifications, additional materials may be required or new challenges may arise for the procurement and distribution of each PrEP product. For example, CAB PrEP may require procurement of additional injection materials, oral pills for the lead-in or in anticipation of missed injections, and other materials for administration (e.g., gloves and alcohol wipes), as well as the establishment of storage and distribution systems that maintain temperature controls. What challenges or considerations do you anticipate may arise for procurement, commodity monitoring, and distribution systems for CAB PrEP?

Responses should include details on:

* Plans for procurement, commodity monitoring, and distribution for CAB PrEP
* Relevant stakeholders involved
* Potential barriers and/or challenges to distributing CAB PrEP to non-HIV channels

S5. Establish **storage and distribution systems** that maintain temperature controls for CAB PrEP, if needed.

S5a. According to clinical guidelines for delivery and use of CAB PrEP, there may be a need to maintain temperature controls to safely distribute CAB PrEP materials. What considerations or challenges do you anticipate may arise for establishing cold chains?

Responses should include details on:

* Current situation for temperature-controlled storage and distribution (e.g., refrigerators)

**PrEP Delivery Platforms (D)**

D1. Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing CAB PrEP use.**

**D1a.** Like oral PrEP delivery, provision of CAB PrEP will require resources for conducting regular HIV tests, initiation visits, and follow-up visits. Where are the resources for oral PrEP implementation coming from? What are the primary barriers to scaling oral PrEP? Do you think the sources of support would be the same for other PrEP methods?

**D1b.** To what extent do providers and PrEP access locations that reach end-user populations have the capacity to offer CAB PrEP (if approved) in their current service offerings? What are potential barriers?

**D1c.** To what extent will sufficient funding be available to build the needed health care capacity? What are the sources of this funding? What specific challenges do you anticipate? What opportunities do you see for overcoming these barriers or facilitating progress?

Responses should include details on:

* Lessons learned from oral PrEP rollout
* Potential opportunities/barriers for the introduction of CAB PrEP
* Required resources for successful CAB PrEP rollout
* Considerations for other channels (e.g., access to HIV tests)

D2. Develop training and materials for **health care workers** on CAB PrEP.

**D2a.** How were training and job aids developed for health care workers for oral PrEP? How was the training conducted, and how were the materials disseminated (e.g., on-site, virtually)? What worked well? What did not work well? What should be done differently when introducing new PrEP methods?

**D2b.** To what extent is there a plan for how health care workers will be trained to deliver new PrEP methods?

**D2c.** Are tools available to help health care workers support client choice of PrEP methods? What can be learned from FP/SRH services about equipping health care workers to support client choice? Are health care workers from non-HIV sectors (such as FP providers) authorized to administer PrEP? What training or capacity building would FP/SRH providers need to provide a method like CAB PrEP?

Responses should include details on:

* Materials and models for provider training on oral PrEP and plans to integrate CAB PrEP
* Opportunities to train other health care providers on CAB PrEP
* Plans to engage and train health care workers on intramuscular injections and how to communicate and support decision-making about multiple methods
* Considerations for training health care workers in non-HIV channels

D3. Establish **referral systems** to link clients from other channels to sites providing CAB PrEP.

**D3a.** Where is oral PrEP currently provided? Please tell me about any referral systems that are in place to link people to oral PrEP where it is not offered. How could these referral systems include the new PrEP methods? What must be done to ensure referral systems support product choice among methods?

**D3b.** Is oral PrEP provided in the private sector? If so, who provides it? Do you think this would be the same for the new PrEP methods?

**D3c.** What are some of the challenges experienced with delivering HIV services in these other service channels?

Responses should include details on:

* Existing referral systems for oral PrEP (e.g., from non-HIV channels such as FP services and/or from HIV testing services)

D4. Integrate support for **partner communication** and services for intimate partner violence response.

**D4a.** When speaking with clients about HIV, do health care workers currently ask about experiences of gender-based violence, including intimate partner violence (IPV)? How are potential oral PrEP users supported to speak with their partners about PrEP? What do you think will need to be done differently for other PrEP methods?

Responses should include details on:

* Existing screening and supportive services for oral PrEP users experiencing IPV and the potential to extend services to CAB PrEP users
* Opportunities to integrate considerations for CAB PrEP into existing IPV support

**Uptake & Effective Use (U)**

U1. Develop and implement **demand generation strategies** that include CAB PrEP promotion.

**U1a.** What is the current awareness about oral PrEP in **[country]**? To what extent has a clear and informative communications plan for oral PrEP education and awareness been developed? Which organizations are expected to implement demand generation strategies for CAB PrEP?

**U1b.** What does demand generation for oral PrEP currently entail? Is there a national communications strategy for PrEP? What has worked well? What is not working well? What should be done differently when integrating other PrEP methods in demand generation?

**U1c.** What challenges do you anticipate in generating demand for CAB PrEP? How would you recommend overcoming these challenges? What existing demand generation programs or platforms do you feel would be well suited to promote the various PrEP methods available in your country?

Responses should include details on:

* Lessons learned from oral PrEP rollout
* Existing campaigns, materials, etc., developed for oral PrEP that could include CAB PrEP
* Plans for demand creation for CAB PrEP or other SRH products that can be relevant for creation of materials for CAB PrEP (e.g., injectable contraception)

U2. Address social norms/stigma to build **community and partner acceptance** of CAB PrEP use.

**U2a.** To what extent do communities and end users’ partners support use of oral PrEP? How may stigma or social norms affect the introduction of CAB PrEP? What do you expect community or partner concerns will be?

**U2b.** What were the most effective ways to address social norms/stigma to build community and partner acceptance of oral PrEP? How can community stakeholders be engaged in addressing social norms/stigma to build awareness and acceptance of and support for PrEP product introduction? How may these strategies need to be adapted for CAB PrEP?

Responses should include details on:

* Key areas of concern for stigma/social norms
* Lessons learned from oral PrEP rollout or other SRH products
* Effective methods for address stigma/social norms for CAB PrEP (e.g., lessons on addressing concerns about injectable products learned from experiences with COVID-19 vaccines)

U3. Develop **information and tools for clients** to support product choice.

**U3a.** Where do focus populations get information about HIV prevention? How is this different for each focus population? Is information about oral PrEP or other HIV prevention methods available to help clients choose prevention options that work for them? How were these materials created and disseminated? How will the additional time needed to counsel clients on all HIV prevention options, including new PrEP methods, affect whether clients have the opportunity to make an informed choice?

**U3b.** To what extent can existing information, education, and communication materials for oral PrEP include CAB PrEP? How may materials be improved to support product choice?

Responses should include details on:

* Existing information and tools for clients developed for oral PrEP that could include CAB PrEP
* Plans/timelines for adapting materials for CAB PrEP introduction
* Need to create materials and/or approaches to support end-user choice among options

U4. Support **effective use** of CAB PrEP.

**U4a.** How are people supported after they start taking oral PrEP? Who was responsible for developing a plan and/or executing programming to support effective use of oral PrEP?

**U4b.** What strategies have been implemented and were effective in supporting effective use of PrEP? How will these data and strategies need to be adapted for CAB PrEP? What plans will be developed to support effective use of CAB PrEP or for when an individual discontinues CAB PrEP or misses a visit?

Responses should include details on:

* Lessons learned from oral PrEP adherence and continuation
* Key opportunities/challenges for CAB PrEP

**Monitoring**

M1. Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.

**M1a.** How has or will oral PrEP be integrated into existing health monitoring systems? What monitoring systems and tools (e.g., at the national, subnational, and facility levels) would need to be adapted to include the other PrEP methods such as CAB PrEP? What new indicators may need to be integrated in existing monitoring tools to support data collection and analysis of new PrEP methods?

**M1b.** How are HIV and SRH monitoring tools different? What opportunities are there for integration or adaptation of tools? What challenges does this pose if CAB PrEP is offered in FP/SRH/MNCH services? How is service delivery or dispensation in the private sector monitored?

Responses should include details on:

* Current systems and indicators for monitoring oral PrEP delivery at the facility, regional, and national levels
* Opportunities to include CAB PrEP in monitoring tools alongside oral PrEP
* Opportunities/barriers to integrating CAB PrEP into monitoring systems for FP and other non-HIV services and/or to linking private sector delivery to public sector monitoring systems

M2. Establish systems for **pharmacovigilance** and to monitor drug resistance.

**M2a.** What pharmacovigilance systems exist for oral PrEP? How were these systems set up? Would you expect the process to be the same for new PrEP methods? Who is responsible for this?

**M2b**. What considerations are needed for monitoring drug use if CAB PrEP is approved for use without a prescription? For example, is there a need to create a hotline?

Responses should include details on:

* Current plans for pharmacovigilance for oral PrEP and plans to integrate CAB PrEP
* Considerations for quality assurance or quality improvement for HIV drug resistance monitoring with a new injectable form

M3. Conduct **implementation science** research to inform policy and programs.

**M3a.** Often countries conduct demonstration projects and/or implementation science research to understand how to adjust policy and scale-up. Was this done for oral PrEP? Why or why not? Would you expect a need for demonstration projects and/or implementation science for CAB PrEP?

Responses should include details on:

* Plans for demonstration projects and/or key implementation science questions for initial, phased CAB PrEP rollout
* Plans for ongoing implementation science research to inform programming of CAB PrEP in future years